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EDITOR'S NOTE

Chad Bass-Meldrum *

Year after year the *McGill Journal of Law and Health* features literature from renowned civil and common law writers in both French and English on current issues at the intersection of law and health with a view to contributing to public life in Canada and abroad. Cette année ne fait pas exception.

To this end, Nola Ries examines a range of legal and policy measures aimed at combatting obesogenic environments and encouraging healthier behaviours. The article concludes with a call for continued empirical research evaluating the effectiveness of different incentives and disincentives as instruments for public health policy.

Next, Jacquelyn Shaw discusses the Canadian Council for Donation and Transplantation's guidelines for the determination of death, which redefine the point at which physicians may declare neurological death so as to increase the number of organ and tissue donations in Canada. The author argues that these brain death guidelines may infringe patients' rights to life and security of the person under section 7 of the *Canadian Charter of Rights and Freedoms*.

Ma'n Zawati se penche ensuite sur le rôle important des conseillers en génétique dans le domaine de la génétique médicale, soulignant le fait qu'au Québec, les conseillers en génétique ne bénéficient pas de la protection accordée à d'autres professionnels par le *Code des professions* du Québec. L'article suggère des solutions législatives aux conséquences juridiques qui découlent du refus d'accorder un statut professionnel aux conseillers en génétique.

Finally, Sheila Wildeman, Gina Bravo, Marie-France Dubois, Carole Cohen, Janice Graham, Karen Painter and Suzanne Bellemare point out that although Canada's aging population presents new incentives for research, policymakers must put their minds to the possible exploitation of research subjects suffering from health conditions correlated with aging who are vulnerable to the designation of legal incapacity. The authors conclude that there is a need for coordinated efforts among the provinces and territories to develop a harmonized approach to the laws concerning persons who lack in the research context.

I would like to express my sincere thanks to our editors, peer reviewers and each of the aforementioned authors for maintaining the high standard of quality the *McGill Journal of Law and Health* has come to expect.

À votre santé!

* Editor-in-Chief, *McGill Journal of Law and Health*, Vol. 6.

LEGAL AND POLICY MEASURES TO PROMOTE HEALTHY BEHAVIOUR: USING INCENTIVES AND DISINCENTIVES TO CONTROL OBESITY

*Nola M Ries**

This article examines incentives as a health policy option to encourage healthier behaviours and considers the emerging body of literature that evaluates the effectiveness and impact of incentives as public health policy tools. Incentives—including rewards and penalties—vary widely in their force, from indirect (or mild) to direct (or strong) incentives. At one end of the incentive spectrum are strategies that invite healthier behaviour, such as urban planning measures to encourage walking and cycling. In the middle of the incentive spectrum are measures such as tax credits for those who participate in sports and fitness programs or “fat taxes” on high-calorie, low-nutrition foods. These strategies target individuals’ pocketbooks and thus may have a stronger influence on behaviour change. The most direct incentives are governmental or private sector schemes that use monetary payments or penalties to induce behaviour change. While this article focuses on incentives targeted at individuals, it briefly discusses several examples of incentives aimed at businesses, particularly food retailers.

The use of incentives as a health policy tool has

Cet article examine les mesures incitatives qui peuvent encourager des comportements sains comme composantes de politiques sur la santé. Il considère également la littérature émergente qui évalue l’efficacité et l’impact de mesures incitatives à titre d’outils en matière de santé publique. Les mesures – qui incluent des pénalités et des primes – agissent avec des forces différentes à travers un spectre de mesures indirectes (ou légères) à directes (ou fortes). D’un côté se trouvent les stratégies qui invitent à adopter des comportements sains comme les mesures de planification urbaine encourageant la marche et le cyclisme. Au centre, on constate la présence de mesures comme des crédits d’impôt pour ceux qui prennent part à des programmes de sports et de conditionnement physique ou encore, des taxes spéciales sur les aliments à haute densité calorique sans grande valeur nutritive. Ces dernières stratégies visent les portefeuilles des particuliers et peuvent donc avoir une plus grande influence sur la modification des comportements. Les mesures incitatives les plus directes consistent en des projets gouvernementaux ou privés qui utilisent des paiements ou des pénalités pour

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Citation: Nola M Ries, “Legal and Policy Measures to Promote Healthy Behaviour: Using Incentives and Disincentives to Control Obesity” (2012) 6:1 MJLH 1.

Référence : Nola M Ries, « Legal and Policy Measures to Promote Healthy Behaviour: Using Incentives and Disincentives to Control Obesity » (2012) 6 : 1 RDSM 1.

several key legal dimensions. First, governments rely on legal powers, such as taxation laws and zoning regulations, to implement certain kinds of incentives. Second, in their operation and impact, incentives may infringe on legally protected rights. In particular, the use of “sticks” rather than “carrots” may be criticized on the grounds that they are coercive, discriminate unfairly, and promote individual blame. Third, public health law is concerned with the use of legal and policy measures to create conditions in which people may be healthy. It is important, therefore, to evaluate incentive programs to determine their effectiveness in ameliorating obesogenic environments and creating conditions for improved dietary and physical activity behaviours.

provoquer des changements comportementaux. Quoique cet article s’attarde aux mesures visant les individus, il discute tout de même brièvement des stratégies qui s’appliquent aux entreprises, tout particulièrement aux détaillants en alimentation.

L’utilisation de mesures incitatives à titre d’outils de politique sur la santé comporte plusieurs aspects légaux clés. D’abord, les gouvernements se fondent sur des pouvoirs légaux, comme la taxation et le zonage, pour implanter certains types de mesures. Ensuite, l’application de telles mesures, ou encore leur impact, risque de brimer certains droits protégés par la loi. En particulier, la stratégie du « bâton » plutôt que celle de la « carotte » peut être critiquée comme étant coercitive, injustement discriminatoire et susceptible d’encourager le blâme individuel. Finalement, le droit de la santé publique est encore soucieux à l’égard de l’utilisation de mesures politiques et légales pour créer des conditions favorables à la bonne santé de la population. Il est donc important d’évaluer les programmes incitatifs pour déterminer l’efficacité avec laquelle ils peuvent améliorer les environnements obésogènes et créer des circonstances qui encouragent de meilleurs comportements alimentaires ainsi que l’exercice physique.

Introduction	3
I. Creating Space for Physical Activity	10
II. Tax Credits for Physical Activity	14
III. Taxes on Energy Dense, Low-Nutrition Foods and Beverages	17
IV. Cash for Weight Loss ... or Penalties for Being Obese	26
V. Another Type of Incentive to Consider: Incentives for Businesses	36
Conclusion	39

Introduction

One of every three adults in the world is overweight and one in nine is obese.¹ No state in the US has an obesity rate of less than 20%² and if current trends persist, half of the American and British populations could be obese by 2030. The burden of chronic diseases associated with being overweight or obese—diabetes, hypertension, cardiovascular disease, and some cancers—is a matter of global public health concern. Rising obesity rates also bring higher health care costs. People who are obese have medical costs that are 30% higher than those of healthy weight, and treatment of obesity-related health problems is “estimated to account for between 0.7% and 2.8% of a country’s total healthcare expenditures.”³ The morbidity and mortality costs of overweight and obesity in the US and Canada are reportedly as high as \$300 billion annually,⁴ and, if the US and UK predictions hold true, this means an “additional 6–8.5 million people with diabetes, 5.7–7.3 million with heart disease and stroke, and 492 000–669 000 with cancer. The projected costs to treat these additional preventable diseases are an increase of \$48–66 billion per year in the USA and £1.9–2 billion per year in the UK.”⁵ A recent analysis demonstrates that “even a modest 1% reduction in body-mass index (BMI) would substantially reduce the number of obesity related diseases and their costs.”⁶ For example, over 2 million new cases of diabetes could be avoided in the US by 2020.⁷

¹ Jacqui Wise, “‘Tsunami of Obesity’ Threatens All Regions of World, Data Show” (2011) 342:7793 *Brit Med J* 354. See generally Mariel M Finucane et al, “National, Regional, and Global Trends in Body-Mass Index Since 1980: Systematic Analysis of Health Examination Surveys and Epidemiological Studies with 960 Country-Years and 9.1 Million Participants” (2011) 377:9765 *Lancet* 557.

² Centers for Disease Control and Prevention, “U.S. Obesity Trends”, online: CDCP <www.cdc.gov/obesity/data/trends.html>.

³ D Withrow & DA Alter, “The Economic Burden of Obesity Worldwide: A Systematic Review of the Direct Costs of Obesity” (2011) 12:2 *Obes Rev* 131 at 131.

⁴ Donald F Behan et al, “Obesity and its Relation to Mortality and Morbidity Costs”, online: Society of Actuaries <www.soa.org/files/pdf/research-2011-obesity-relation-mortality.pdf>.

⁵ Editorial, “Urgently Needed: A Framework Convention for Obesity Control” (2011) 378:9793 *Lancet* 741 at 741.

⁶ William H Dietz, “Reversing the Tide of Obesity” (2011) 378:9793 *Lancet* 744 at 744.

⁷ David King, “The Future Challenge of Obesity” (2011) 378:9793 *Lancet* 743 at 744.

Modern environments are aptly described as “obesogenic,” with multiple intricate factors promoting excessive energy intake and limiting energy expenditure.⁸ These prevalent environmental cues⁹ for overeating and sedentari-ness, combined with inherent biological susceptibilities and preferences,¹⁰ often test best intentions to eat a nutritious diet, exercise regularly, and maintain a healthy body weight. Some observers argue that the “increasing fatness [in populations around the world] is the result of a normal response, by normal people, to an abnormal situation.”¹¹ A desire to be fit and healthy is motivation enough for some to resist these abnormal, obesogenic circumstances, but for many the possibility of avoiding high blood pressure or heart disease, or adding additional months to one’s aged life sometime in the distant future, is not enough to provoke behaviour change in the present.

It is difficult to make healthier choices in a modern environment in which numerous forces encourage unhealthy behaviour. A British government report illustrates the problem with an apt example:

[D]iet is an area where short-term emotional responses tend to overpower longer-term, more “rational” thinking ... In a study, where workers were offered a prize next week of fruit or chocolate, 74 per cent chose fruit. But when the delivery van arrived

⁸ Boyd Swinburn, Garry Egger & Fezeela Raza, “Dissecting Obesogenic Environments: The Development and Application of a Framework for Identifying and Prioritizing Environmental Interventions for Obesity” (1999) 29:6 *Prev Med* 563. See generally Frederick J Zimmerman, “Using Marketing Muscle to Sell Fat: The Rise of Obesity in the Modern Economy” (2011) 32 *Annu Rev Public Health* 285.

⁹ “Most of us don’t overeat because we’re hungry. We overeat because of family and friends, packages and plates, names and numbers, labels and lights, colors and candles, shapes and smells, distractions and distances, cupboards and containers” (Brian Wansink, “FAQ About the Book”, online: *Mindless Eating* <www.mindlesseating.org/faq.php>). The book in question is Brian Wansink, *Mindless Eating, Why We Eat More Than We Think* (New York: Bantam Books, 2006).

¹⁰ A growing body of literature examines neurobiological responses to particular foods, especially sweet, fatty and salty foods. For a recent review, see Edmund T Rolls, “Taste, Olfactory and Food Texture Reward Processing in the Brain and Obesity” (2011) 35:4 *Int J Obes* 550 at 556. Parallels between overeating and drug addiction are also under investigation. See e.g. Karen M von Deneen & Yijun Liu, “Obesity as an Addiction: Why do the Obese Eat More?” (2011) 68:4 *Maturitas* 342; Valerie H Taylor, Claire M Curtis & Caroline Davis, “The Obesity Epidemic: The Role of Addiction” (2010) 182:4 *CMAJ* 327.

¹¹ Harry Rutter, “Where Next for Obesity?” (2011) 378:9793 *Lancet* 746 at 746.

on the day and said they had “lost” the form and again asked what the person wanted, around 70 per cent claimed to have chosen chocolate.¹²

Governments and health promotion organizations are experimenting with various tools to encourage healthier behaviour. The aim is to control obesity rates, to reduce the incidence of obesity-related diseases, and, for public and private health insurance programs, to save health care costs. While individual behaviour concerning nutrition and physical activity may be viewed narrowly as a personal matter, the adverse medical, economic, and social impacts of obesity-related illnesses make the issue one of public concern. An emerging body of literature examining the cost-effectiveness of obesity prevention and control measures shows that “many population-based prevention policies are cost-effective, largely paying for themselves through future health gains and resulting reductions in health expenditures.”¹³

¹² Cabinet Office Behavioural Insights Team, “Applying Behavioural Insight to Health”, online: UK Government Cabinet Office <www.cabinetoffice.gov.uk/resource-library/applying-behavioural-insight-health>, citing Daniel Read & Barbara van Leeuwen, “Predicting Hunger: The Effects of Appetite and Delay on Choice” (1998) 76:2 *Organ Behav Hum Decis Process* 189.

¹³ Y Claire Wang et al, “Health and Economic Burden of the Projected Obesity trends in the USA and the UK” (2011) 378:9793 *Lancet* 815 at 824. Wang cites, in particular, Michele Cecchini et al, “Tackling of Unhealthy Diets, Physical Inactivity, and Obesity: Health Effects and Cost-Effectiveness” (2010) 376:9754 *Lancet* 1775. The authors conclude:

Compared with the alternative strategy of treating only individuals who develop cardiovascular disease or cancer, our findings suggest that several population-based prevention policies can be expected to generate much needed health gains while entirely or very largely paying for themselves through their reduction of future healthcare costs. These policies include health information and communication strategies that improve population awareness and behaviour about the benefits of healthy eating and physical activity; fiscal measures that increase the price of unhealthy food content (fat) or reduce the price of healthy foods rich in fibre (fruits and vegetables); and regulatory measures that improve nutritional information content or restrict the marketing of unhealthy food products (at 1781).

For further discussion of cost-effectiveness and obesity control, see R Carter et al, “Assessing Cost-Effectiveness in Obesity (ACE-Obesity): An Overview of the ACE Approach, Economic Methods and Cost Results” (2009) 9 November *BMC Public Health* 419.

Provision of information about healthy nutrition and physical activity is a common public health intervention.¹⁴ Examples include Canada's Food Guide for Healthy Eating, nutrition labels on packaged foods¹⁵ and, in 2010, new legislation passed by the US federal government requiring chain restaurants with over 20 locations to disclose calorie information on menu boards.¹⁶

Yet information alone has been shown to be a weak motivator of diet and exercise behaviour change.¹⁷ An evaluation of calorie labelling in fast food outlets in New York City concluded:

Eating behavior is notoriously resistant to change. A large body of research has shown that weight-loss interventions designed to educate people about healthful food choices are generally ineffective. Thus, simply displaying information about the caloric value of various food options may fail to translate into attitudinal, motivational, or—most importantly—behavioural changes in line with choosing healthier food options.¹⁸

¹⁴ For general discussion of social marketing as a public health tool, see Ross Gordon et al, "The Effectiveness of Social Marketing Interventions for Health Improvement: What's the Evidence?" (2006) 120:12 *Public Health* 1133.

¹⁵ For information about nutrition labelling requirements in Canada, see Health Canada, "Food and Nutrition: Nutrition Labelling", online: HC <www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/index-eng.php>.

¹⁶ See generally US Food and Drug Administration, Press Release, "FDA Releases Guidance on Federal Menu Labeling Requirements" (24 August 2010), online: FDA <www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm223880.htm> (the labelling requirements apply to chain restaurants with 20 or more locations that trade under the same name and whose menu items are substantially the same).

¹⁷ See generally Helen L Walls et al, "Why Education and Choice Won't Solve the Obesity Problem" (2009) 99:4 *Am J Public Health* 590.

¹⁸ Brian Elbel et al, "Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City" (2009) 28:6 *Health Aff* w1110 at w1119. Other studies have found that calorie counts on menus have limited or no statistically significant impact on customers' food choices. See e.g. Maya K Vadiveloo, L Beth Dixon & Brian Elbel, "Consumer Purchasing Patterns in Response to Calorie Labeling Legislation in New York City" (2011) 8:1 *Int J Behav Nutr Phys Act* 51; Eric A Finkelstein et al, "Mandatory Menu Labeling in One Fast-Food Chain in King County, Washington" (2011) 40:2 *Am J Prev Med* 122; B Elbel, J Gyamfi & R Kersh, "Child and Adolescent Fast-Food Choice and

Indeed, public health officials and experts have promoted a consistent basic message about healthy eating and physical activity: “[F]or nearly half a century almost every authoritative government or professional committee that has reviewed research on diet and chronic disease ultimately has arrived at the same basic dietary advice: eat less; move more; eat more fruits, vegetables, and whole grains; and avoid junk food.”¹⁹ Rising rates of overweight and obesity suggest that, for many people, information alone is not enough to counter the obesogenic hazards of modern environments. As Philipson and Posner observe, “If the majority of people understand how to lose weight, simply by eating less or exercising more, public education programs will have small effects. Indeed, given that obesity has increased during an era in which people know more about the effects of being overweight, lack of knowledge is an unlikely explanation for that increase.”²⁰

Governments may adopt more coercive legal measures in the interests of public health, such as restrictions or prohibitions on products or activities linked with unhealthy weight gain. Schools may prohibit the sale of sugar-sweetened beverages and high calorie, low-nutrition snack foods from vending machines and cafeterias.²¹ Such bans may even prevent students from celebrating birthdays with cake or selling baked goods and confectionary items for school fundraisers.²² Numerous analysts have advocated for prohibitions on food advertising aimed at children.²³ Québec, Sweden, and Nor-

the Influence of Calorie Labeling: A Natural Experiment” (2011) 35:4 Int J Obes 493.

¹⁹ Steven H Woolf & Marion Nestle, “Do Dietary Guidelines Explain the Obesity Epidemic?” (2008) 34:3 Am J Prev Med 263 at 263.

²⁰ Tomas A Philipson & Richard J Posner, “The Long Run Growth in Obesity as a Function of Technological Change” (2003) 46:3 Perspect Biol Med 87 at 97.

²¹ See Mary Story, Marilyn S Nanney & Marlene B Schwartz, “Schools and Obesity Prevention: Creating School Environments and Policies to Promote Healthy Eating and Physical Activity” (2009) 87:1 Milbank Q 71.

²² See e.g. “Schoolgirl’s Birthday Cake Banned Under Healthy Eating Rules”, *The Telegraph* (16 October 2009) online: The Telegraph <www.telegraph.co.uk/news/uknews/6345012/Schoolgirls-birthday-cake-banned-under-healthy-eating-rules.html>; Jennifer Medina, “A Crackdown on Bake Sales in City Schools”, *The New York Times* (2 October 2009) online: The New York Times <www.nytimes.com/2009/10/03/nyregion/03bakesale.html>.

²³ See e.g. Bridget Kelly et al, “Television Food Advertising to Children: A Global Perspective” (2010) 100:9 Am J Public Health 1730; Kaye Mehta, “Statutory Restrictions on Unhealthy Food Marketing to Children: the Debate Continues” (2010) 13:7 Public Health Nutr 1001.

way have laws prohibiting advertising directed at children younger than age 13 and, in 2006, the media regulator in the UK began phasing-in restrictions on junk food advertisements during children's television programs. In 2008, the Los Angeles city council enacted a ban on new fast food restaurants in South LA, the area that reportedly has the highest concentration of fast food outlets in the city and an obesity rate that is almost 20% higher than other LA neighbourhoods.²⁴ As another example of governmental intervention to control unhealthy behaviour, the mayor of New York City requested federal approval to prohibit low-income residents from using food stamps to buy sugar-sweetened sodas.²⁵ These types of restrictive legal measures attract criticism on the basis that they are excessively paternalistic, impose compliance costs, and pre-empt voluntary measures.²⁶

As a middle ground between information provision strategies and restrictions or bans, governments may choose to implement incentive strategies to influence people to engage in healthier behaviours. In theory, well-designed incentives may help individuals resist temptations to engage in near-term behaviours, such as overeating or skipping a workout at the gym, that can have cumulative effects in causing unhealthy weight gain. Incentives may take the form of rewards or punishments and other areas of public health provide examples of the use of incentives or disincentives. "Sin products" like tobacco and alcohol are heavily taxed in many countries and, as discussed below, some advocate for taxes on high calorie, low-nutrition foods and drinks, especially sugar-sweetened beverages. More directly, health insurers or employers may implement penalty programs that charge higher premiums or reduce pay for persons who are obese. Use of "sticks" rather than "carrots" may be criticized for many reasons: they are coercive, they

²⁴ Molly Hennessy-Fiske & David Zahniser, "Council Bans New Fast-Food Outlets in South LA", *Los Angeles Times* (30 July 2008) online: Los Angeles Times <articles.latimes.com/2008/jul/30/local/me-fastfood30>.

²⁵ See generally Robert Pear, "Soft Drink Industry Fights Proposed Food Stamp Ban", *New York Times* (30 April 2011) A11. The federal government rejected the request in August 2011, reportedly "because of the logistical difficulty of sorting out which beverages could or could not be purchased with food stamps and because it would be hard to gauge how effective the step was in reducing obesity" (Patrick McGeehan, "U.S. Rejects Mayor's Plan to Ban Use of Food Stamps to Buy Soda", *New York Times* (20 August 2011) A15).

²⁶ M Gregg Bloche, "Obesity and the Struggle Within Ourselves" (2005) 93:4 *Geo LJ* 1335 at 1337-38.

discriminate unfairly and they promote individual blame.²⁷ Rewards, then, might be a preferable tool. Governments could give tax breaks to individuals who enrol in a fitness program, or, instead of developing complicated taxation schemes, governments or employers could offer the most direct of incentives: financial payments for those who lose weight or achieve other health-related goals, such as reduced cholesterol and blood pressure. Incentives could also be offered to businesses, such as grants to convenience stores in low-income neighbourhoods to supply more fresh fruits and vegetables at a reasonable price.

This article discusses several types of incentives that aim to encourage healthier individual behaviour and considers the emerging body of literature that evaluates the effectiveness and impact of incentives as tools for public health policy. Incentives vary widely in intensity, from indirect (or mild) to direct (or strong) incentives. At one end of the incentive spectrum are strategies that simply invite healthier behaviour. For example, a local government may designate road lanes for bicycles and preserve park spaces in urban areas. Applying “build it and they will come” logic by providing physical environments that invite activity may encourage urban residents to cycle to work or play in the park with their children. In the middle of the incentive spectrum are measures like tax credits for those who participate in sports and fitness programs or “fat taxes” on high calorie, low-nutrition foods. These strategies target individuals’ pocketbooks and thus may have a stronger influence on behaviour. The most direct incentives are governmental or private sector schemes that use monetary payments or penalties to induce behavioural change. While this article focuses on incentives targeted at individuals, it also briefly discusses several examples of incentives aimed at businesses, particularly food retailers.

The use of incentives as a health policy tool has three key legal dimensions. First, governments rely on legal powers to implement certain types of incentives, such as the use of zoning authority by local governments and taxation statutes to create incentive programs by federal or provincial governments.²⁸ Second, in their operation and impact, incentives may infringe on legally protected rights. Both public and private sector organizations must comply with human rights and employment standards legislation in the de-

²⁷ For discussion of ethical problems in a range of obesity policy interventions, including incentives, see M ten Have et al, “Ethics and Prevention of Overweight and Obesity: An Inventory” (2011) 12 *Obes Rev* 669.

²⁸ For further discussion of legal jurisdiction issues in the Canadian context, see Nola M Ries & Barbara von Tigerstrom, “Legal Interventions to Address Obesity: Assessing the State of the Law in Canada” (2011) 43:2 *UBC L Rev* 361.

sign and implementation of incentives. Disincentives in the form of penalties may be particularly vulnerable to legal challenge. Third, public health law is concerned with the use of legal and policy measures to create conditions in which people may be healthy.²⁹ It is important, therefore, to evaluate incentive programs to determine their effectiveness in ameliorating obesogenic environments and creating conditions for improved dietary and physical activity behaviours.

I. Creating Space for Physical Activity

The built environment in which we live, work, and play influences both our diet and physical activity. This environment encompasses urban design, land use, transportation systems, access to amenities for fitness and leisure activities, green space, socio-economic characteristics, sense of safety, and impressions of neighbourhood attractiveness. People who live in walkable neighbourhoods are less likely to be obese; indeed, a man living in a highly walkable neighbourhood can weigh up to ten pounds less than a peer in a very unwalkable neighbourhood.³⁰

In contrast, people who live in urban neighbourhoods that have no sidewalks (or even a sidewalk on just one side of the road) and are distant from fitness facilities and shops are more likely to be overweight.³¹ Adults and

²⁹ For comprehensive discussion of the scope and aims of public health law, see Lawrence O Gostin, *Public Health Law: Power, Duty, Restraint*, 2d ed (Berkeley, New York; University of California Press, Milbank Memorial Fund, 2008). Gostin states:

Public health law is the study of the legal powers and duties of the state, in collaboration with its partners (e.g., health care, business, the community, the media, and academy), to assure the conditions for people to be healthy (to identify, prevent, and ameliorate risks to health in the population) and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the common good. The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice (at xxii).

³⁰ Ken R Smith et al, “Walkability and Body Mass Index: Density, Design, and New Diversity Measures” (2008) 35:3 *Am J Prev Med* 237 (“[w]alkable neighborhoods are those designed to include the 3Ds: population density, pedestrian-friendly design, and a diversity of destinations” at 241).

³¹ Billie Giles-Corti et al, “Environmental and Lifestyle Factors Associated With Overweight and Obesity in Perth, Australia” (2003) 18:1 *Am J Health Promot* 93. Regarding access to fitness facilities, the authors write that “those who had poor

children who live in sprawling suburban areas walk less and weigh more, likely due to the fact that they spend more time in automobiles.³² Heavy automobile traffic also poses hazards to pedestrians and cyclists, especially children, and pollutes the air, creating even more impediments to active commuting and outdoor activity. Perceptions of neighbourhood safety are also critically important, especially for parents and women. Children who walk or cycle to school have significantly higher rates of physical activity, and healthier body composition and cardiorespiratory fitness than do children who travel to school in automobiles.³³ Long commute distances and concerns about children's safety are examples of barriers to active commuting for schoolchildren.³⁴

The use of legal tools to change the built environment has been advocated as a means to facilitate healthier behaviour and reduce obesity rates.³⁵ Options include using municipal planning and zoning powers along with public spending allocations; mandating mixed use, higher-density urban developments; designating pedestrian-only areas; creating cycling lanes; and protecting parks and other spaces for physical activity.³⁶ Local governments may al-

access to four or more recreational facilities were 68% more likely to be obese compared with others" (at 97).

³² Reid Ewing et al, "Relationship Between Urban Sprawl and Physical Activity, Obesity, and Morbidity" (2003) 18:1 *Am J Health Promot* 47.

³³ See Kirsten K Davison et al, "Children's Active Commuting to School: Current Knowledge and Future Directions" (2008) 5:3 *Prev Chronic Dis A100*; David R Lubans et al, "The Relationship Between Active Travel to School and Health-Related Fitness in Children and Adolescents: A Systematic Review" (2011) 8:1 *Int J Behav Nutr Phys Act* 5. After reviewing 27 relevant articles, Lubans et al conclude that some evidence indicates that physically active travel to school is associated with a healthier body composition and cardiorespiratory fitness. They state: "Strategies to increase ATS [active travel to school] are warranted and should be included in whole-of-school approaches to the promotion of physical activity" (at 5).

³⁴ See Jenna R Panter et al, "Attitudes, Social Support and Environmental Perceptions as Predictors of Active Commuting Behaviour in School Children" (2010) 64:1 *J Epidemiol Community Health* 41.

³⁵ See e.g. Mark J Eisenberg et al, "Legislative Approaches to Tackling the Obesity Epidemic" (2011) 183:13 *CMAJ* 1496; Susan E Chen & Raymond JGM Florax, "Zoning for Health: The Obesity Epidemic and Opportunities for Local Policy Intervention" (2010) 140:6 *J Nutr* 1181; Lawrence O Gostin, "Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity" (2007) 297:1 *JAMA* 87.

³⁶ See e.g. Graham M Catlin, "A More Palatable Solution? Comparing the Viability of Smart Growth Statutes to Other Legislative Methods of Controlling the Obesity

so authorize the use of land for community gardens or farmers' markets as a means to enhance accessibility to fresh fruits and vegetables.³⁷ As will be further discussed below, business licensing powers may also be used to create incentives for food retailers to offer healthy food options as well as to establish themselves in under-served communities.³⁸

Green spaces and pedestrian- and cyclist-friendly urban planning have the objective of motivating residents to be more physically active. A reduction in automobile use and related environmental impacts may be a corollary benefit. It is unclear, however, whether mere proximity to green spaces and recreational amenities promotes physical activity and, in turn, helps maintain a healthier body weight. A 2011 systematic review considered 60 studies that examined the relationship between green space and obesity and concluded that “[t]here is some evidence for an association between green space and obesity-related health indicators, but findings were inconsistent and mixed

Epidemic” (2007) 5 Wis L Rev 1091; Lynn Parker, Annina Catherine Burns & Eduardo Sanchez, eds, *Local Government Actions to Prevent Childhood Obesity*, (Washington, DC: The National Academies Press, 2009).

³⁷ For a review of relevant literature, see Lacey Arneson McCormack et al, “Review of the Nutritional Implications of Farmers' Markets and Community Gardens: A Call for Evaluation and Research Efforts” (2010) 110:3 J Am Diet Assoc 399.

³⁸ For more detail on legal powers available to manage urban design under municipal and planning statutes, see Ontario, Ministry of Municipal Affairs and Housing, “Planning by Design: A Healthy Communities Handbook” (2009), online: MMAH <www.mah.gov.on.ca/Page6737.aspx>. This document discusses provisions in the *Planning Act*, RSO 1990, c P 13 relevant to official community plans; community improvement plans; minimum and maximum building height, density and lot size; site plan controls; parkland dedication; subdivision review and approval; and developer permits. It also describes 21 case studies providing best practice suggestions. The Public Health Agency of Canada provides information on healthy urban design initiatives by federal, provincial, and territorial departments and agencies, as well as non-governmental organizations. See Public Health Agency of Canada, “Healthy Living E-Bulletin, The Built Environment” (May 2011), online: PHAC <www.phac-aspc.gc.ca/hp-ps/hl-mvs/ipchls-spimmvs/bulletin/2011/may-mai/e-bulletin-eng.php>. The Healthy Canada by Design initiative (www.uphn.ca/CLASP), launched in 2009, aims “to examine the impact of and to improve neighborhood design and community planning with respect to health and chronic disease, working with planners, public health officials, developers, policy-makers and the public through partnerships in British Columbia, Ontario, and Quebec. (Healthy Canada by Design, “Healthy Canada by Design CLASP Initiative: Health Authorities’ Project Summaries” (2011), online: NCCHPP <www.ncchpp.ca/docs/HCBD_ProjectSummaries2011.pdf>).

across the studies.”³⁹ For example, a UK analysis found that urban residents who lived closest to parks were more likely to achieve recommended levels of physical activity, but after adjustment for a variety of environmental and respondent characteristics, this did not necessarily translate to lower rates of overweight and obesity.⁴⁰ Paradoxically, a 2008 study of nearly five thousand Dutch people found that those living near green spaces, such as parks, walked and cycled *less* often.⁴¹ One explanation is that green spaces may separate homes from shops, so people are more likely to use a car to run errands. A British study found “no evidence of clear relationships between recreational physical activity and access to green spaces,”⁴² at least for the 4,732 middle-aged to elderly people included in this analysis.⁴³

Some studies suggest that proximity to green space makes people *feel* healthier,⁴⁴ and may provoke higher self-rated scores of health and well-being.⁴⁵ Living near green space has been correlated to lower rates of some health problems, particularly depression and anxiety disorders.⁴⁶

Other researchers point out that most existing studies do not take account of selection bias; that is, people of healthy weight who enjoy physical activi-

³⁹ K Lachowycz & AP Jones, “Greenspace and Obesity: A Systematic Review of the Evidence” (2011) 12:5 *Obes Rev* e183 at e187.

⁴⁰ Emma Coombes, Andrew P Jones & Melvyn Hillsdon, “The Relationship of Physical Activity and Overweight to Objectively Measured Green Space Accessibility and Use” (2010) 70:6 *Soc Sci Med* 816.

⁴¹ Jolanda Maas et al, “Physical Activity As a Possible Mechanism Behind the Relationship Between Green Space and Health: A Multilevel Analysis” (2008) 8 *BMC Public Health* 206.

⁴² M Hillsdon et al, “The Relationship Between Access and Quality of Urban Green Space with Population Physical Activity” (2006) 120:12 *Public Health* 1127 at 1130.

⁴³ *Ibid.* A recent New Zealand study also did not find a connection between proximity to green space and cardiovascular disease mortality (Elizabeth Richardson et al, “The Association Between Green Space and Cause-Specific Mortality in Urban New Zealand: An Ecological Analysis of Green Space Utility” (2010) 10 *BMC Public Health* 240, online: <www.biomedcentral.com/content/pdf/1471-2458-10-240.pdf>).

⁴⁴ Jolanda Maas et al, “Green Space, Urbanity, and Health: How Strong is the Relation?” (2006) 60:7 *J Epidemiol Community Health* 587.

⁴⁵ Peter P Groenewegen et al, “Vitamin G: Effects of Green Space on Health, Well-Being, and Social Safety” (2006) 6:1 *BMC Public Health* 149.

⁴⁶ J Maas et al, “Morbidity is Related to a Green Living Environment” (2009) 63:12 *J Epidemiol Community Health* 967.

ty may be more likely to choose to live in highly walkable communities with many recreational amenities, while obese or overweight people may be more likely to choose neighbourhoods suited to automobile use because they prefer driving.⁴⁷ Eid et al dispute studies claiming that urban sprawl *causes* obesity, arguing that self-selection is the explanation for the association. They contend “that recent calls to redesign cities in order to combat the rise in obesity are misguided. Our results do not provide a basis for thinking that such redesigns will have the desired effect, and therefore suggest that resources devoted to this cause will be wasted. The public health battle against obesity is better fought on other fronts.”⁴⁸ A 2011 systematic review of studies evaluating the impact of community-wide interventions to promote physical activity, including environmental changes such as investments in walking paths and better signage and lighting to improve safety, concluded that the evidence reviewed “does not support the hypothesis that multi-component community wide interventions effectively increase population levels of physical activity.”⁴⁹

Urban planning initiatives focused on encouraging physical activity may be commendable for improving environmental sustainability in cities by reducing automobile use, but their impact on obesity rates appears to be relatively weak. Building walking and cycling paths and protecting green space may simply not be enough incentive to motivate non-exercisers into regular physical activity. If the “build it and they will exercise” approach does not have its desired benefits, stronger incentives may be warranted.

II. Tax Credits for Physical Activity

Financial incentives for taking up exercise, losing weight, or meeting other health-related targets are another policy option to promote improved health status. Such incentives may be direct, such as cash payments for reaching medically supervised weight-loss goals, or indirect, such as tax credits for money spent on fitness and recreation programs. These measures counter prevailing economic incentive structures in which calories are relatively inexpensive and high-wage rates reward sedentary occupations.⁵⁰

⁴⁷ Jean Eid et al, “Fat City: Questioning the Relationship between Urban Sprawl and Obesity” (2008) 63:2 *Journal of Urban Economics* 385 at 385-86.

⁴⁸ *Ibid* at 399.

⁴⁹ PRA Baker et al, “Community Wide Interventions for Increasing Physical Activity” (2011) 4 *The Cochrane Library* 1 at 2, online: <onlinelibrary.wiley.com/doi/10.1002/14651858.CD008366.pub2/pdf>.

⁵⁰ Tomas J Philipson & Richard A Posner, “The Long-Run Growth in Obesity as a Function of Technological Change” (2003) 46:3 *Perspect Biol Med* S87.

Philipson points out that “historically, work was strenuous; in effect, individuals got paid to exercise. Now work is more sedentary: individuals have to pay (in terms of foregone earnings and gym memberships) to exercise.”⁵¹

Some jurisdictions are experimenting with tax laws to create incentives for physical activity. In Canada, the federal government launched a children’s physical activity tax credit for the 2007 taxation year that allows claims of up to \$500 for eligible activities.⁵² To qualify for the tax credit, a physical activity program must meet a minimum time requirement (eight consecutive weeks or, in the case of a children’s camp, five consecutive days) and include “a significant amount of physical activity that contributes to cardiorespiratory endurance, plus one or more of: muscular strength, muscular endurance, flexibility, and/or balance.”⁵³ Several Canadian provinces and the US have also adopted similar “healthy living” tax credits, with some offering credits for both adult and children’s fitness activities.⁵⁴

These tax credits are intended to encourage physical activity by offsetting the cost of sports and fitness programs. But the limitations of these tax measures hinder their capacity to have any significant impact on improving physical activity levels among the majority of Canadian adults and children. In turn, the impact on obesity rates is likely to be negligible. First, the federal program allows claims of *up to* \$500, but the actual amount a parent is eligi-

⁵¹ Tomas J Philipson, “The World-wide Growth in Obesity: an Economic Research Agenda” (2001) 10:1 Health Economics 1-7.

⁵² *Income Tax Act*, RSC 1985, c 1 (5th Supp), s 118.03; *Income Tax Regulations*, CRC, c 945, s 9400(1)-9400(2).

⁵³ See Canada Revenue Agency, “Line 365 - Children’s Fitness Amount”, online: CRA <www.cra-arc.gc.ca/fitness>.

⁵⁴ See Manitoba’s Children’s Fitness Tax Credit, *Income Tax Act*, CCSM, c 110, ss 4.6(10.2-10.4); Nova Scotia’s Healthy Living Tax Credit, *Income Tax Act*, RS 1989, c 217, s 12A; Saskatchewan’s *Active Families Benefit Act*, SS 2008, c A-4.01; and Ontario’s Children’s Activity Tax Credit, *Taxation Act, 2007*, SO 2007, c 11, Schedule A, s 103.1. United States tax law permits individuals to claim tax credits for the cost of membership in weight loss programs, provided they enrol in such a program under medical supervision to address a diagnosed condition which, according to the Internal Revenue Service, includes obesity, hypertension and heart disease. Fees for gym memberships or speciality diet food products are not eligible expenses. See Internal Revenue Service, “What Are Medical Expenses?”, online: IRS <www.irs.gov/publications/p502/ar02.html#en_US_publink1000179034>.

ble to receive may be much lower.⁵⁵ The amount of the credit is determined by multiplying the cost of the eligible program by the lowest marginal tax rate (15%). If a parent spends \$1,000 for their child to play hockey for a winter season, they are eligible for a \$150 tax credit ($\$1,000 \times 15\%$). If a parent spends \$150 for a session of swimming lessons, they qualify for a mere \$22.50 ($\$150 \times 15\%$). Second, tax credit schemes involve a degree of administrative burden on claimants, who must keep receipts to prove their expenses and remember to file for the credit on their tax return. Third, the tax credit does not immediately help to offset the cost of sports and recreational programs. A parent must be able to pay the cost at the time of enrolment, so the tax credit offers no assistance to families who cannot initially afford to pay the fees for fitness activities.

A 2009 survey of Canadians provided evidence of these shortcomings of the federal fitness tax credit, as parents in the lowest-income quartiles did not apply for these tax credits.⁵⁶ Of respondents with children aged 2 to 18, about half (54%) said their child was enrolled in organized physical activity and nearly the same proportion (55%) said they were aware of the Children's Fitness Tax Credit. However, the survey revealed a wide gap between respondents in the lowest and highest income brackets. Only 40% of those in the lowest income quartile had children in an organized physical activity program, compared to almost 70% (67.7%) in the highest income quartile. Just 28% of low-income earners claimed the fitness tax credit, while 55% of high-income earners took advantage of the credit. Indeed, over 60% of Canadian children who live in poverty do not participate in organized sports and recreation, so these families will not benefit from the tax credit.⁵⁷ A recent analysis of economic interventions to address obesity described the Children's Fitness Tax Credit as an example of "potentially inefficient economic measures to encourage increases in physical activity" and recommended that public funds be allocated "to economic measures that show

⁵⁵ During the 2011 federal election campaign, Conservative leader Stephen Harper promised to increase the child's tax credit to \$1000 and expand the program to include a similar tax credit for adults. Such measures would have to await a balanced federal budget, possibly by 2015. See CBC News, "Harper would extend fitness tax credit" (3 April 2011), online: CBC News <www.cbc.ca/news/politics/canadavotes2011/story/2011/04/03/cv-election-harper-ottawa.html>.

⁵⁶ John C Spence et al, "Uptake and Effectiveness of the Children's Fitness Tax Credit in Canada: The Rich Get Richer" (2010) 10 *BMC Public Health* 356 at 358-360, online: <www.ncbi.nlm.nih.gov/pmc/articles/PMC2908091>.

⁵⁷ Sheila Block, "Children's Fitness Tax Credit: Less than Meets the Eye" (2007), online: Canadian Women's Health Network <www.cwhn.ca/en/node/39436>.

more promise (e.g. subsidized participation for targeted populations).”⁵⁸ Such programs could help to reduce identified barriers by, for example, directing funds to support participation of children from low-income families in sports and recreation programs. Just as with the Children’s Fitness Tax Credit, the effectiveness of targeted programs requires evaluation of uptake and impact: “The promise of such economic measures should be tested ... to determine the actual effects of such measures on increasing physical activity participation and reducing obesity.”⁵⁹

Taxes and subsidies may also be applied to food products to attempt to improve dietary choices and to promote healthier body weight. As with tax credits, however, some analysts contend that relatively small price adjustments will not provoke widespread changes in eating patterns. Moreover, while “carrot” approaches such as physical activity tax credits attract support from the sports and fitness sector, which stands to see greater enrolment and revenues, “fat taxes” generate food industry opposition and the criticism that potentially regressive taxation amounts to a government revenue grab rather than effective public health policy.

III. Taxes on Energy Dense, Low-Nutrition Foods and Beverages

Governments have a long history of taxing the production and sale of “sin products,” such as tobacco and alcohol, and these taxes have been shown to be effective in reducing consumption.⁶⁰ Smoking rates in the United States have dropped from over 40% in 1965 to less than 20% by 2007, a decrease attributed to heavy taxation and greater public awareness of the health hazards associated with tobacco use. High taxes on cigarettes also dissuade young people from taking up the habit.⁶¹ Increasing the price of alcoholic beverages through taxation also reduces consumption, especially

⁵⁸ Guy Faulkner et al, “Economic Policy, Obesity and Health: A Scoping Review” (Final Report submitted to the Heart and Stroke Foundation of Canada, July 2010) at 30, online: <www.hsf.ca/research/sites/default/files/hsfc_epoh_finalrpt_july_2010.pdf>.

⁵⁹ *Ibid* at 30.

⁶⁰ See Frank J Chaloupka, Kurt Straif & Maria E Leon, “Effectiveness of Tax and Price Policies in Tobacco Control” (2011) 20:3 *Tob Control* 235.

⁶¹ For a discussion of the use of taxation to reduce demand for tobacco products, see Frank J Chaloupka, Melanie Wakefield & Christina Czart, “Taxing Tobacco: The Impact of Tobacco Taxes on Cigarette Smoking and Other Tobacco Use” in Robert L Rabin & Stephen D Sugarman, eds, *Regulating Tobacco* (New York: Oxford University Press, 2001) 39.

among younger drinkers.⁶² Taxes are linked with lower rates of drinking and driving, and fewer alcohol-related car crashes.⁶³ Higher alcohol prices also help reduce adverse health consequences of excessive drinking, such as liver disease and certain cancers associated with alcohol consumption. One study even found that higher liquor and beer taxes reduced rates of syphilis and gonorrhoea, an outcome the researchers attributed to less “sex under the influence.”⁶⁴

While “sin products” are often heavily taxed—and regulated in other ways, such as imposing age limits for the legal purchase of alcohol and tobacco—“fat taxes” on high calorie, low-nutrition products are not yet standard public policy. Advocates of such taxes argue that price increases would be beneficial in reducing consumption of less healthy foods and beverages and generate government revenue that could be allocated to fund health services or other programs to address obesity. Tax revenue collected on alcohol and tobacco products is already directed to some degree at legislative enforcement and health programs. In 2007, the Government of Québec adopted legislation to create a special fund to promote healthy lifestyles, and partial funding (\$20 million annually) is obtained from tobacco tax revenues.⁶⁵ The fund, co-supported by a private charitable foundation, finances public information campaigns and school-based interventions to promote healthy living. In announcing the fund, the provincial health minister identified obesity, inadequate physical activity, and smoking as leading lifestyle factors linked with premature death.⁶⁶

⁶² For a review of relevant studies, see AC Wagenaar, MJ Salois & KA Komro, “Effects of Beverage Alcohol Price and Tax Levels on Drinking: A Meta-Analysis of 1003 Estimates from 112 Studies” (2009) 104:2 *Addiction* 179.

⁶³ See Frank J Chaloupka, Michael Grossman & Henry Saffer, “The Effects of Price on Alcohol Consumption and Alcohol-Related Problems” (2002) 26:1 *Alcohol Res Health* 22 at 29; Frank J Chaloupka, Henry Saffer & Michael Grossman, “Alcohol-Control Policies and Motor-Vehicle Fatalities” (1993) 22:1 *J Legal Stud* 161 at 181-82.

⁶⁴ H Chesson et al, “Sex Under the Influence: The Effect of Alcohol Policy on Sexually Transmitted Disease Rates in the United States” (2000) 43:1 *JL & Econ* 215.

⁶⁵ *An Act to Establish the Fund for the Promotion of a Healthy Lifestyle*, RSQ c F-4.0021.

⁶⁶ See Canadian Broadcasting Corporation, “Quebec, Private Foundation to Spend Millions on Healthy Living”, 23 October 2006, online: CBC <www.cbc.ca/canada/montreal/story/2006/10/23/healthylivingprogram.html>.

Some countries impose differential tax levels on foods based on whether they are considered part of a basic diet, as opposed to a snack or treat, though existing taxes were generally implemented with a view to revenue generation rather than as a specific measure to control obesity rates.⁶⁷ In Canada, the federal government imposes a 5% sales tax on goods and services. Basic groceries are zero-rated, however, and these include “fresh, frozen, canned, and vacuum sealed fruits and vegetables, breakfast cereals, most milk products, fresh meat, poultry and fish, eggs, and coffee beans.”⁶⁸ Numerous snack food products are not considered basic groceries and are taxed at the 5% rate. These include carbonated sodas, chocolate bars and other candies, ice cream bars, “chips, crisps, puffs, curls or sticks (such as potato chips, corn chips, cheese puffs, potato sticks, bacon crisps, and cheese curls),”⁶⁹ salted nuts, and ice cream bars. Over 30 US states tax sugar-sweetened beverages.⁷⁰ Research indicates that states without snack taxes, and those that repealed such taxes, have experienced a greater increase in obesity prevalence than states with snack taxes, though the taxes are not high enough to explain the changes in obesity rates.⁷¹ In France, candy, chocolate, and margarine are taxed at

⁶⁷ See Tatiana Andreyeva, Frank J Chaloupka & Kelly D Brownell, “Estimating the Potential of Taxes on Sugar-Sweetened Beverages to Reduce Consumption and Generate Revenue” (2011) 52:6 *Prev Med* 413.

⁶⁸ Canada Revenue Agency, “GST/HST Memoranda Series: 4.3 Basic Groceries”, (January 2007), online: CRA <www.cra-arc.gc.ca/E/pub/gm/4-3/4-3-e.pdf> at 3.

⁶⁹ *Ibid* at 9.

⁷⁰ See Trust for America’s Health, “F as in Fat: How Obesity Threatens America’s Future 2010”, online: TFAH <www.healthyamericans.org/reports/obesity2010/Obesity2010Report.pdf> at 7, 42. For information on tax rates, see Jamie F Chriqui et al, “State Sales Tax Rates for Soft Drinks and Snacks Sold Through Grocery Stores and Vending Machines, 2007” (2008) 29:2 *J Public Health Policy* 226. The authors note that tax rates “vary by state, intended retail location (grocery store vs. vending machine), and product” (at 226). Items in vending machines and pop are generally taxed at a higher rate than snack products purchased in grocery stores.

⁷¹ Daniel Kim & Ichiri Kawachi, “Food Taxation and Pricing Strategies to ‘Thin Out’ the Obesity Epidemic” (2006) 30:5 *Am J Prev Med* 430. After pointing out that the taxes are not high enough to explain lower obesity rates in some states, Kim & Kawachi suggest that residents in states with snack taxes might have “social norms, beliefs, and/or values regarding obesogenic behaviors” that make them more likely to have healthier lifestyles (at 433). They may also be more inclined to vote into office public officials who will enact snack taxes.

around 20%, much higher than the 5.5% tax that applies to other foods.⁷² In the UK, sugary beverages and candies are taxed at 15% or higher. In early 2010, the Romanian government announced a controversial junk food tax, described as “one of the most far-reaching of its kind in the world,”⁷³ though implementation was delayed as government officials “struggle[d] to identify upwards of 40,000 products”⁷⁴ to be taxed and the legislation was ultimately withdrawn “amid fierce opposition.”⁷⁵

Energy dense, low-nutrition foods are typically inexpensive and convenient to eat, and consumption of sugary drinks and salty snack foods has increased dramatically over the past three decades.⁷⁶ Intake of sugar, especially from sweetened drinks, is on the rise. These caloric beverages, including soft drinks, energy drinks, iced tea, and coffee drinks, are fingered as a major culprit in increased obesity rates. In the late 1970s, people in the United States consumed, on average, about 70 calories per day from sugar-sweetened beverages; by 2000, this intake increased to approximately 190

⁷² One analysis of French food prices and population BMI did not find that higher prices necessarily produced desirable body weight outcomes. See Christine Boizot-Szantai & Fabrice Etile, “The Food Prices/Body Mass Index Relationship: Theory and Evidence from a Sample of French Adults” (paper delivered at the 11th Congress of the European Association of Agricultural Economists, 2005), online: AgEcon <ageconsearch.umn.edu/bitstream/24734/1/cp05bo07.pdf>. The authors conclude that taxes on specific foods “will not curb the epidemic of obesity in the short-term,” but their analysis did not allow predictions about longer-term impacts (at 13). For example, the authors could not infer from their analysis whether higher prices on certain low-nutrition foods would reduce the lifetime risk of obesity for the current generation of French children (*ibid*).

⁷³ Ed Holt, “Romania Mulls Over Junk Food Tax” (2010) 375:9720 *Lancet* 1070 at 1070. The tax would apply to a wide range of foods, including “hamburgers, chips, fizzy drinks, and other fast foods with high sugar and fat levels,” but “kebabs—one of Romania’s favourite foods—and pizza will be exempt” (at 1070).

⁷⁴ Jeremy Laurance, “How to Solve the Junk Food Problem: Tax” *The Independent* (3 April 2010), online: The Independent <www.independent.co.uk/life-style/health-and-families/health-news/how-to-solve-the-junk-food-problem-tax1934716.html>.

⁷⁵ Ed Holt, “Hungary to Introduce a Broad Range of Fat Taxes” (2011) 378:9793 *Lancet* 755 at 755.

⁷⁶ For a review of US data, see Kim & Kawachi, *supra* note 71.

calories per day. Some individuals, especially children and teens, consume 10–15% of their daily calorie intake in beverages.⁷⁷

In light of this evidence about high calorie liquid consumption, some public health advocates champion a specific tax on sugar-sweetened beverages. An expert panel convened by the Canadian Heart and Stroke Foundation recommended a tax on caloric sweetened beverages based on research indicating that “adult weight is modestly responsive to soft-drink taxes.”⁷⁸ In the United States, Brownell and Frieden argue for a penny-per-ounce excise tax on beverages made with caloric sweeteners like sugar and corn syrup.⁷⁹ They estimate this tax would reduce consumption by at least two drinks per week, adding up to eight thousand fewer calories and two lost pounds over the course of a year. Nationally, a penny-per-ounce tax is also estimated to bring in USD\$14.9 billion in revenue that could be directed to obesity-prevention programs and the health care costs associated with obesity.⁸⁰ In the United States, medical costs associated with overweight and obesity are estimated at \$147 billion. Half these costs are covered through the federally-financed Medicare and Medicaid programs.⁸¹

Taxes on sugar-sweetened beverages may become an increasingly attractive public policy measure as a means to raise revenue to pay for escalating health care costs or targeted anti-obesity programs. For example, in 2009, the US Senate Finance Committee proposed an excise tax on sugary beverages as a means to generate funds for health care reform.⁸² In 2010, the District of Columbia City Council gave preliminary approval for a six percent tax on soft drink sales to generate funds for healthy nutrition programs in schools. The proposed tax would have increased the price of a two-litre bottle of soda

⁷⁷ See Kelly D Brownell & Thomas R Frieden, “Ounces of Prevention – The Public Policy Case for Taxes on Sugared Beverages” (2009) 360:18 N Engl J Med 1805 at 1805.

⁷⁸ Faulkner et al, *supra* note 58 at 20 (the authors acknowledge that a soda tax may have a minimal impact on the weight of children and adolescents).

⁷⁹ Brownell & Frieden, *supra* note 77.

⁸⁰ See Kelly D Brownell et al, “The Public Health and Economic Benefits of Taxing Sugar-Sweetened Beverages” (2009) 361:16 N Engl J Med 1599 at 1602.

⁸¹ Eric A Finkelstein et al, “Annual Medical Spending Attributable To Obesity: Payer-And Service-Specific Estimates” (2009) 28:5 Health Affairs w822 at w828.

⁸² US Senate Finance Committee, “Financing Comprehensive Health Care Reform: Proposed Health System Savings and Revenue Options” (20 May 2009), online: APA Practice Central <www.apapracticecentral.org/advocacy/reform/finance-may20.pdf>.

by 10 to 12 cents and would have generated net revenue of around \$10 million annually.⁸³ This proposal was ultimately rejected.⁸⁴

Economists debate the price elasticity of goods, which refers to the degree to which consumer demand fluctuates with the price of a product, and predict that small price increases will have minimal impact on caloric consumption and body weight. If the retail price of sugary beverages or high-fat snacks rises, some consumers will simply pay the higher price and not change their consumption. One US study explored the impact of a hypothetical 20% tax on potato chips and salty snacks and found that individual consumption would drop only by about four to six ounces over the course of a year,⁸⁵ which translates to fewer than one thousand calories. The long-term impact of taxes on health outcomes is difficult to predict, but these calculations suggest the benefits will be slight. Two UK economists recently estimated the potential dietary and health impacts of a tax on saturated fat, coupled with a subsidy on fruits and vegetables. While they concluded that these fiscal measures would likely improve nutritional intake for some people, a large portion of the British population would still consume an unhealthy diet and “[o]nce the changes in diet are converted into changes in the risks of disease, the impacts of the policy are negligible.”⁸⁶ In 2011, the Danish government implemented a saturated fat tax on meat and dairy products, oils, and processed foods, despite strong opposition by dairy, meat, and other food producers. The Danish Commission on Disease Prevention estimated that a drop in heart disease attributable to lower fat consumption would extend individual life expectancy by 3 to 11 days.⁸⁷

⁸³ Tim Craig, “DC Council Launching Campaign Against Childhood Obesity” *The Washington Post* (2 May 2010), online: [Washington Post <www.washingtonpost.com/wpdyn/content/article/2010/05/01/AR2010050103193.html>](http://www.washingtonpost.com/wpdyn/content/article/2010/05/01/AR2010050103193.html).

⁸⁴ Alan Suderman, “DC Soda Tax Fizzles” *The Washington Examiner* (21 May 2010), online: [Washington Examiner <washingtonexaminer.com/local/dc-soda-tax-fizzles>](http://washingtonexaminer.com/local/dc-soda-tax-fizzles) (council members who opposed the tax expressed concern that “the tax applies too broadly, hurts lower-income families, and hadn’t followed the typical procedural process”).

⁸⁵ Fred Kuchler et al, “Taxing Snack Foods: Manipulating Diet Quality or Financing Information Programs?” (2005) 27:1 *Review of Agricultural Economics* 4.

⁸⁶ R Tiffin & M Arnoult, “The Public Health Impacts of a Fat Tax” (2011) 65 *Eur J Clin Nutr* 427 at 427.

⁸⁷ Forebyggelses kommissionen [Prevention Commission], *Vi kan leve længere og sundere* [We can live longer and healthier], *Forebyggelses kommissionens anbefalinger til en styrket forebyggende indsats* [Prevention Commission's

Interestingly, a recent Canadian study found that a government-mandated label declaring that a product is taxed would be more effective at reducing consumption than an actual tax. The researchers tested a label stating: “This product is high in fat. It has been taxed due to its less healthy nutritional content.” They concluded:

A warning label that points out that the less healthy food is taxed and why would be an effective way to discourage the consumption of these products. Overall, it appears that it is more important to tell people that the product is taxed because it is less healthy than to actually tax it. An increase in price appears not to be necessary; a label stating that the food is taxed because it is less healthy may be enough to significantly reduce purchases of that product.⁸⁸

This finding implies that less healthy foods ought to be stigmatized, similar to the ways in which smoking has been de-normalized “as a dirty and disgusting habit.”⁸⁹ Zimmerman explicitly advocates for the use of taxes as a means to promote negative attitudes towards foods and beverages that have low nutritional value: “a tax that was widely perceived as a sin tax on particular food types could send a powerful social signal about shifting norms of appropriate consumption and could have an effect much larger than the monetary value of the tax.”⁹⁰ This position is not supported by those who point out that almost all foods and drinks, even “junk” foods, can be consumed occasionally without adverse health impacts. As a British Columbia government report on childhood obesity stated, “[t]o demonize eating is not an op-

recommendations for strengthening prevention efforts] (April 2009), online: Forebyggelses kommissionen <www.forebyggelseskommissionen.dk/Materialer.aspx> (the Commission states at 150 that the tax will increase life expectancy by 0.031 years (11.3 days) on an optimistic calculation of impact, and only by 0.008 years (2.9 days) on a conservative estimate).

⁸⁸ Ryan D Lacanilao, Sean B Cash & Wiktor L Adamowicz, “Heterogeneous Consumer Responses to Snack Food Taxes and Warning Labels” (2011) 45:1 *Journal of Consumer Affairs* 108 at 121 (such a false claim—that a food is taxed when it is not—may, however, contravene advertising standards laws).

⁸⁹ James Colgrove, Ronald Bayer & Kathleen E Bachynski, “Nowhere Left to Hide? The Banishment of Smoking from Public Spaces” (2011) 364:25 *N Engl J Med* 2375 at 2376.

⁹⁰ Zimmerman, *supra* note 8 at 299.

tion,”⁹¹ or at least not in the view of legislators and policy-makers who wish to avoid nanny-state criticisms.

Indeed, governments must tread a fine line in any taxation policy that targets an “unhealthy” product: a tax must be high enough that it will cause some reduction in consumption, and therefore be more likely to have positive health impacts, but cannot be so high that it will decimate consumption and generate fierce backlash from industry players who are hurt by plummeting profits. Consumers may also argue that high taxes restrict their freedom of choice. Existing taxes on soft drinks and snack foods are generally considered to be too small to bring about a discernable reduction in consumption and, in turn, on rates of overweight and obesity. In the United States, for example, the average state tax on soda pop amounts to 0.0425 cents on a one-dollar bottle of pop,⁹² and analysts suggest that prices would need to increase by at least 10% to reduce consumption by an estimated 8-10%.⁹³ Another model suggests that an even higher 20% tax on sugar-sweetened beverages could bring about an average annual per capita weight loss of only 1.5 to 2.5 pounds.⁹⁴ It has been demonstrated that higher taxes on sugary beverages may lead to substitution behaviour among consumers, where they increase intake of other beverages and foods, meaning that overall calorie consumption is not reduced.⁹⁵

⁹¹ British Columbia, Select Standing Committee on Health, *A Strategy for Combatting Childhood Obesity and Physical Inactivity in British Columbia* (Legislative Assembly of British Columbia, 2006) at 1, online: <www.leg.bc.ca/CMT/38thparl/session-2/health/reports/Rpt-Health-38-2-29Nov2006.pdf>.

⁹² Lisa M Powell, Jamie Chriqui & Frank J Chaloupka, “Associations between State-Level Soda Taxes and Adolescent Body Mass Index” (2009) 3545:3 *J Adolesc Health* S57 at S62.

⁹³ T Andreyeva et al, “The Impact of Food Prices on Consumption: A Systematic Review of Research on Price Elasticity of Demand for Food” (2010) 100:2 *Am J Public Health* 216.

⁹⁴ Senarath Dharmasena & Oral Capps Jr, “Intended and Unintended Consequences of a Proposed National Tax on Sugar-Sweetened Beverages to Combat the U.S. Obesity Problem” (2011) *Health Econ*.

⁹⁵ One study of the impact of beverage prices on children and adolescent body weight concluded that any reduction in consumption of higher-prices caloric-sweetened soft drinks was offset by increased consumption of other beverages, such as milk. While milk provides nutrition and soft drinks do not, overall calorie intake was not reduced. See Jason M Fletcher, David E Frisvold & Nathan Tefft, “The Effects of

Food and beverage taxes are also considered regressive taxes in that they have a disproportionate impact on low-income earners. A person who spends \$1,000 a month on food can absorb higher product prices more easily than a person who has a monthly food budget of only \$250. Some argue that the regressive nature of junk food taxes is justified as rates of overweight and obesity are highest among lower-income groups, and the health of this population may be improved if sugar-sweetened drinks or other high calorie, low-nutrition foods became more affordable. A Canadian expert review panel states: “[a]nother rationale for government intervention is to improve the welfare of low income households. Those with limited means often economize by purchasing calorie-dense, processed foods and drinks. The reason is that, although these items are not particularly nutritious, they may provide the most calories per dollar.”⁹⁶ Others criticize this paternalistic approach and argue that a “policy of taxing foods that are commonly preferred by low-income households would exacerbate inequality in income, which might be expected to increase inequality in health outcomes, with negative effects on health for society as a whole.”⁹⁷

It is also argued that “fat taxes” on low-nutrition foods and beverages should be accompanied by “thin” subsidies on healthier foods to make the latter more affordable. It is even suggested that the price of artificially sweetened beverages should be reduced by subsidies to encourage people who consume caloric drinks to substitute zero or low-calorie options.⁹⁸ Economic models suggest that reducing the price of healthier foods like vegetable and fruits through subsidies could be a cost-effective way to increase consumption and reduce morbidity and mortality associated with poor nutritional in-

Soft Drink Taxes on Child and Adolescent Consumption and Weight Outcomes” (2010) 94:11-12 *Journal of Public Economics* 967.

⁹⁶ Faulkner et al, *supra* note 58 at 10.

⁹⁷ Grace Lordan & John Quiggin, “Should We Put a Thin Subsidy on the Policy Table in the Fight Against Obesity?” (2011) 14:2 *Forum for Health Economics & Policy*, citing Richard G Wilkinson & K Pickett, *The Spirit Level: Why More Equal Societies Almost Always Do Better* (London: Allen Lane, 2009).

⁹⁸ *Ibid.*

take.⁹⁹ Paradoxically, however, other economic models suggest that subsidies could increase weight gain in some individuals.¹⁰⁰

To date, studies indicate that taxes on high-energy, low-nutrition foods and beverages must be relatively high to decrease consumption of the targeted products; likewise, subsidies would need to “significantly lower prices [to] result in a substantial increase in the consumption of healthful foods.”¹⁰¹ A 2009 systematic review concluded that: “the limited existing evidence suggests that small taxes or subsidies are not likely to produce significant changes in BMI or obesity prevalence.”¹⁰² At best, taxes will generate revenue that may be directed to other, more effective, interventions to promote healthy lifestyles. Social marketing campaigns that publicize that certain foods and beverages are taxed because of their poor nutritional content may also help shift public attitudes and, in effect, “demonize” consumption of those products, though industry players can be expected to counter such messages.

IV. Cash for Weight Loss ... or Penalties for Being Obese

While governments may use taxation policy to create incentives or disincentives for specific behaviours, another option is more direct: pay people to lose weight or achieve other health-related targets. As discussed below, em-

⁹⁹ Sean B Cash, David L Sunding & David Zilberman, “Fat Taxes and Thin Subsidies: Prices, Diet, and Health Outcomes” (2005) 3:4 *Acta Agriculturae Scand Section C* 167 at 168-69, 171-72 (this study focused on the impact of fruit and vegetable consumption on rates of coronary heart disease and ischemic stroke).

¹⁰⁰ Gideon Yaniv et al, “Junk Food, Home Cooking, Physical Activity and Obesity: The Effect of the Fat Tax and the Thin Subsidy” (2009) 93:5-6 *Journal of Public Economics* 823. The authors explain:

The results show that for a non weight conscious individual a fat tax will unambiguously reduce obesity, whereas a thin subsidy may increase obesity. The reason for the latter result is that while the substitution effect of the subsidy acts to increase the purchase of cooking ingredients (at the expense of junk-food), the income effect acts to increase leisure ... reducing the time left for cooking. However, for a weight conscious individual, particularly one who is physically active, even a fat tax may increase obesity! This is so because a fat tax will generate substitution away from junk-food meals towards cooking more at home, leaving less time for physical activity. Although calorie intake will fall, calorie burning may fall by more (at 824).

¹⁰¹ Lordan & Quiggin, *supra* note 97.

¹⁰² Lisa M Powell & Frank J Chaloupka, “Food Prices and Obesity: Evidence and Policy Implications for Taxes and Subsidies” (2009) 87:1 *Milbank Quarterly* 229 at 229.

employers may also implement incentive schemes to promote healthier workforces, thinking it is better to spend money on paying employees to lose weight than to pay for more sick days and health insurance claims.

Some individuals who wish to shed pounds pay to join a commercial weight loss program (like Weight Watchers or Jenny Craig), or a community or online support group. A 2005 review of these types of programs reached the tepid conclusion that: “the evidence to support the use of the major commercial and self-help weight loss programs is suboptimal.”¹⁰³ Other research suggests that structured weight loss programs can work if people comply with them, but dropout rates are typically high.¹⁰⁴ Financial incentives are an option for promoting adherence to healthy lifestyle programs. Tangible, near-term monetary rewards may be more effective in motivating behavioural change than exhortations that a healthy body weight and regular physical activity will produce health benefits over the long term. As one study shows, giving non-exercisers a pamphlet about the benefits of exercise does not incite them to go to the gym, but paying them \$25 to go to the gym once a week does. Offer them an extra \$100 to go eight more times over a month, and they do.¹⁰⁵

¹⁰³ Adam Gildea Tsai & Thomas A Wadden, “Systematic Review: An Evaluation of Major Commercial Weight Loss Programs in the United States” (2005) 142:1 *Ann Intern Med* 56 at 56. A 2011 study found, however, that overweight or obese patients referred to Weight Watchers by their primary care provider lost twice as much weight as their peers who did not participate in this commercial program (5.06 kg weight loss at 12 months compared to 2.25 kg). The completion rate of the Weight Watchers program was 61% (Susan A Jebb et al, “Primary Care Referral to a Commercial Provider for Weight Loss Treatment Versus Standard Care: A Randomised Controlled Trial” (2011) 378:9801 *Lancet* 1485). A commentary on this study pointed out that the participants were predominantly mildly obese women in their 40s without major health problems, thus the study simply shows that “if you randomise a group of otherwise healthy low-risk marginally overweight/obese women to a (albeit, admittedly great) commercial weight loss program, they do better at losing weight than when told to do so by their doctors” (Arya Sharma, “Should We Outsource Obesity Treatment to Weight Watchers?” (9 September 2011), online: Arya M Sharma, MD <www.drsharma.ca/should-we-outsource-obesity-treatment-to-weight-watchers.html>).

¹⁰⁴ Cheryl L Graffagnino et al, “Effect of a Community-Based Weight Management Program on Weight Loss and Cardiovascular Disease Risk Factors” (2006) 14:2 *Obesity* 280.

¹⁰⁵ Gary Charness & Uri Gneezy, “Incentives to Exercise” (2009) 77:3 *Econometrica* 909.

Some governments are experimenting with offering monetary rewards to citizens who would benefit from weight loss. In 2007, the mayor of an Italian town announced an incentive scheme to promote weight loss among overweight residents: residents who lost three kilograms in a month were eligible to receive €50, and they could receive another €100 five months later if they had maintained the weight loss.¹⁰⁶ Participants in the program required a medical note confirming that they were overweight or obese by body mass index standards. The Italian national health ministry suggested that this incentive could be adopted elsewhere in the country.

In England, a regional health authority is offering a financial incentive program to promote weight loss. Called Pounds for Pounds, residents can sign up for a plan that specifies weight loss targets over a period of time.¹⁰⁷ Participants who achieve their targets and maintain weight loss are eligible for financial rewards of up to £400. Participants must have a physician's permission to participate in the program, and must have monthly weigh-ins signed off by a health professional. The average weight loss goal is about 33 pounds over a ten-month period.

The Pounds for Pounds program was created by a private company, Weight Wins, which describes its service as "air miles for dieters."¹⁰⁸ Interestingly, in its pilot run of the weight loss incentive scheme, the company offered participants no diet or exercise advice.¹⁰⁹ Participants reported that they achieved weight loss by modifying their diet (97%) and by getting more exercise (86%). Sixty percent made changes on their own, while 40% took additional steps such as joining a gym, participating in a weight loss group, or buying special weight loss meals. The finding that the majority of participants lost weight on their own by changing their diet and exercise patterns suggests that a lack of information is not a major impediment to individual action. If people already have general knowledge about moderating calorie consumption and increasing physical activity, appropriate incentives may be a useful tool to motivate behaviour change.

Some governments have a longer history with incentive schemes to encourage healthy behaviours among citizens. In 1989, Germany introduced

¹⁰⁶ Tom Kington, "Mayor Offers Too-Fat Italians Money to Diet" *The Guardian* (14 August 2007), online: The Guardian <www.guardian.co.uk/world/2007/aug/14/italy.international>.

¹⁰⁷ See Weight Wins, "Weight Wins and Public Health", online: <www.weightwins.co.uk/Public_Health.aspx>.

¹⁰⁸ *Ibid.*

¹⁰⁹ *Ibid.*

incentives into its national health insurance system to reduce the co-payments for those who engaged in preventative health screening. Today, German health insurers offer creative schemes where individuals can accumulate points for engaging in healthy behaviour, such as annual health screening (200 points), nutrition classes (150 points), licensed fitness programs (100-150 points per program), or tests of endurance, strength and coordination (100-150 points). The fitness test regime is called “Germany Moves” and results are used to develop a personal fitness training regimen. Individuals can redeem points for rewards like sports watches and bicycle helmets (500 points each), put points toward “partial funding of a short wellness holiday,”¹¹⁰ or pool points within a family to redeem for higher-value items such as a Nintendo Wii Fit. Most recently, cash rebates have been offered for individuals who meet targets for body mass index, blood pressure, blood sugar and cholesterol.

A major health insurer in South Africa, Discovery Health,¹¹¹ offers a similar incentive program that provides members with reduced-fee gym memberships and the opportunity to earn points for fitness activities. Members receive discounts at participating businesses, and the discounts increase as individual members accumulate more healthy-lifestyle points.

In Canada, a private company has recently launched Best Life Rewarded[®], a points-based health incentive program.¹¹² Registration in the program is free; members earn points for engaging in healthy behaviours, such as physical activity, cholesterol, and blood pressure check-ups, and compliance with medication regimes to control existing conditions. Points can be redeemed for rewards, such as fitness gadgets, healthy lifestyle books and magazines, and consultations with professionals, including registered dietitians, and kinesiologists. The company receives funding from sources such as pharmaceutical and food companies, and has partnered with such not-for-profit organizations as the Dietitians of Canada and the Canadian Obesity Network.

Some employers are also adopting incentive programs—of both carrot and stick varieties—to help reduce insurance costs and health claims for workers with obesity-related health problems. According to a US survey of 505 pri-

¹¹⁰ See Harald Schmidt, Andreas Gerber & Stephanie Stock, “What Can We Learn from German Health Incentive Schemes” (2009) 339 *Brit Med J* 725 at 726.

¹¹¹ Vitality HealthStyle (Pty) Ltd, *Discovery Vitality*, online: Discovery <www.discovery.co.za/portal/loggedout-individual/vitality>.

¹¹² BestLifeRewarded, “Learn more about BestLifeRewarded”, online: BestLifeRewarded <www.bestliferewarded.com/faq.aspx>.

vate and public sector organizations with at least 50 employees, 67% expressed concern about higher numbers of obese workers driving up medical expense claims.¹¹³ They have reason to be concerned:

The impact of unhealthy behaviour and its attendant outcomes is significant: health care costs for ‘moderately’ obese workers [BMI 30-35] are about 21 percent higher than they are for workers of normal weight, costing employers an additional \$670 per employee each year. Similarly, health care costs are 75 percent higher for ‘severely’ obese workers [BMI 35-40] (an additional \$2,441 annually per employee).¹¹⁴

Another US survey found almost universal agreement (91%) among employers that health care costs would be reduced if employees could be persuaded to adopt healthier behaviours.¹¹⁵

Consequently, some companies are implementing programs to improve awareness of healthy living and to inculcate personal accountability for behaviour through incentives or penalties. A large health care company in the United States, Clarian Health (now known as Indiana University Health), attracted much criticism for a proposed penalty scheme, which was to take effect in 2008-2009.¹¹⁶ Employees would have been required to undergo a health risk assessment and targets for blood pressure, blood sugar and cholesterol would be established. Employees who failed to achieve their target would have been docked five dollars per paycheque. Those with a BMI over 30 (in the obese range) would have been docked ten dollars per paycheque. After employee outcry and negative media attention, the company opted for a reward system instead. Employees who meet specified health targets may qualify for up to \$30 bonus for each pay period.

In Pennsylvania, Lincoln University encountered opposition from students and some staff members regarding its requirement that obese undergraduates complete a course, Fitness for Life, in order to obtain their degree. Those with a BMI under 30 were exempt from the three-hour-a-week class,

¹¹³ Jon R Gabel et al, “Obesity and the Workplace: Current Program and Attitudes among Employers and Employees” (2009) 28:1 Health Affairs 46 at 49.

¹¹⁴ Steven D Pearson & Sarah R Lieber, “Financial Penalties for the Unhealthy? Ethical Guidelines for Holding Employees Responsible for Their Health” (2009) 28:3 Health Affairs 845 at 846.

¹¹⁵ *Strategic Health Perspectives Data Sheet Questionnaires 2007*, (New York: Harris Interactive, 2007).

¹¹⁶ See Clarian Health case study appended to Pearson & Lieber, *supra* note 114 at 852.

which included physical activity and education about nutrition and healthy living. In the fall of 2009, university administrators realized that approximately 80 senior students among the predominantly African-American student body had neither taken a BMI test nor completed the course, placing some in jeopardy of not meeting graduation requirements. Minutes from a faculty meeting posted on the university website acknowledged that the course requirement places “an extra burden on some students because of their weight.”¹¹⁷ While it was recommended that “the university attorney [should] look at this requirement to determine if it is legal,”¹¹⁸ the Chair of the Department of Health, Physical Education and Recreation took the view that the university has “an obligation to notify students that their health might hinder them in their performance as student.”¹¹⁹ By the end of 2009, however, the university had decided to eliminate the requirement.¹²⁰

Many incentive schemes that offer financial rewards or penalties for behaviours relevant to obesity are relatively new; longitudinal evaluation is needed to determine their effectiveness, and whether they have unintended adverse consequences. Studies of incentives in other areas of health behaviour reveal some successes, particularly to encourage short-term uptake of services such as immunisation, disease screening, and compliance with medication regimes.¹²¹ Longer-term maintenance of changed lifestyles or a reduced body weight is a pressing challenge, and the effectiveness of incentives in promoting long term behaviour change is not yet clear.

In tobacco cessation programs, financial incentives have been shown to encourage smokers to enrol, but once the incentive is gone, many return to tobacco use. One study showed, however, that smokers who received finan-

¹¹⁷ Lincoln University Department of Academic Affairs, “Faculty Meeting: Minutes Tuesday November 3, 2009”, online: Lincoln University <www.lincoln.edu/academicaffairs/minutes2009-10/minutes110309.html>.

¹¹⁸ *Ibid.*

¹¹⁹ *Ibid.*

¹²⁰ See “Lincoln Ends BMI Requirement” *US News* (7 December 2009), online: US News <www.usnews.com/education/blogs/paper-trail/2009/12/07/lincoln-ends-bmi-requirement>.

¹²¹ See e.g. Adam Oliver, “Can Financial Incentives Improve Health Equity?” (2009) 339 *Brit Med J* 705; Theresa M Marteau, Richard E Ashcroft & Adam Oliver, “Using Financial Incentives to Achieve Healthy Behaviour” (2009) 338 *Brit Med J* 983.

cial incentives were more likely to be non-smoking at an 18-month follow-up than smokers who did not receive the incentive.¹²²

In weight loss, several studies have found that financial incentives are effective in motivating body weight reduction, but many people eventually regain weight after the incentive intervention ends.¹²³ An evaluation of the UK Pounds for Pounds program found that nearly half (44.8%) of participants lost a clinically significant amount of weight, with mean weight loss being 6.4 kilograms (14 lbs).¹²⁴ Participants who adhered to a 12-month program, including monthly weigh-ins, had significantly greater weight loss (mean weight loss of 11.5 kg) than those who did not follow through with their intended program.¹²⁵ Plan completion rates in Pounds for Pounds were lower than completion rates reported for other weight loss programs, such as Weight Watchers, and longer-term follow-up is necessary to assess whether weight loss is sustained over time.¹²⁶ An analysis of five years of data from the South African Discovery Health program reached the positive conclusion that participation in the rewards program helped sustain exercise adherence over time.¹²⁷ Moreover, health plan members who had higher levels of physical activity had fewer medical care claims, and were less likely than their inactive peers to require treatment for illnesses like cardiovascular disease and some cancers.¹²⁸

¹²² See Kevin G Volpp, “Paying People to Lose Weight and Stop Smoking”, online: (2009) 14:3 LDI Issue Brief <ldihealtheconomist.com/media/paying-people-to-lose-weight-and-stop-smoking.original.pdf>.

¹²³ See e.g. Kevin G. Volpp et al, “Financial Incentive-Based Approaches for Weight Loss: A Randomized Trial” (2008) 300:22 JAMA 2631; Leslie K John et al, “Financial Incentives for Extended Weight Loss: A Randomized, Controlled Trial” (2011) 26:6 J Gen Intern Med 621.

¹²⁴ Clare Relton et al, “The ‘Pounds for Pounds’ Weight Loss Financial Incentive Scheme: An Evaluation of a Pilot in the NHS Eastern and Coastal Kent” (2011) 33:4 J Public Health (Oxf) 536 at 536 (clinically significant weight loss is defined as loss of $\geq 5\%$ of starting body weight).

¹²⁵ *Ibid* at 539.

¹²⁶ *Ibid* at 540.

¹²⁷ Deepak N Patel et al, “The Association Between Medical Costs and Participation in the Vitality Health Promotion Program Among 948,974 Members of a South African Health Insurance Company” (2010) 24:3 Am J Health Promot 199.

¹²⁸ Deepak Patel et al, “Participation in Fitness-Related Activities of an Incentive-Based Health Promotion Program and Hospital Costs: A Retrospective Longitudinal Study” (2011) 25:5 Am J Health Promot 341.

Incentive programs have been criticized on ethical grounds as being paternalistic, coercive bribes that interfere with autonomous decision-making, though some scholars have offered cogent defences against these charges. For example, Ashcroft argues that incentive programs are respectful of individual autonomy in that personal agency over health decisions is preserved; incentives influence behaviour, but do not eliminate choice, nor are they necessarily coercive.¹²⁹

It has also been suggested that incentives may worsen social and health inequalities if they are based on the false assumption that all persons have the same resources available to engage in healthy behaviours. Pearson and Lieber point out that “[p]eople do not voluntarily choose their health outcomes—poor personal health is not a simple product of informed voluntary choices. Biological, environmental, and socioeconomic factors greatly affect health, regardless of how a person behaves.”¹³⁰ Incentive programs may also make some people worse off if “previously available services are made conditional upon individuals meeting certain requirements.”¹³¹ Voigt cites the example of a US company that increased employee health insurance deductibles by \$2000 (from \$200 to \$2200), then made employees eligible to revert to the lower deductible if they met targets for body mass index, cholesterol and blood pressure.¹³²

Another important question is whether incentives motivate the intended target population (i.e. those with unhealthy behaviours) or whether they principally attract people who already engage in healthy activities. Socioeconomic status has been shown to affect participation in incentive schemes. In Germany, people in the highest socioeconomic quintile are almost twice as

¹²⁹ Richard E Ashcroft, “Personal Financial Incentives in Health Promotion: Where Do They Fit in an Ethic of Autonomy?” (2011) 14:2 Health Expectations 191. Ashcroft explains that:

The idea behind actively shaping the environmental influences on choice is that while the individual patient or citizen retains ultimate decision-making and deliberative authority over their own conduct, contextual and situational factors can be modified so as to facilitate making choices which are coherent and acting consistently with those choices. The moral concept of the authority of the patient in making decisions in line with his preferences and values, without undue influence, domination or coercion, is usually termed autonomy (at 192).

¹³⁰ Pearson & Lieber, *supra* note 114 at 848.

¹³¹ Kristin Voigt, “Incentives, Health Promotion and Equality” (2010) Health Econ Policy Law 1 at 5.

¹³² *Ibid.*

likely to take advantage of incentive programs as those in the lowest quintile.¹³³ Designing financial incentive programs for specific risk groups most likely to benefit can help address these issues.

Some incentive programs that reward (or penalize) a person's compliance (or non-compliance) with recommended prevention, screening or treatment regimes may require a health care professional to track a patient's behaviour, and report to health insurers whether the person is following through with behaviour modification. It has been speculated that this "policing" function may adversely affect the professional-patient relationship.¹³⁴ Further empirical research is required to investigate this issue.

Some commentators argue that incentive programs should reward behaviour change alone (e.g. regular participation in a walking group) and not penalize failure to achieve specific physical outcomes (e.g. weight loss of 20 pounds). Pearson and Lieber suggest that employers should not penalize workers who do not lose weight or lower their blood pressure; rather, penalties, if used at all, should only apply to those who opt not to enrol in a weight-loss or health monitoring program offered to them.¹³⁵ The latter activities are within the employee's control, but even with regular attendance at a weight loss program, other factors outside the employee's control may thwart their efforts to shed pounds. For instance, the employer may not permit a flexible work schedule to allow the employee sufficient time to participate in fitness activities.

Legally, penalty programs that impose differential treatment against persons who are overweight or obese because of that status may be subject to challenge for violating provincial human rights codes. Human rights legislation across Canada prohibits discrimination in employment and in services available to the public on the basis of a physical disability.¹³⁶ Obesity may be recognised as a disability on a case-by-case basis, particularly where medical causes or consequences can be established.¹³⁷

¹³³ Harald Schmidt, Andreas Gerber & Stephanie Stock, "What Can We Learn from German Health Incentive Schemes" (2009) 339 *BMJ* 725 at 727.

¹³⁴ Harald Schmidt, Kristin Voigt & Daniel Wikler, "Carrots, Sticks, and Health Care Reform – Problems with Wellness Incentives" (2010) 362:2 *N Engl J Med* e3(1).

¹³⁵ Pearson & Lieber, *supra* note 114 at 848.

¹³⁶ See e.g. *Human Rights Code*, RSBC 1996, c 210; *Alberta Human Rights Act*, RSA 2000, c A-25.5; *Human Rights Code*, RSO 1990, c H-19.

¹³⁷ For a discussion of obesity as a disability in the human rights context, see e.g. *McKay-Panos v Air Canada*, 2006 FCA 8, [2006] 4 FCR 3; *Rogal v Dalglish*,

An organization that denies employment or a service to an obese person because of their weight, or treats that person differently because of their weight, may violate rights protected under human rights statutes unless the organization has a bona fide justification for its conduct. Situations have been reported where physicians have refused to treat obese patients¹³⁸ (which may violate professional ethics rules as well as human rights legislation) and airlines have charged extra fees for obese passengers.¹³⁹ In 2008, the state of Mississippi proposed a law that would have required restaurants to refuse to serve obese customers, similar to legal prohibitions against serving alcohol to inebriated patrons. This bill provided that state-licensed food establishments “shall not be allowed to serve food to any person who is obese, based on criteria prescribed by the State Department of Health after consultation with the Mississippi Council on Obesity Prevention and Management ... ”¹⁴⁰ The bill was voted down in the state legislature; the member who introduced it stated that his intention was to draw attention to the serious obesity problem in Mississippi, but that he never expected the bill to become law.¹⁴¹ This type of proposed legislation provides an extreme example of a penalty—namely, a legally mandated denial of service to obese persons—that, if attempted in Canada, would be subject to challenge under provincial human rights statutes and the *Canadian Charter of Rights and Freedoms*.

An individual who participates in an incentive (or penalty) program that is premised on the grounds of reducing obesity-related health risks and costs

2000 BCHRT 22, [2000] BCHRTD No 22 (QL); *Saskatchewan (Human Rights Commission) v St Paul Lutheran Home of Melville et al* (1993), 108 DLR (4th) 671, [1994] 2 WWR 270 (SK CA).

¹³⁸ David W Freeman, “Fat-Phobic Doctors Refuse to Treat Obese Patients: Is that Fair?” *CBS News* (17 May 2011) online: CBS News <www.cbsnews.com/8301-504763_162-20063541-10391704.html>.

¹³⁹ In 2008, the Canadian Transportation Agency issued a “one passenger, one fare” rule that prohibits Canadian airlines from charging an obese passenger an extra fee if they require two seats to be accommodated comfortably on the flight. For Air Canada’s policy response, see Air Canada, News Release, “Extra Seating for Passengers with Special Needs” (8 January 2009) online: Air Canada <www.aircanada.com/en/news/090108.html>.

¹⁴⁰ US, HB 282, *An Act to Prohibit Certain Food Establishments from Serving Food to any Person who is Obese*, Reg Sess, Miss, 2008, s 1, online: <billstatus.ls.state.ms.us/documents/2008/html/HB/0200-0299/HB0282IN.htm>.

¹⁴¹ “Mississippi Considers Restaurant Ban for Obese”, *CBS News & Associated Press* (11 February 2009) online: CBS News <www.cbsnews.com/stories/2008/02/05/national/main3790418.shtml>.

can likely advance a stronger claim that the status of being obese constitutes a physical disability or, at least, that it is perceived as such by the employer or public service provider that offers (or requires compliance with) the program. To avoid potential legal challenges on grounds of discrimination, incentive programs ought to provide positive rewards for healthier behaviours, and not deny benefits or impose disadvantages.¹⁴²

V. Another Type of Incentive to Consider: Incentives for Businesses

Before concluding, it is worth noting that individuals are not the only targets for incentive programs. Food retailers have been identified as another potential target for incentives to encourage retailers to provide healthier food options in neighbourhoods that currently have poor access to nutritious foods.¹⁴³ Access to markets to purchase healthy foods can vary dramatically across neighbourhoods and regions.¹⁴⁴ Higher income communities typically have ready access to supermarkets that sell a wide range of healthy foods and beverages at reasonable prices and access to supermarkets is associated with more nutritious diets.¹⁴⁵ In contrast, convenience stores and fast food outlets

¹⁴² For an overview of US law and incentive programs, see Michelle Mello & M Rosenthal, “Wellness Programs and Lifestyle Discrimination – The Legal Limits” (2008) 359:2 *N Engl J Med* 192.

¹⁴³ For a summary of a recent symposium on the topic of policy options to improve geographic access to food, see Donald Rose, “Access to Healthy Food: A Key Focus for Research on Domestic Food Insecurity” (2010) 140:6 *J Nutr* 1167.

¹⁴⁴ For data concerning American communities, see e.g. Nicole I Larson et al, “Neighborhood Environments: Disparities in Access to Healthy Foods in the U.S.” (2009) 36:1 *Am J Prev Med* 74; Lisa M Powell et al, “Food Store Availability and Neighborhood Characteristics in the United States” (2007) 44:3 *Prev Med* 189. For the Canadian context, see e.g. Jim Latham & Tina Moffat, “Determinants of Variation in Food Cost and Availability in Two Socioeconomically Contrasting Neighbourhoods of Hamilton, Ontario, Canada” (2007) 13:1 *Health Place* 273; Kristian Larsen & Jason Gilliland, “Mapping the Evolution of ‘Food Deserts’ in a Canadian City: Supermarket Accessibility in London, Ontario, 1961–2005”, online: (2008) 7:16 *Int J Health Geogr* 16 <www.ij-healthgeographics.com>; Karen E Smoyer-Tomic, John C Spence & Carl Amrhein, “Food Deserts in the Prairies? Supermarket Accessibility and Neighborhood Need in Edmonton, Canada” (2006) 58:3 *Prof Geogr* 307. Compare Philippe Apparicio, Marie-Soleil Cloutier & Richard Shearmur, “The Case of Montréal’s Missing Food Deserts: Evaluation of Accessibility to Food Supermarkets”, online: (2007) 6:4 *Int J Health Geogr* 4 <www.ij-healthgeographics.com>.

¹⁴⁵ Mary Story et al, “Creating Healthy Food and Eating Environments: Policy and Environmental Approaches” (2008) 29 *Annu Rev Public Health* 253; Barbara

tend be more concentrated in lower income areas. With a commercial imperative to maximize the sale of the most profitable items, shops may offer little in the range of fresh fruits and vegetables and some business owners express concern that they will “suffer a major profit loss if they stopped selling snack foods and sodas.”¹⁴⁶

To improve availability of healthy foods, governments could offer incentives to full-service grocery stores to locate in under-served neighbourhoods and to existing convenience stores or food vendors to provide a wider range of affordable healthy foods.¹⁴⁷ Options for financial incentives include tax benefits and discounts, loans, loan guarantees, and grants to cover start-up and investment costs (e.g., improving refrigeration and warehouse capacity). Non-financial incentives include supportive zoning, and increasing the capacity of small businesses through technical assistance in starting up and maintaining sales of healthier foods and beverages.¹⁴⁸

Some governments are already acting on these ideas. The State of Michigan passed legislation in 2008 offering a property tax exemption for up to ten years for food retailers that open, expand or improve in underserved areas.¹⁴⁹

Alaraia et al, “Proximity of Supermarkets is Positively Associated with Diet Quality Index for Pregnancy” (2004) 39:5 *Prev Med* 869; Kimberly Morland, Steve Wing & Ana Diez Roux, “The Contextual Effect of the Local Food Environment on Residents’ Diets: The Atherosclerosis Risk in Communities Study” (2002) 92:11 *Am J Public Health* 1761.

¹⁴⁶ J Nicholas Bodor, “The Rationale Behind Small Food Store Interventions in Low-Income Urban Neighbourhoods: Insights from New Orleans” (2010) 140 *J Nutr* 1185 at 1187.

¹⁴⁷ The City of Los Angeles took a more forceful approach in 2008, using its zoning authority to prohibit new fast food restaurants from opening in South LA. South LA reportedly has the highest concentration of fast food outlets in the city and an obesity rate that is almost 20% higher than other LA neighbourhoods. See Hennessy-Fiske & Zahniser, *supra* note 24.

¹⁴⁸ Laura Kettel Khan et al, “Recommended Community Strategies and Measurements to Prevent Obesity in the United States” (2009) 58:RR-7 *MMWR Recomm Rep* 1 at 9. For an analysis of the legal jurisdiction of local governments to enact such measures in the US, see Paul A Diller & Samantha Graff, “Regulating Food Retail for Obesity Prevention: How Far Can Cities Go?” (2011) 39:S1 *J Law Med Ethics* 89.

¹⁴⁹ Healthy Kids, Healthy Michigan, “Increasing Access to Healthy Foods: Michigan’s New Property Tax Incentive for Retail Food Establishments (Public Act 231 of 2008)”, online: Government of Michigan, <www.michigan.gov/documents/mda/FINALPA231FactSheet_290187_7.pdf>.

In New York State, the Healthy Food & Healthy Communities Initiative was announced in May 2009 to create a ten million dollar loan program to finance new food markets in underserved communities in low-income and rural areas throughout the state. New York City launched the FRESH (Food Retail Expansion to Support Health) Program to provide zoning and financial incentives to increase the number of healthy food markets. For example, zoning changes will allow residential buildings to be larger if a grocery store is operated out of the ground floor. Parking requirements will be reduced in pedestrian-oriented areas to lower costs for developers. Financial incentives include property tax reductions and exemptions on sales taxes that apply to building and renovation materials.

Increasing the number and quality of food markets in communities that currently have limited choices is another version of the “build it and they will come” theory that underpins the development of green spaces and recreation amenities. Improved access to a healthier range of foods in deprived communities may help promote more nutritious diets and, in turn, be a tool to improve body weight.¹⁵⁰ Spin-off benefits, such as new employment opportunities,¹⁵¹ could also improve income security and influence improvements in health status.

Local or provincial governments interested in the use of business incentives to influence neighbourhood food options may trial pilot programs to allow data collection and evaluation about the impacts of such initiatives. It is also recommended that governments and businesses seek community input about residents’ preferences for healthier food options. For example, they “should discuss with the community what they would like as a replacement for fast-food ... [t]his information would allow for incentive zoning to negotiate for things that the community really wants and needs, instead of only what officials think they should have.”¹⁵² As with other policy interventions, evaluation will be necessary to assess the impacts over time of incentives made available to businesses.

¹⁵⁰ See e.g. Chen & Florax, *supra* note 35 (this paper uses a simulation model to demonstrate that increasing the availability of healthy food options in low-income neighbourhoods would reduce average BMI).

¹⁵¹ The FRESH program in New York City is anticipated to create 1,100 jobs in new and expanded markets.

¹⁵² Christina A Lydon, Sophia C Yi & Mark A Mattaini, “How Far do you have to go to get a Cheeseburger around here? The Realities of an Environmental Design Approach to Curbing the Consumption of Fast-Food” (2011) 20 *Behavior and Social Issues* 6 at 18.

Conclusion

Incentive measures are one category of policy options that may be used to help counter obesogenic aspects of modern environments. But to have any impact on public health, incentives must effectively compete against the many other factors and forces that allow for and encourage excessive caloric intake and minimal energy expenditure. Incentives vary in their force and the benefit of milder incentives—that they are less intrusive in the lives of individuals—is also their main weakness as a public health policy tool. Unless individuals are aware of and respond in desirable (i.e. health-promoting) ways to incentives, these measures will fail to live up to their conjectured benefits.

As discussed in this article, some incentives on their own may not be sufficiently compelling to have any measurable effect on obesity rates. It is possible, however, that combinations of incentives could have additive, beneficial effects. If governments invest in building green spaces and recreational facilities, residents could be encouraged to use these amenities through tax credits that offset the costs of fitness activities or through participation in government or employer-sponsored programs that offer financial rewards for achieving regular exercise, weight loss or other goals. Given the complex range of factors implicated in obesity, it has been stated that “a ‘portfolio of policies’ is needed to combat chronic diseases stemming from unhealthy modern environments [and that] a comprehensive approach must be built piece by piece ...”¹⁵³

The burgeoning attention to the use of direct financial incentives, including cash payments and reward programs, underscores the significance of the health burdens and costs associated with obesity-related conditions.¹⁵⁴ It is

¹⁵³ Nola M Ries & Barbara von Tigerstrom, “Roadblocks to Laws for Healthy Eating and Activity” (2010) 182:7 CMAJ 687 at 690. A UK government report echoes this view, concluding that incentives “may be most effective as *one element* of a multi-component programme that addresses the complexity of individual, social and economic factors that influence people’s lifestyle choices” (Tammy Boyce, Ruth Roberson & Anna Dixon, *Commissioning and Behaviour Change: Kicking Bad Habits Final Report* (London: The King’s Fund, 2008) at 14).

¹⁵⁴ Two leading academic research centres are presently dedicated to studying the impact of incentives and other policy measures on eliciting and sustaining healthy behaviour changes: in the UK, the Centre for the Study of Incentives in Health in London (<www.kcl.ac.uk/schools/biohealth/research/csincentiveshealth>), and in the US, as part of a broader behavioural economics research mandate, the Center for Health Incentives at the University of Pennsylvania (<www.med.upenn.edu/ldichi>). Research findings from these groups, and others, will contribute to the evidence base for assessing whether and how incentives

telling that some governments and employers reckon it is more cost-effective to pay individuals to become healthier than it is to bear the costs of medical care, disability claims, and sick leave. Further economic modeling and analysis would help quantify costs and benefits of various incentive options to show where there is greatest value in paying particular groups to achieve and, most importantly, sustain a healthier body weight. Ongoing empirical study will also help assess the effectiveness of both carrot and stick incentives in instigating and sustaining long-term behaviour change. To avoid legal challenges—and negative publicity, in general—direct penalties ought to be avoided as they impose disadvantages on individuals because of their physical status of being overweight or obese.

might be used to promote nutritious diets, sufficient physical activity and healthier body weights over the long term.

A DEATH-DEFYING LEAP: SECTION 7 *CHARTER* IMPLICATIONS OF THE CANADIAN COUNCIL FOR DONATION AND TRANSPLANTATION'S GUIDELINES FOR THE NEUROLOGICAL DETERMINATION OF DEATH

*Jacquelyn Shaw**

Created by a Federal-Provincial/Territorial inter-governmental agreement in 2001, the non-profit Canadian Council for Donation and Transplantation ("CCDT") was mandated to increase Canada's organ and tissue supplies and the viability of organ transplants. The CCDT satisfied this mandate by creating, inter alia, guidelines for the determination of death, before being merged with the Canadian Blood Services ("CBS") in 2008. These brain death guidelines, adopted in some parts of Canada by both policy-makers and practitioners, with possible effects on organ and tissue supplies, substantially redefine the point at which physicians may declare neurological death.

Aspects of this redefinition raise patient safety concerns because they reveal a potential for physicians to declare death significantly earlier, and with greater chance of error, than previous brain death guidelines. For instance, the CCDT recommends that Canada employ a brainstem criterion of death, as used in the United Kingdom. There are concerns that the CCDT recommendations may infringe patients' section 7 rights to life and security of the person under the *Charter*, if government involvement can be shown to permit *Charter* review.

Le Conseil canadien pour le don et la transplantation (CCDT), créé en 2001 par une entente fédérale-provinciale/territoriale, a pour mandat d'augmenter les réserves de tissus et d'organes ainsi que la viabilité des transplantations. Avant sa fusion avec la Société canadienne du sang en 2008, le CCDT a comblé ces exigences entre autres en créant de nouvelles directives sur la fixation des conditions du décès. Ces directives sur la mort cérébrale, adoptées en certains endroits à la fois par des praticiens et les législateurs, redéfinissent substantiellement le moment où les médecins peuvent déclarer une mort cérébrale et pourraient donc avoir des conséquences sur les réserves d'organes et de tissus.

Certains aspects de cette redéfinition soulèvent des inquiétudes quant à la sécurité des patients étant donné la possibilité offerte aux médecins de déclarer une mort considérablement plus tôt, avec un plus grand risque d'erreur, comparativement aux directives précédentes sur la mort cérébrale. Par exemple, le CCDT recommande que le Canada emploie le critère du tronc cérébral comme au Royaume-Uni. Des inquiétudes existent également quant à la possible suffisante violation par ces directives du droit des patients à la vie et à la sécurité garanti par l'article 7 de la

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Citation: Jacquelyn Shaw, "A Death-Defying Leap: Section 7 *Charter* Implications of the Canadian Council for Donation and Transplantation's Guidelines for the Neurological Determination of Death" (2012) 6:1 MJLH 41.

Référence : Jacquelyn Shaw, « A Death-Defying Leap: Section 7 *Charter* Implications of the Canadian Council for Donation and Transplantation's Guidelines for the Neurological Determination of Death » (2012) 6 : 1 RDSM 41.

Despite the CCDT's claims of independent, non-governmental status, the author argues that the CCDT can be shown to be a part of the fabric of government. Alternatively, the CCDT brain death guidelines may also qualify as government activity, in either case permitting *Charter* application. The author argues that, due to their irrational, arbitrary, and disproportionate elements, the CCDT's infringing recommendations do not appear to adequately comply with the principles of fundamental justice. These recommendations seem unlikely to be upheld under section 1 of the *Charter*. Yet, while a *Charter* challenge to the CCDT brain death guidelines appears justified, it may not be feasible. Alternative approaches may be required.

Charte canadienne des droits et libertés si des liens suffisants avec le gouvernement peuvent être établis afin de permettre un examen selon celle-ci.

Malgré les revendications d'indépendance du CCDT, l'auteur soutient qu'il puisse être réputé comme faisant partie de la structure gouvernementale. Autrement, il se peut que les directives du CCDT sur la mort cérébrale puissent également être qualifiées de « gouvernementales », dans les deux cas permettant l'application de la Charte à leur égard. L'auteur soutient qu'en raison de leurs éléments irrationnels, arbitraires et disproportionnés, les recommandations du CCDT contrevenantes ne semblent pas satisfaire aux principes de justice fondamentale. En dernier lieu, ces directives ont peu de chances d'être validées en vertu de l'article 1 de la Charte. Même si une contestation des directives du CCDT fondée sur la Charte semble justifiée, elle pourrait s'avérer impossible, nécessitant par le fait même des solutions alternative

Introduction	43
I. The CCDT and the Guidelines for the Determination of Death	45
A. <i>The CCDT</i>	45
B. <i>The CCDT Guidelines</i>	47
C. <i>Authorization and Creation of the CCDT Guidelines</i>	53
II. Does the Canadian <i>Charter</i> Apply to the CCDT Guidelines	61
A. <i>The Law: When Does the Charter Apply?</i>	61
B. <i>Applying the Law to the Facts: Does the Charter Apply to the CCDT Guidelines?</i>	65
1. Was the CCDT "Government"?	65
2. Are the CCDT Guidelines "Government Activity"?	85
III. <i>Charter</i> Rights Infringements Under the CCDT Guidelines	91
A. <i>Are Charter Rights Infringed by the CCDT Guidelines?</i>	91
B. <i>Are the Section 7 Deprivations "In Accordance with the Principles of Fundamental Justice"?</i>	112
C. <i>Could the Suspected Section 7 Infringements be Justified under Section 1 of the Charter?</i>	121
D. <i>Alternative Legal and Disciplinary Responses to the CCDT Guidelines</i>	128
Conclusion	134

"No man is an island entire of itself; ... any man's death diminishes me, because I am involved in mankind. And therefore never send to know for whom the bell tolls; it tolls for thee."

- John Donne, 1572-1631

Introduction

The eventuality of death is one of the few certainties in human life. The determination of death requires that physicians employ certain methodologies to test critical functions before declaring a patient to be dead. In Canada, the methodology by which death is declared for organ donation purposes is found in voluntary protocols or guidelines, rather than in primary legislation, such as provincial and territorial human tissue and organ donation statutes. These non-statutory guidelines have historically been defined solely by physician groups, without input from other professions, legislatures, or the public. The most recent such guidelines were created by the Canadian Council for Donation and Transplantation ("CCDT"), an organization established to improve Canada's organ transplantation system, including its relatively low organ donation rates. Claimed to be "a significant, positive advance,"¹ the CCDT guidelines have been included in the Canadian Medical Association's ("CMA") online "Practice Guidelines InfoBase" as the current practice guidelines for the neurological determination of death.

Many experts argue that human biological death involves a continuum of progressive functional losses (e.g. loss of certain organ or nerve functions, including consciousness) spanning the period between birth and complete bodily decay.² In contrast, human legal death is conceptualized as a discrete moment within that continuum, as declared by a physician pursuant to clinical guidelines. Past guidelines have changed incrementally over time, keeping pace with scientific advances. However, analysis of the CCDT guidelines' substance reveals a number of major changes, the scientific justifica-

¹ CCDT, *Severe Brain Injury to Neurological Determination of Death: A Canadian Forum* (2003), online: Trillium Gift of Life Network <www.giftoflife.on.ca/assets/pdfs/1SBINDD_English.pdf> ("Members of the panels came to unanimous agreement on recommendations that mark a significant positive advance on [previously] existing guidelines" at 3) [*SBINDD*].

² See e.g. D Alan Shewmon, "'Brainstem Death,' 'Brain Death' and Death: A Critical Re-Evaluation of the Purported Equivalence" (1998) 14 *Issues L & Med* 125 at 142-43. Others disagree, arguing that biological death is a moment. This paper will adopt the view that human biological death is best described as a functional continuum, with legal death as a point in time within this continuum.

tion for which is unclear. The guidelines have been adopted by a number of large Canadian hospitals, providing some enforceability.³

One guideline change includes the CCDT recommendation that Canadian physicians adopt a brainstem criterion for death. This criterion was previously applied only in the UK, in contrast to the whole-brain criterion, which has been applied in Canada since 1968.⁴ Other concerning changes include weakening or removing some earlier safeguards intended to prevent erroneous (i.e. premature) declarations of brain death. Taken together, such changes may systematically increase the speed with which patients can be declared brain-dead and therefore legally eligible for organ harvest.

This paper explores whether the CCDT guidelines violate the *Canadian Charter of Rights and Freedoms*⁵ and suggests that the guidelines be replaced. Part I provides some context for the discussion. Part II analyses Canadian jurisprudence and the characteristics of the CCDT, and argues that, according to the jurisprudence, the CCDT and its guidelines should be regarded as “government” or “government activity,” respectively, and must therefore comply with the *Charter*. Part III(a) analyses the possible infringement of *Charter* rights by the CCDT guidelines, focussing on section 7 rights to life and security of the person; Part III(b) assesses whether the suspected section 7 deprivations have occurred “in accordance with the principles of fundamental justice”; Part III(c) assesses whether these section 7 infringements might still be upheld under section 1 of the *Charter*, and Part III(d) considers non-*Charter* remedies. Finally, Part IV concludes that the CCDT guidelines may unjustifiably infringe Canadian patients’ section 7

³ This includes major hospitals in Atlantic Canada, Edmonton, and Calgary. See Barrington Research Group, *Canadian Council for Donation and Transplantation (CCDT) Summative Evaluation Final Report* (2006) at 39-40, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Summative_Evaluation_Report.pdf> [*Summative Evaluation*].

⁴ The CCDT’s recommendation would mean that to be declared brain-dead in Canada, only the brainstem (the lower portion of the brain, which controls many reflexes, breathing, and wakefulness), need be shown to be non-functional, in contrast with the earlier requirement to show that both the upper and lower portions of the brain (i.e. the entire brain, including the cortex, which governs conscious thought, memory, personality, voluntary movement, and pain-sensation, as well as the brainstem) are non-functional. The CCDT’s change in criterion is therefore a very significant change.

⁵ Part I of the Constitution Act, 1982, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [*Charter*].

rights, suggests that a *Charter* challenge to these guidelines is justified, and discusses possible responses to the guidelines.

I. The CCDT and the Guidelines for the Determination of Death

A. The CCDT

During the 1990s, Canada's federal government became increasingly concerned about the disparity between the organ donation rate, which was low relative to nations such as Spain,⁶ and the increasing number of patients requiring organ transplants in an aging and sedentary society. Unlike many nations, and partly due to Canada's constitutional division of powers, Canada's organ donation system was fragmented, lacking a central coordinating body to oversee it. Between 1996 and 1999, three major nation-wide government reports were produced, providing "the rationale, impetus and structure" for a solution.⁷ A Federal-Provincial/Territorial ("FPT") strategy was

⁶ Health Canada states that "Canada's organ and tissue donation rate is one of the lowest among western industrialized countries. Donation rates have levelled off ... at a time when the need for transplants has increased by 50 per cent" (Health Canada, *Government Response to the Report of the Standing Committee on Health, Organ and Tissue Donation and Transplantation: A Canadian Approach* (September 1999) at 1, online: HC <www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/announce-annonce/govresp_repgouv-eng.php> [Health Canada, *Government Response*]). According to the House of Commons, in 1999, Canada reported 14.4 donors per million population, while countries such as Spain reported rates of 31.5 donors per million population. Reportedly, Spain's donor consent rate doubled in the eight years following the creation of its national OTDT coordinating body, while transplant numbers tripled. See House of Commons, Standing Committee on Health, *Organ Tissue Donation and Transplantation: A Canadian Approach* (3 April 1999) ch 3(A) [*1999 Standing Committee Report*].

⁷ Three seminal documents provided the rationale for the establishment of the CCDT: the Advisory Committee on Health Services, *Organ and Tissue Donation and Distribution in Canada: A Discussion Document* (1996) [Advisory Committee, *Distribution Discussion Document*]; the *1999 Standing Committee Report*, *ibid*; and Health Canada, National Coordinating Committee for Organ and Tissue Donation and Transplantation, *A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada* (18 November 1999) [1999 NCCOTDT *Strategy*]. The NCCOTDT *Strategy* in particular provided the targets, means, core functions and support processes for the establishment of an OTDT system coordinated by the CCDT. The content of the 1999 NCCOTDT *Strategy* was approved by the CDM in September 1999 (*Summative Evaluation*, *supra* note 3 at 10).

drawn up to create a central coordinating body, the CCDT,⁸ which was staffed with members chosen for their expertise in organ and tissue donation and transplantation (“OTDT”).⁹

Established as a government body in October 2001 by the Conference of Deputy Ministers of Health (“CDM”),¹⁰ the CCDT was tasked, generally, with advising the CDM and, specifically, with creating guidelines, standards, and best practices to improve OTDT and significantly increase Canada’s organ supplies, for CDM approval.¹¹ CCDT directors, authors, and panellists at guideline-creation fora were self-described as “agents of change.”¹² In 2005, the CCDT was incorporated as a non-profit organization, and in 2006 it became a registered charity, operating at arm’s length from government and funded by a Health Canada Contribution Agreement.¹³

⁸ Health Canada, *Interim Funding of the Canadian Council for Donation and Transplantation (CCDT) - Health Canada 2003-05-08* (8 May 2003), online: HC <www.hc-sc.gc.ca/ahc-asc/performance/audit-verif/2004-list/fund-finan-eng.php> [Health Canada, *Interim Funding*].

⁹ Health Canada indicated that “CCDT Board members were selected for their expertise and knowledge of [organ and tissue donation and transplantation]” (*Final Audit Report: Audit of the Management of Contribution Agreements with the Canadian Council for Donation and Transplantation and the Canadian Blood Services*, (September 2009) at 1, online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_audit-verif/2009-22/index-eng.php> [Health Canada, *Final Audit*]). The CCDT was self-described as an organization “dedicated exclusively to the interests and issues of the organ and tissue donation and transplantation system in Canada” (CCDT, *Collaborate. Support. Enhance: 2006 Annual Report*, (2006) at 17, online: Government of Canada Depository Services Program <dsp-psd.pwgsc.gc.ca/Collection/H1-9-16-2006E.pdf> [CCDT, *2006 Annual Report*]).

¹⁰ Health Canada, *Final Audit*, *ibid* at 1.

¹¹ The CCDT “arose from concerns about the shortage of organs and tissues for transplantation in Canada ... The CCDT was established in October of 2001 as an advisory body to the Federal/Provincial-Territorial Conference of Deputy Ministers of Health (CDM) in its efforts to coordinate activities related to organ and tissue donation and transplantation” (*Summative Evaluation*, *supra* note 3 at 1). As one of the CCDT’s list of nine tasks of its mandate, established 7 June 2001, the CCDT was to “[r]ecommend [OTDT] practice guidelines based on an assessment of best practices” (*ibid* at 12).

¹² *SBINDD*, *supra* note 1 at 1.

¹³ The precise date of the CCDT’s incorporation is unclear: it is listed as 25 February 2005 in Letters Patent; as 1 April 2005 in the CCDT’s Form 3 Annual Summary Report to Industry Canada (19 May 2006); and as 29 April 2005 in the Canada

B. The CCDT Guidelines

In Canada, very little legislation addresses death. In the context of *post mortem* organ and tissue donation, existing legislation stipulates only that death be determined in accordance with “accepted medical practice,”¹⁴ or variants on this phrase. The content of “accepted medical practice” in the context of brain death has traditionally been determined by clinical practice guidelines. Thus, the methodological requirements of brain death declaration appear in guidelines periodically updated by Canadian physician groups.¹⁵ Although voluntary and non-binding by themselves, the CCDT guidelines have served as the template for some Canadian hospitals’ institutional rules for brain death declaration.¹⁶ Through uptake and adoption, the guidelines have acquired enforceability. The CCDT also introduced the guidelines in education sessions for nursing and medical students.¹⁷ There are other suggestions that the guidelines may receive greater uptake due to their seemingly independent, non-governmental origins.¹⁸ As long as the CCDT guidelines

Gazette.

¹⁴ See e.g. *Human Tissue Gift Act*, RSNS 1989, c 215, s 8(1); Bill 121, *Human Organ and Tissue Donation Act*, 2nd Sess, 61st General Assembly, Nova Scotia, 2010, c 36, s 16.

¹⁵ Past guideline-authoring groups included the CMA (1968), the Canadian Congress of Neurological Sciences (1987), and the Canadian Neurocritical Care Group (1999). In 2003, the CCDT acknowledged the 1999 Canadian Neurocritical Care Group guidelines as “broadly reflecting current practices in the declaration of brain death in Canada” (CCDT, *A Review of the Literature on the Determination of Brain Death* (2003) at 13, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Brain-Death-Long-Lit-Review.pdf> [CCDT, Literature Review Brain Death]; *1999 Standing Committee Report*, *supra* note 6 ch 4).

¹⁶ In Atlantic Canada “*SBINDD* ... recommendations have been adopted by the only two hospitals in the region that do transplants” (*Summative Evaluation*, *supra* note 3 at 40). In Alberta, before the CCDT existed, “[hospitals in] Edmonton and Calgary had different guidelines for [brain death determination]; after the [*SBINDD*] forum ... a consistent [brain death declaration] protocol between both health regions was developed” (*ibid* at 39). The CCDT was headquartered in Edmonton, Alberta after 2005.

¹⁷ *Ibid* at 35.

¹⁸ This seemed to be implied in several reports. According to surveyed OTDT stakeholders, “one of the greatest strengths of the CCDT is the realization by these diverse [OTDT stakeholder] groups that the CCDT is able to provide an objective perspective to discussions since the CCDT is an arm’s length NGO” (CCDT, *CCDT Summative Evaluation* (31 March 2007) at 6, online: Canadian Blood

remain in circulation, they may also provide a foundation upon which to base future, more dramatic changes.¹⁹

It should be noted that physicians must follow some set of guidelines to declare death. Ideally, in light of the physician-patient fiduciary duty, a physician recognizing any set of medical guidelines as risky might wish to select another set of guidelines. However, especially in smaller hospitals, not all physicians declaring death may have a sufficient neurology background to recognize the risks the CCDT guidelines pose. This also assumes that no institutional recommendations exist as to guideline choice, that the physician knows that alternative guidelines exist, and that he or she has no qualms about rejecting recent, “widely endorsed”²⁰ guidelines created by a “national forum of experts.”²¹ Even if these assumptions prove correct, the only brain death guidelines available from the CMA’s online database are the CCDT guidelines; this means that a physician must spend valuable time combing the medical literature for alternative guidelines.

Services <organesettissus.ca/s/wp-content/uploads/2011/11/Summ_Eval_Mngmt_Rsp.pdf> [2007 *CCDT Summative Evaluation*]). The *Summative Evaluation*, *supra* note 3 at 28, 29, reported that “[survey participants] indicated that the CCDT is well placed and well informed on issues, [and] is both objective and inclusive ...” as part of the basis for their conclusions that the CCDT was “doing a good job” in providing initiatives to CDM that had “already been put into practice” and should continue doing so. These responses suggest that past stakeholder receptivity to CCDT recommendations was based, at least partly, on the perception of the CCDT’s objective, arm’s length relationship to government.

¹⁹ The CCDT commented on its guidelines’ lack of enforceability, arguing that the CCDT advisory mandate “needed strengthening to support the implementation of widespread Canadian solutions” (*ibid* at viii, 46). However the CCDT also noted that “[f]uture OTDT policy change is planned. CCDT reports and recommendation are being accessed as an information resource... that various provincial governments are planning in the near future” (*ibid* at 41).

²⁰ The *SBINDD* guidelines are described as “widely endorsed and implemented in Canada,” suggesting some consensus of Canadian medical practitioner opinion supporting their use (CCDT, *Brain Blood Flow in the Neurological Determination of Death Expert Consensus Meeting Report* (2006) at 1, online: Government of Canada <publications.gc.ca/collections/collection_2007/hc-sc/H14-17-2007E.pdf> [*BBFNDD*]).

²¹ SD Shemie et al, “Severe Brain Injury to Neurological Determination of Death: Canadian Forum Recommendations” (2006) 174:6 *Can Med Assoc J* at S1 [*SBINDD 2006*] describes its brain death guidelines as the product of a “national forum of experts,” which may convey a sense of authority that physicians using the guidelines may be reluctant to question.

It should also be clarified that the CCDT guidelines may be applied in declaring brain death in any context, not only those involving organ donors.²² A patient cannot, therefore, necessarily avoid the application of the guidelines simply by exercising a choice not to become a *post mortem* organ donor.²³ The CCDT has described its guidelines as marking “a significant, positive advance on [pre-]existing guidelines.”²⁴ Although previous Canadian brain death guidelines were produced by physician groups and involved minor procedural changes made over time, the CCDT guidelines have made the most substantial changes to brain death declaration procedures.²⁵

The CCDT brain death guidelines were created in a series of four versions. The first CCDT guideline version, created in April 2003 and entitled *Severe Brain Injury to the Neurological Determination of Death (SBINDD)*, was initially disseminated to more than 1,400 healthcare practitioners and policy-makers across Canada over several years following its creation.²⁶ Reportedly, through this informal dissemination,²⁷ the guidelines achieved some

²² Nothing in the CCDT guidelines prevents their use to declare death in non-donors.

²³ Given the physician-patient “knowledge asymmetry,” patients may not understand the risks posed by the guidelines, nor even know that such guidelines exist. Thus it is unreasonable to ask patients to assume responsibility for avoiding the risks of the guidelines, even if they could somehow do so.

²⁴ *SBINDD*, *supra* note 1 at 3.

²⁵ This article restricts itself to discussing guidelines of Canadian national scope. It is not known and outside the scope of this discussion whether any of the more local or regional organ procurement organizations issuing brain death declaration protocols have attempted similar local changes.

²⁶ *SBINDD*, *supra* note 1. Chronologically, dissemination of the CCDT guidelines was planned to take place via a multiple-phase approach: first via the CCDT advising the CDM; then informal dissemination involving CCDT forum participants and formal dissemination through journal publication, etc. (*ibid* at 25). A similar process was cited elsewhere, involving first a CCDT provision of recommendations to CDM for acceptance and possible FPT policy-maker implementation, then dissemination broadly. “OTDT stakeholders receive either hard or electronic copies of reports, information and reports are posted on the CCDT website, and information is compiled for presentations or journal publications.” (*Summative Evaluation*, *supra* note 3 at 19). Monitoring of adoption was added in late 2004.

²⁷ By 2006 “[a]pproximately 1400 hard copies [of *SBINDD* were] distributed (with a CD ROM included) to Forum Participants, Organ Procurement Organizations, Transplant Program, Health Professional Associations, Non-government Organizations, Critical Care Units across Canada and posted on CCDT website,” and that “[k]nowledge diffusion [of CCDT publications] is occurring through

success in being adopted, “sometimes quite rapidly.”²⁸ Marked tissue supply increases were subsequently reported in some regions, such as Nova Scotia, with smaller national increases observed as well.²⁹ The second guideline version, almost identical to the first, was formally published in March 2006 in the *Canadian Medical Association Journal*.³⁰ This version was also included in the CMA’s online “Clinical Practice Guidelines InfoBase” after July 2006.³¹

informal channels” (*ibid* at 39).

²⁸ *Ibid* at 39. According to the CCDT, the guidelines are also in use in Alberta hospitals and by policy-makers in Ontario, where “CCDT materials are routinely used to prepare Ministry briefs” (at 108). By November 2006, the CCDT reported that its guidelines had “been widely endorsed and implemented in Canada” (*BBFNDD*, *supra* note 20 at 1).

²⁹ Recently, regional increases have included a tripling of Nova Scotia’s tissue supplies in less than three years, soon after adoption of the CCDT guidelines in local transplant hospitals (*Summative Evaluation*, *supra* note 3 at 40). The CCDT claimed credit for this change: “In Nova Scotia, tissue donor numbers have tripled as a result of the work of the CCDT” (*ibid*). The Department of Health in 2005 confirmed this increase, but credited other factors (Nova Scotia Department of Health and Wellness, News Release, “Organ Donation Program Wins National Award” (20 June 2005) online: Government of Nova Scotia <www.gov.ns.ca/news/details.asp?id=20050620004>). It is not stated whether CCDT reports all used the word “tissue” the same way, to differentiate non-organ donations such as blood, skin, cartilage, and bone from whole or partial organs (as in the 1999 NCCOTDT *Strategy*, *supra* note 7 at 8), or whether both organs and non-organs such as blood, skin, cartilage, and bone were included. A smaller national increase in organ availability may have occurred since the CCDT guidelines’ issuance. The CCDT argued in March 2007 that the Canadian Organ Replacement Register had reported, in 2006, a nation-wide increase of 13% in deceased donors, described as “the first [national] increase in five years,” attributed in part to CCDT efforts (2007 *CCDT Summative Evaluation*, *supra* note 18). In contrast, the Canadian Institute for Health Information reported that from 1998-2008 organ supplies rose 28%, of which 9% was due to a decrease in donors (Canadian Institute for Health Information, *Organ Donations Increasing in Canada but not Keeping Pace with Demand*, online: CIHI <www.cihi.ca/CIHI-extportal/internet/en/document/types+of+care/specialized+services/organ+replacements/release_22dec2009> [CIHI, *Keeping Pace with Demand*]).

³⁰ *SBINDD 2006*, *supra* note 21 at S1.

³¹ See Letter of Agreement from Seema Nagpal, Associate Director of Epidemiology, Office for Public Health, CMA, to Kimberly Young, Chief Executive Officer, CCDT, signed 13 July 2006, CCDT <www.ccdt.ca/english/publications/final-pdfs/CMA-CCDT-Agreement.pdf>.

The third guideline version, *Brain Blood Flow in the Neurological Determination of Death (BBFNDD)*, both complements and significantly alters *SBINDD*.³² *BBFNDD* was written in November 2006³³ and posted to the CMA InfoBase with *SBINDD 2006*.³⁴ A final version, *BBFNDD 2008*, was formally published in the *Canadian Journal of Neurological Sciences* in May 2008,³⁵ one month after the CCDT was dissolved as an entity.³⁶ Upon the dissolution of the CCDT, its mandate was transferred to the CBS on 1 April 2008.

The versions of the CCDT guidelines interrelate and may be used simultaneously.³⁷ Their use is concerning because, while previous Canadian brain death guidelines have incorporated minor, incremental changes to keep pace with scientific developments, numerous changes in the CCDT guidelines are far less incremental. Moreover, some appear to contradict established, mainstream scientific thinking on brain death and have possible *Charter* implications.

The role of the CMA and its InfoBase also deserve mention. The CMA is not generally an official standard-setting body; however, in relation to brain death determination, the CMA has acquired some prominence due to historical practice over more than three decades. Since Canada's adoption of brain death as a legal criterion of death in 1968, the CMA has acquired visibility

³² *BBFNDD*, *supra* note 20.

³³ It is not known when *BBFNDD*, copyrighted in February 2007, was posted to the CMA InfoBase. Like *SBINDD*, *BBFNDD* may also have been informally disseminated, via the CMA InfoBase or other means, in the 18 months between its creation and journal publication.

³⁴ *Supra* note 21 (its basic medical recommendations are identical to those of *SBINDD*, *supra* note 1).

³⁵ Sam D Shemie et al, "Brain Blood Flow in the Neurological Determination of Death: Canadian Expert Report" (2008) 35:2 *Can J Neurol Sci* 140 [*BBFNDD 2008*] (these recommendations were identical to those of *BBFNDD*, *supra* note 20).

³⁶ The CCDT ceased to exist as an entity after 31 March 2008, and was dissolved as a corporation on 22 June 2009, with voluntary revocation of its charitable status occurring on 20 February 2010.

³⁷ Brain death can be declared using only the definition in *SBINDD* (*supra* note 1) or *BBFNDD* (*supra* note 20). However, certain methodological details are provided only in *SBINDD*, relating to pediatric diagnosis, temperature effects, etc., while *BBFNDD* contains added details on brain blood flow testing and some changes relative to *SBINDD* (e.g. treatment of high-dosage barbiturate-affected patients).

and importance with respect to the subject of brain death by issuing, commissioning, approving, and more recently hosting, brain death guidelines on its InfoBase. In 2000, the CMA issued a policy to deliberately move away from issuing or endorsing brain death guidelines. This indicates the CMA's recognition of its long-standing association with Canadian brain death guidelines.³⁸ Therefore, the CMA's dissemination of the CCDT guidelines may be more influential than it at first appears.

Notably, also in 2000, the CMA commenced systematic efforts to disseminate clinical practice guidelines, generally, via its online InfoBase, as part of a CMA "Quality of Care program."³⁹ The CMA stated: "We encourage physicians to use these guidelines for national, provincial, territorial and local guideline initiatives, and in doing so, to promote evidence-based clinical practice and ongoing improvement in the quality of care for Canadians."⁴⁰ Reportedly, the InfoBase was planned as "a one-stop, comprehensive national resource" for guidelines.⁴¹ The CMA's mission in creating the InfoBase was "to 'provide leadership and to promote the highest standard of health and healthcare for Canadians' ... [by] collaborating with other organizations to facilitate and coordinate the clinical practice guideline process in Canada."⁴² One such collaborating organization was the educational body the Royal College of Physicians and Surgeons of Canada. These factors suggest

³⁸ The CMA preferred after 2000 that death determination in the context of OTDT be made "according to widely accepted guidelines established by expert medical groups" (*Organ and Tissue Donation (Update 2000)*, s 7.1, online: <policybase.cma.ca/dbtw-wpd/PolicyPDF/PD00-07.pdf>). The CCDT has been self-described as an expert group that claimed its *SBINDD* guidelines were "widely accepted" (*BBFNDD*, *supra* note 20 at 1).

³⁹ See CMA, "Guidelines for Canadian Clinical Practice: Guidelines" at Foreword, online: CMA <prismadmin.cma.ca/index.php?ci_id=54703&la_id=1 or mdm.ca/cpgsnew/cpgs/gccpg-e.htm> [CMA, "Guidelines"].

⁴⁰ *Ibid.*

⁴¹ B Skidmore, "New and Improved: CMA's Guidelines InfoBase Now at Physicians' Fingertips" (2000) 162:9 *Can Med Assoc J* 1342 at 1342. InfoBase was intended to be "an alternative source of free clinical practice guidelines to the [CMA] National Guideline Clearinghouse" (Roberta Bronson Fitzpatrick, "CMA InfoBase: Clinical Practice Guidelines" (2008) 27:4 *Med Ref Serv Q* 419 at 419).

⁴² CMA, "Guidelines", *supra* note 39 at Introduction. The CMA stated that it was "collaborating with other organizations [including the Royal College of Physicians and Surgeons of Canada] to facilitate and coordinate the clinical guideline process in Canada."

that the CCDT guidelines may have a noticeable impact on Canadian medical practice in this area.

C. Authorization and Creation of the CCDT Guidelines

It is worth examining the CCDT's brain death guideline-creation process and authority in detail. As per the 1999 National Coordinating Committee for Organ and Tissue Donation and Transplantation ("NCCOTDT") *Strategy*, the CCDT was to "advise ... on overall policy direction, standards and guidelines for the delivery ... of organ and tissue donation and transplantation; to facilitate the development [and] implementation of practice and safety standards."⁴³ Yet reports indicate that the CDM specifically instructed the CCDT to address not only OTDT, but also, as a first priority, brain death determination, a possibility the 1999 Standing Committee had also raised.⁴⁴ In December 2002, "[t]he CDM selected certain priorities from the [CCDT Work-]Plan for the CCDT to address ... essentially putting the work of the other [CCDT] committees on hold."⁴⁵ The CDM's priorities⁴⁶ from the

⁴³ *Supra* note 7 at 23.

⁴⁴ According to authors Robert and Doreen Jackson, "A [deputy minister] possesses only the power that the Minister chooses to delegate [to the deputy minister]." Thus the powers and authority vested in the CDM were delegated to it by the FPT Ministers of Health. They also note that tenure is insecure and that deputy ministers who advise against ministerial policies "risk being viewed as obstacles to the government in pursuit of its partisan political objectives and being removed" (Robert J Jackson & Doreen Jackson, *Politics in Canada: Culture, Institutions, Behaviour and Public Policy*, 3d ed (Scarborough: Prentice-Hall, 1994) at 386.

⁴⁵ *Summative Evaluation*, *supra* note 3 at 20.

⁴⁶ The other priority mentioned was an OTDT social marketing campaign. The CCDT engaged in significant efforts to canvass the organ donation attitudes of indigenous peoples, the general Canadian public, and also health care providers. See e.g. CCDT, *Diverse Communities: Consultation to Explore Peoples' Views on Organ and Tissue Donation*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Chinese-Cdn-Summary-english.pdf>; CCDT, *Public Awareness and Attitudes on Organ and Tissue Donation and Transplantation Including Donation After Cardiac Death: Final Report*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Public_Survey_Final_Report.pdf> [CCDT, *Public Awareness Report*]; CCDT, *Health Professional Awareness and Attitudes on Organ and Tissue Donation and Transplantation: Including Donation after Cardiac Death*, online: Canadian Blood Services <organesettissus.ca/s/wp-content/uploads/2011/11/Survey-Health-Prof.pdf> [CCDT, *Health Professional Survey*].

CCDT's work-plan included addressing the neurological determination of death: "Some components of [the CCDT work-plan] (for example, ... the Neurological Determination of Death component) were approved by the CDM at its December 2002 meeting, and the CCDT was mandated to pursue these initiatives."⁴⁷

The *SBINND* 2003 guidelines were created four months later. They were the CCDT's first guidelines, and they reflected the CDM's prioritization of the neurological determination of death, among other things. Justifying its revision of earlier brain death guidelines and the link to OTDT, the CCDT observed that "consistency and standardization [in brain death determination] will ... enhance the conduct of organ and tissue donation."⁴⁸

Reports reveal that the CCDT was authorized to issue guidelines through a cooperative partnership with the CDM, in which the CCDT provided medical "advice" and the CDM provided the necessary legal approval for the guidelines' dissemination.⁴⁹ The CCDT described a seven-step "advice cycle," the later stages of which included CCDT submission of recommendations to the CDM, CDM approval, guideline dissemination, and uptake monitoring.⁵⁰ CDM approval was described as an integral step in the CCDT's guideline-creation: "The advice is ... forwarded to the CDM for acceptance. It is then distributed to FPT governments for consideration and implementation at the policy level."⁵¹

⁴⁷ *Summative Evaluation*, supra note 3 at 16.

⁴⁸ *SBINDD*, supra note 1 at i.

⁴⁹ The CCDT stressed that its products merely provided advice to the CDM and required CDM approval for the CCDT to disseminate them (*Summative Evaluation*, supra note 3 at 19). This was envisaged in the 1999 NCCOTDT *Strategy*, with the CCDT's duties being to "establish program standards, guidelines and outcome goals for" OTDT initiatives, based on FPT recommendations (*supra* note 7 at Appendix B-1).

⁵⁰ This was followed in the case of *SBINDD*, at least (*Summative Evaluation*, supra note 3 at 19, 22).

⁵¹ *Ibid* at 19. "The CCDT's mandate is to provide advice to the CDM ... It was then up to the provincial and territorial levels [of government] ... to implement or not the recommendations" (at 11). "[T]he mandate of the [CCDT] is to provide advice to the FPT Conference of Deputy Ministers of Health in support of their efforts to coordinate FPT activities relating to organ and tissue donation and transplantation. The authority to make decisions with respect to organ and tissue donation and transplantation matters shall remain with the FPT governments" (at 12). This

However, even before CDM approval was received, the CCDT guidelines appear to have reflected significant government input. Government officials were required to attend CCDT meetings to provide unspecified input.⁵² The CCDT reported that an unnamed CDM liaison linked the CCDT and the CDM.⁵³ In addition, after 2003, the CCDT chair was a former CDM member.⁵⁴ It is unclear from the available information whether the CDM liai-

arrangement was anticipated in the 1999 NCCOTDT *Strategy*: “[p]olicies, standards and guidelines of national concern will be drafted by the [CCDT] ... for approval by the Ministers of Health” (*supra* note 7 at 26). *SBINND* also lists the plan for dissemination as occurring in two phases, the first involving the CDM, followed by formal and informal dissemination of the guidelines to users (*supra* note 1 at 25).

⁵² *Ex officio* government members attended CCDT meetings during both its government secretariat and non-profit phases, not only permitting government awareness of its activities, but also providing mandatory government input into the creation of the CCDT guidelines. The CCDT’s first set of by-laws, CCDT by-laws No 1, *A By-law Relating Generally to the Transaction of the Business and Affairs of CCDT* (15 October 2001) [CCDT by-laws No 1], stated that, in addition to the 15 CCDT members, there were eight “ex-officio observers” (including FPT government representatives) as non-voting members “entitled to attend [CCDT] meetings,” who could provide written submissions to the CCDT, at the chair’s invitation (s 4). Additional *ex officio* members were added after 2003 (*Summative Evaluation, supra* note 3 at 113). While these members were appointed by government (the provincial and territorial Advisory Committee on Health Services) under CCDT’s by-laws No 1, they were appointed by the CCDT under a third set of by-laws in 2006 (CCDT by-laws No 3, (2 October 2006) [CCDT by-laws No 3]). A 2008 report indicated that Health Canada attended CCDT meetings as *ex officio* members “to brief [CCDT] members on the development and implementation of [OTDT] regulations ... ” (House of Commons, *Standing Committee on Health*, 39th Parl, 2nd Sess, No 15 (4 March 2008) (Kimberly Young) at 6, online: Parliament of Canada <www2.parl.gc.ca/HousePublications/Publication.aspx?DocID=3325761&language=E&mode=1&Parl=39&Sess=2> [2008 *Standing Committee Report*]). As noted elsewhere, Leah Hollins, the CCDT Chair after 2004, was a recent ex-CDM member. An unnamed CDM liaison may have also provided a permanent connection between the CDM and CCDT (CCDT, *2006 Annual Report, supra* note 9 at 4), suggesting the CDM may have been represented at CCDT meetings. This government input was considered mandatory by the CDM (*Summative Evaluation, supra* note 3 at 28). The details of this advice were not described but were reportedly considered important for “credibility” with the CDM.

⁵³ CCDT, *2006 Annual Report, supra* note 9 at 4.

⁵⁴ Ms. Hollins served as British Columbia’s Deputy Minister of Health Services from 1 November 1999 until 27 August 2001 (28 September 2010 email to Jacquelyn

son was the same individual as the CCDT Chair who had recently served on the CDM. There also appears to have been substantial potential for guideline-creation bias through CDM's selection of the CCDT directors for their "expertise and knowledge of OTDT."⁵⁵ Neurologists—whose expertise is vital to the creation of safe guidelines—were conspicuously absent from the selection of CCDT directors.⁵⁶

Neurological expertise is needed to supply details vital to brain death determination, such as information regarding particular drug clearance times, the reliability of certain medical tests, and the safe interpretation of ambiguous results. OTDT expertise alone will not provide the knowledge necessary for the development of brain death guidelines. The government refined the CCDT's board membership, based on its performance observations, through CDM replacement of the CCDT's Chair.⁵⁷ Numerous other directors also left following a recommendation made in a 2003 CDM-commissioned report on CCDT operations by the consultancy KPMG/BearingPoint that the CDM replace directors, but it is unknown whether the CDM deliberately removed any of these other directors.⁵⁸ This governmental shaping of CCDT member-

Shaw from Jennifer Kitching, Reference Librarian, The Legislative Library of British Columbia). This would have made Hollins a CDM member until August 2001. She officially joined the CCDT in January 2004.

⁵⁵ "The Conference [of Deputy Ministers of Health] will select [CCDT] members. The federal Minister of Health will officially appoint the [CCDT] members and designate the Chair." Subject to the discretion of the CDM, members' terms may be renewed (CCDT by-laws No 1, *supra* note 52 s 3.2).

⁵⁶ As determined by reference to the CCDT directors listed in the CCDT application for charitable status in June 2006 [CCDT Charity Application]. While some neurologist non-directors did help to author *SBINDD*, they were a minority (23% in total). Moreover, the directors formulated the questions and discussions, and edited panellists' opinions.

⁵⁷ In October 2003, KPMG/BearingPoint suggested that CDM "re-consider" certain CCDT members and carry out future appointments of the chair and other directors. This recommendation (number 8) was not listed as rejected (*Summative Evaluation*, *supra* note 3 at 112-13). The reported CCDT response to Recommendation 10, which also urged CDM replacement of the chair, was that founding Chair Philip Belitsky resigned and that his replacement, ex-CDM member Leah Hollins, was installed for the term ending 31 March 2007 (*ibid*).

⁵⁸ Overall, 11 of 16 CCDT directors (69%) left, most in the first five years. After the October 2003 KPMG/BearingPoint suggestion that CDM "re-consider" certain CCDT directors and carry out future appointments, 4 of the 16 founding CCDT directors, including Chairman Belitsky, with directors H Ross, Stoyles, and Loertscher, left in late 2003 to early 2004. Four more—Berreza, Craig, Ferre, and S

ship may have helped to produce brain death guidelines more sensitive to OTDT needs than to those of brain-injured patients.

To fully understand the government's influence over the CCDT guidelines' content requires re-visiting the CCDT's origins in the 1990s.⁵⁹ In an effort to establish the future CCDT and to coordinate OTDT improvement, the 1999 Standing Committee on Health recommended that "the federal Minister of Health immediately seek support from the [National Coordinating Committee for Organ and Tissue Donation and Transplantation (NCCOTDT)] and provide it with a small team of Health Canada personnel to initiate action."⁶⁰ Similarly, the Standing Committee recommended "that the CDM establish the [CCDT] to oversee organ and tissue donation and transplantation, [and] to report annually through the CDM to the federal Minister of Health and Parliament."⁶¹ Accordingly, in June 1999, the CDM directed the NCCOTDT to produce a strategy, including "[a] framework for action ... that would result in a sustained systematic approach to increasing the rates of organ and tissue donation and transplantation in Canada."⁶²

Ross had left by the 2005 non-profit conversion date, bringing total departures to half of the original directors. Three more directors—Mohr, Lakey, and Doig—left in 2005-6, after the CCDT became a non-profit. The reasons for most of the turnover were not discussed in CCDT reports.

⁵⁹ The committee initially recommended that the national coordinating body, identical in characteristics to the CCDT, be named the "Canadian Transplant Network" (1999 *Standing Committee Report*, *supra* note 6 ch 3B). In 1995-1996, even before the 1999 *Standing Committee Report*, the Ministers of Health and CDM had begun to take an interest in the issue of OTDT shortages (*Summative Evaluation*, *supra* note 3 at 8; 1999 *NCCOTDT Strategy*, *supra* note 7 at 2-3).

⁶⁰ 1999 *Standing Committee Report*, *supra* note 6 at Recommendation 18.1. The 1999 *Standing Committee Report* strongly urges the strict separation of individual physicians performing brain death determination and those performing transplantation in order to "assure the public intending to donate that their critical care needs will never be jeopardized by the transplantation needs of another individual" (ch 3). It also recommends precisely the opposite regarding staffing the future CCDT with members of existing OTDT organizations (at Recommendation 2.2).

⁶¹ *Summative Evaluation*, *supra* note 3 at 10.

⁶² 1999 *NCCOTDT Strategy*, *supra* note 7 at 4. In setting its principles, goals, and targets in the strategy, the NCCOTDT "considered the goals agreed to by the federal Ministers of Health" of improving Canadians' health, ensuring reasonable access to health benefits, and promoting long-term healthcare system sustainability (*ibid* at 5).

Specific targets and a deadline were required as part of this NCCOTDT strategy. The resulting report urged the swift establishment of the CCDT and set as five-year targets very high, organ-specific increases: 20-95% in the number of transplantable organs and 250% increases for tissues other than organs.⁶³ The CDM approved this plan in September 1999.⁶⁴ Realistically, increases of this magnitude would be impossible without significant amendment of brain death guidelines, particularly since the target increases are for numbers of transplantable organs and, due to disease or damage, not all donated organs can meet transplantation quality standards.⁶⁵ The significant target increases in organs are extremely unlikely to be met through OTDT social marketing campaigns, given the difficulty of altering public behaviours, values, beliefs, and concerns.⁶⁶ Prior to the development of the guide-

⁶³ *Ibid* at 5, 7-8. The 1999 NCCOTDT *Strategy* set as specific goals: 20% more transplantable lungs, 50% more transplantable hearts, 85% more transplantable livers, 95% more transplantable kidneys, and 250% more transplantable tissues (e.g. skin, cartilage, bone, blood, etc) (at 7-8). Target numbers of available organs and tissues would actually have to be much higher to offset the fact that some donated organs are of poor quality by the time they are available for harvest.

⁶⁴ *Ibid* at 4. "In September 1999, the CDM approved the [NCCOTDT] framework for action" (*Summative Evaluation, supra* note 3 at 10).

⁶⁵ Therefore, even if modest increases (e.g. 25%) in donor consent were achieved, this would translate to a smaller increase in the number of organs made available. Achieving a very large increase (e.g. 95%) in transplantable organ numbers would require a more dramatic approach such as amending guidelines to declare death earlier in the biological continuum from birth to bodily decay.

⁶⁶ The 1999 *Standing Committee Report, supra* note 6 ch 6, concluded as much, stating that "it is the second stage of ... donor identification, management and procurement, where the most significant effect can be made on increasing donor numbers," rather than through the first step of influencing donor intent and choice. However, a CMA submission to the Standing Committee urged that organ donation remain "rooted in the gift philosophy," arguing that "any means or measure to procure organs will tend to be more ethically dubious the more coercive they are and the less they rely on autonomy, personal choice and altruistic giving" (CMA, "State of Organ and Tissue Donation in Canada: Submission to the House of Commons Standing Committee on Health", Brief BR1999-05 (6 March 1999) at 1, online: CMA <policybase.cma.ca/dbtw-wpd/BriefPDF/BR1999-05.pdf>). The CCDT, *Health Professional Survey, supra* note 46 at 8, states that even among healthcare professionals, only 68% signed donor cards while 99% claimed to support organ donation. This suggests that awareness may not be the limiting factor.

lines, donation rates had been stagnant for several years.⁶⁷

According to Trillium Gift of Life, as many as eight useable organs and additional tissues (e.g. skin, blood) can be transplanted from a consenting donor, although an average donor yields at least three transplantable organs.⁶⁸ Current technology does not yet permit growing new replacement organs from stem cells. Nor can it salvage the many available but damaged organs to increase the transplantable organ pool.⁶⁹ Therefore, short of requiring mandatory organ donation, social marketing (to encourage growth in donor numbers), and altering brain death guidelines (to increase the proportion of donors eligible for organ harvesting), are the only available means of increasing organ supplies.⁷⁰

With past social marketing efforts having yielded little increase, it seems that a major component of the CDM-approved plan involved significant amendment of previous brain death guidelines. Amending brain death guidelines to allow brain death declaration earlier in the biological continuum offers two means of achieving OTDT targets, through the required “sustained, systematic approach.” First, among the existing pool of brain-injured patients, some of them donors, brain death guideline amendment can increase the proportion of those who may legally be declared brain-dead. Second, such amendment may also increase the proportion of those brain-dead donors who possess transplantation-quality organs.⁷¹ The decision to amend particular guideline details (e.g. replacing whole-brain death with a brainstem criterion) may have been left to CCDT discretion; no evidence exists on the mat-

⁶⁷ *Summative Evaluation*, *supra* note 3 at 9.

⁶⁸ Trillium’s Annual Report for 2009-10 reported an average yield of 3.6 organs per donor, and a targeted goal of 3.75 organs per donor (online: Trillium Gift of Life Network <www.giftoflife.on.ca/pdf/TrilliumAR_09-10_ENG_Spreads.pdf>).

⁶⁹ See Nick Lane, *Power, Sex and Suicide: Mitochondria and the Meaning of Life* (Oxford: Oxford University Press, 2005) at 314.

⁷⁰ These would affect, respectively, the number of donors per million population and the number of organs available per donor.

⁷¹ According to some scholars, the viability of the energy-supplying mitochondria within transplanted organs is vital to transplantation success (Lane, *supra* note 69 at 314). As summarized by Lane, mitochondria become progressively more damaged with patient age due to lack of oxygen, disease or drug side effects. Therefore organs harvested as early as possible in the biological continuum, which suffer less cumulative mitochondrial damage, will normally experience greater transplantation success (*ibid.*).

ter. However, it appears clear from the target organ numbers that substantial amendments were impliedly required.

Healthcare sustainability seems to be an enduring concern in the CCDT's history. In documents heralding the CCDT's establishment, sustainability was a recurring theme. A 1999 report accepted the Standing Committee recommendations as "the framework for discussions ... towards the establishment of a sustainable solution for transplantation in Canada."⁷² The CDM then demanded of the NCCOTDT a "sustained, systematic approach" to OTDT improvement. Subsequently, the NCCOTDT's blueprint for CCDT establishment identified healthcare system sustainability as one of its three "over-arching goals," and added that it is "essential that the donation and transplantation system be sustainable for the future."⁷³ The reason may relate to the aging of the baby-boomer generation and anticipated inundation of age-related ill-health. It has been predicted that the over-65 year-old population will double by 2025, expanding the need for hospital beds, staff, replacement organs, and other resources.⁷⁴ There appears to be an implicit belief that OTDT can aid in meeting these needs and achieving sustainability.⁷⁵

Regardless of CCDT content choices, CCDT recommendations were always subject to the requirement of CDM approval before dissemination. As the CDM acted as final arbiter (on behalf of the Federal Minister of Health and Parliament), presumably CCDT guideline drafts could have been denied approval and sent back for correction, thereby shaping the guidelines to fit government priorities. However, given the input from government representatives during the guideline-crafting process, it is unknown whether the CDM ever needed to request guideline corrections before issuing approval.⁷⁶ Early

⁷² Health Canada, *Government Response*, *supra* note 6 at 1.

⁷³ 1999 NCCOTDT *Strategy*, *supra* note 7 at 4-5. The NCCOTDT claimed to have done as the CDM directed by "releas[ing] ... recommendations ... to direct a sustained effort to increase the level of organ and tissue donation and transplantation in Canada" (at A-1).

⁷⁴ See World Health Organization, "50 Facts: Global Health Situation and Trends 1955-2025", online: WHO <www.who.int/whr/1998/media_centre/50facts/en/>.

⁷⁵ See 1999 *Standing Committee Report*, *supra* note 6 ch 3(B)(1)(c). While kidney transplantation may reduce long-term healthcare costs, the issue is complex and no such supporting data exist for other organs.

⁷⁶ However, it is known that the CDM required the CCDT to revise its overall workplan several times before the CDM would accept the final version in June 2004. See *Summative Evaluation*, *supra* note 3 at 20. Work done prior to that date was high-priority work that the CDM selected and approved for the CCDT.

comments suggest confidence regarding the potential for CCDT recommendations to become medical standards, directly influencing practice. As the Chair asserted in 2003: “A purpose of [the *SBINDD*] forum is to clearly define and standardize ‘accepted medical practice’ [in brain death determination, with the result] intended to be a clear and standardized process for the determination of death.”⁷⁷ *SBINDD* was also intended “[to] provide minimum standards and a code of practice.”⁷⁸

II. Does the Canadian *Charter* Apply to the CCDT Guidelines?

For the purposes of *Charter* review, it must first be determined whether the guidelines fall within the ambit of section 32 or whether their publication by a charitable, non-profit organization renders them purely “private” activity.⁷⁹ Answering this question requires an examination of Canadian jurisprudence and CCDT characteristics.

A. *The Law: When Does the Charter Apply?*

In *Retail, Wholesale and Department Store Union, Local 580 (RWDSU) v Dolphin Delivery Ltd*, a majority of the Supreme Court of Canada, in interpreting section 32, found that the *Charter* does not apply to purely private entities.⁸⁰ Yet, discerning which entities are truly “private” is not always straightforward. In *Slaight Communications Inc v Davidson*, the Supreme Court recognized that an entity, such as a board-appointed adjudicator, need not be a traditional part of government to attract constitutional scrutiny.⁸¹ Of concern in much of the Supreme Court’s section 32 jurisprudence is the po-

⁷⁷ *SBINDD*, *supra* note 1 at 30.

⁷⁸ *Ibid* at i.

⁷⁹ Section 32(1) of the *Charter*, *supra* note 5 states:

This Charter applies

(a) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and

(b) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.

⁸⁰ [1986] 2 SCR 573 at para 39, 33 DLR (4th) 174, [*Dolphin Delivery*] (“Where ... private party ‘A’ sues private party ‘B’ relying on the common law and where no act of government is relied upon to support the action, the Charter will not apply”).

⁸¹ [1989] 1 SCR 1038 at para 87, 59 DLR (4th) 416, Lamer J (dissenting, but not on this point).

tential for government to delegate powers to bodies described as “independent” and “arm’s length,” which may nonetheless conduct governmental activities. The fear is that such bodies could, by adopting the superficial appearance of private, non-governmental entities, insulate governmental activities from *Charter* review. Justice LaForest, writing for the Court in *Godbout v Longueuil (City of)*, stated:

Were the *Charter* only to apply to those bodies that are institutionally part of government but not to those that are—as a simple matter of fact—governmental in nature (or performing a governmental act), the federal government and the provinces could easily shirk their *Charter* obligations by conferring certain of their powers on other entities and having those entities carry out what are, in reality, governmental activities or policies. In other words, Parliament, the provincial legislatures and the federal and provincial executives could simply create bodies distinct from themselves, vest those bodies with power to perform governmental functions and, thereby, avoid the constraints imposed upon their activities through the operation of the *Charter*. Clearly, this course of action would indirectly narrow the ambit of protection afforded by the *Charter* in a manner that could hardly have been intended ... [I]n view of their fundamental importance, *Charter* rights must be safeguarded from possible attempts to narrow their scope unduly or to circumvent altogether the obligations they engender.⁸²

Accordingly, the Supreme Court has wrestled with the problem of identifying when an entity that appears private and independent may be considered a government entity, for *Charter* review purposes. In *Eldridge v British Columbia (AG)*, the Court held that the *Charter* may apply to an entity on one of two possible bases:

1. First, it may be determined that the entity is itself “government” for the purposes of section 32;⁸³

or:

⁸² [1997] 3 SCR 844 at 48, 152 DLR (4th) 577.

⁸³ The Court stated: “This involves an inquiry into whether the entity whose actions have given rise to the alleged *Charter* breach can, either by its very nature or in virtue of the degree of governmental control exercised over it, properly be characterized as government within the meaning of s 32(1)” ([1997] 3 SCR 624 at para 44, 151 DLR (4th) 577 [*Eldridge*]).

2. an entity may be found to attract Charter scrutiny with respect to a particular activity that can be ascribed to government.⁸⁴

Under the first branch, if an entity is found to be “government,” all of its activities will be considered governmental and therefore subject to the *Charter*, including activities that might ordinarily be considered private. In contrast, under the second branch, only the governmental activity in question will be subject to *Charter* review.

Eldridge involved a hospital that had discontinued funding of sign-language interpretation for deaf patients. The Supreme Court found that the appellant hospital was a private body that the government had chosen to deliver a comprehensive social program on behalf of government.⁸⁵ Accordingly, the program, as delivered by the hospital, was required to conform to the *Charter*.⁸⁶ In a judgment criticized by some, the Court held that there was “a direct and ... precisely defined connection between a specific government policy and the impugned act,”⁸⁷ so that the hospital, despite exercising autonomy with respect to day-to-day operations, was effectively under government control and served as an agent of the government in providing medical services.⁸⁸ However, the Court stated that, in general, the factors identifying a private body as carrying out governmental activity did “not readily admit of *a priori* elucidation.”⁸⁹

The Supreme Court’s most recent treatment of section 32 was the seven-justice majority decision in *Greater Vancouver Transportation Authority v Canadian Federation of Students* in 2009.⁹⁰ The case dealt with the section 32 status of two British Columbia regional transit corporations, BC Transit and Translink, whose policies of refusing to post political advertisements on their buses were found to contravene freedom of expression under section 2(b) of the *Charter*. The Court in *Canadian Federation of Students* con-

⁸⁴ “This demands an investigation not into the nature of the entity whose activity is impugned but rather into the nature of the activity itself. In such cases, one must scrutinize the quality of the act at issue, rather than the quality of the actor” (*ibid* at para 44).

⁸⁵ *Ibid* at para 50.

⁸⁶ *Ibid* at para 51.

⁸⁷ *Ibid*.

⁸⁸ *Ibid*.

⁸⁹ *Ibid* at para 42.

⁹⁰ 2009 SCC 31, [2009] 2 SCR 295 at para 17 [*Canadian Federation of Students*].

firmed that the “control test” remains the relevant legal test for determining government status under section 32 and provided a number of indicia relevant to determining whether the test is met.

Although their factual circumstances differed, the two corporations were both found to be government entities whose activities were subject to the *Charter*. The basis for so classifying the first, BC Transit, was that its enabling legislation designated it as an agent of the government, the entirety of its Board of Directors was appointed by the Lieutenant-Governor in Council, and government had the power to manage BC Transit’s affairs and operations via regulations. Concluding that the provincial government “exercised substantial control over [BC Transit’s] day-to-day affairs,” the Court held that BC Transit was a government agent and could not be said to be operating independently of government.⁹¹

The second corporation, Translink, was found to qualify as “government” on a different basis, not having been legislatively designated an agent of government. Translink’s governmental status derived from a variety of factors, including the Greater Vancouver Regional District’s (“GVRD”) “substantial control over [Translink’s] day-to-day operations” and the GVRD’s power to appoint the “vast majority” (80%) of Translink’s Board of Directors. GVRD was also obliged to ratify Translink’s taxation by-laws, levying by-laws, and overarching transportation plan, with which Translink’s capital and service plans had to be consistent.⁹² Final factors considered by the Supreme Court were Translink’s history and agenda, neither of which had ever been independent of government.⁹³ The Supreme Court agreed that together these indicia met the control test.⁹⁴ The Court also added that, unlike BC Transit, “[to] the extent that the GVRD does not have complete control over Translink, control is shared by the provincial government,”⁹⁵ confirming Translink’s governmental nature.

The Court in *Canadian Federation of Students* commented on governmental practices of creating ostensibly independent, non-governmental organizations, to effect government policy through delegation, without constitutional constraints:

⁹¹ *Ibid.*

⁹² *Ibid* at para 21.

⁹³ *Ibid* at para 20.

⁹⁴ *Ibid.*

⁹⁵ *Ibid.*

government should not be able to shirk its *Charter* obligations by simply conferring its powers on another entity ... The devolution of provincial responsibilities ... cannot therefore be viewed as having created a “*Charter-free*” zone.⁹⁶

Having reviewed key section 32 jurisprudence, the next section considers whether a reviewing court might view the CCDT as attempting to establish a *Charter-free* zone for the creation of clinical guidelines.

B. Applying the Law to the Facts: Does the Charter Apply to the CCDT Guidelines?

Despite the CCDT’s non-profit, charitable status, it remains possible for a court to find that the *Charter* applies to the CCDT guidelines. Applying *Eldridge*, there are two means by which the *Charter* may apply. Through the first test branch, if the CCDT can be shown to qualify as “government,” then all CCDT activities, including the guidelines, will be governmental and therefore subject to *Charter* scrutiny. Alternatively, if the CCDT cannot be shown to be government, then, through the second branch of the *Eldridge* test, the *Charter* may still apply to the guidelines alone, if they can be shown to constitute a form of “government activity” performed by the CCDT.

1. Was the CCDT “Government”?

As noted above, indicia of governmental character include government control over an entity’s day-to-day operations, government appointment (or removal) of those running the organization, and government ratification of the organization’s plans and by-laws, as well as any non-governmental history or agenda the organization may have had. Each factor is considered in turn.

Unlike BC Transit, the CCDT did not display the more obvious indicia of government character, such as legislative designation as an agent of government, nor the stipulation that the Lieutenant-Governor in Council be empowered to manage CCDT affairs and operations by means of regulations. Nonetheless, there does appear to have been evidence of substantial government control over the CCDT.

⁹⁶ *Ibid* at para 22.

Government control over directorial appointments: Evidence suggests there was significant government control over CCDT staff appointment and removal. During the CCDT's initial government phase, the CDM—a government body reporting to the federal Minister of Health and Parliament—appointed 100% of the CCDT's original directors and was initially responsible for renewing the directors' terms.⁹⁷ In October 2006, after the *SBINDD 2006* guidelines had been published,⁹⁸ the CDM relinquished to the CCDT responsibility for directorial appointment and renewal, when the CCDT's by-laws were changed to allow the CCDT to remove, replace, or nominate new directors by 2/3 majority vote.⁹⁹

However, the CCDT's choice in the matter of directors and other appointees may ultimately be argued to reflect the will of those who urged or permitted the CCDT to alter its by-laws, following the first set of by-laws. Notably, in 2003, KPMG/BearingPoint's Recommendation 4 urged the CCDT to alter its original by-laws to be consistent with the proposed FPT CDM *Memorandum of Understanding* and Letter of Agreement.¹⁰⁰ The CCDT "responded" in April 2006 by changing its by-laws "to accommodate requirements of a not-for-profit." Recommendation 4 was not listed among the rejected recommendations, suggesting CDM support for the change. In addition, since the CCDT was converted to a non-profit through Health Canada's support, the CCDT's adoption of its second set of by-laws to allow non-profit functioning appears to have derived ultimately from Health Canada, rather than from the CCDT. Since Health Canada's signing of the Contribution Agreement was conditional on the CCDT satisfying Health Canada's requirements, the contents of the second set of by-laws may be argued to have been directed (or at least permitted) by Health Canada.

⁹⁷ Under CCDT by-laws No 1, *supra* note 52 ss 3.2, 3.3, CCDT members were selected by the CDM and appointed by the Federal Minister of Health, but could be removed before term completion by the CDM.

⁹⁸ The second set of CCDT by-laws was unavailable so its contents are not directly known. However, the KPMG/BearingPoint report suggests that the second set took effect in April 2006 in response to KPMG/BearingPoint's 2003 recommendation that CCDT revise its by-laws for consistency with the FPT *Memorandum of Understanding* and Letter of Agreement (*Summative Evaluation, supra* note 3 at 112 (Recommendation 4)).

⁹⁹ CCDT by-laws No 3, *supra* note 52 ss 13, 28, 30. This by-law change appears to have occurred at the CDM's direction (*Summative Evaluation, supra* note 3 at 112 (Recommendation 4)).

¹⁰⁰ *Ibid.*

Unfortunately no direct information is available on the content of the second set of by-laws regarding who selected the CCDT directors. No reports indicate who instigated the CCDT's third set of by-laws, in October 2006, which allowed the CCDT to appoint directors, but presumably this third set must also have received Health Canada's approval, as it would have been open to Health Canada to withdraw its Contribution Agreement funds if dissatisfied with the change. The original CCDT by-laws, under which directors were CDM-selected, operated from 2001 until April 2006, covering most of the CCDT's existence, including the period when *SBINDD 2006* was published and the CCDT began non-profit operations. The third set of by-laws took effect around the time *BBFNDD* was written, permitting the CCDT to choose its own directors thereafter. However, no new CCDT directors were added until 2009, well after *BBFNDD 2008* had been published, when several new CCDT directors were appointed from CBS.¹⁰¹

During the CCDT's non-profit phase, it was apparent that government requirements strongly affected the CCDT's membership. For instance, the CCDT stated that "credibility with CDM" was a decisive factor in the selection of CCDT members:

The organization of the CCDT (i.e. involving experts, members of the public and government reps [*sic*]) was deliberately set up so that CCDT would have credibility with the CDM. An organization with only government representatives or with no government representatives would either a) not meet the needs of the transplant providers and community; and/or b) not have credibility with the CDM.¹⁰²

Thus, while a non-profit organization, the CCDT required government representatives in its membership for its recommendations to be approved by the CDM for dissemination. This may explain the appointment of an ex-CDM member as CCDT Chair.¹⁰³ The required governmental presence with-

¹⁰¹ According to the director lists available in the CCDT charitable returns, CBS director Graham Sher and Gale Watson were both appointed as CCDT directors in January 2009.

¹⁰² *Summative Evaluation*, *supra* note 3 at 28.

¹⁰³ According to CCDT by-laws No 1, *supra* note 52, eight "ex officio observers," including FPT government representatives, were non-voting members "entitled to attend [CCDT] meetings," but who could only address or provide written submissions to the CCDT at the Chair's invitation (s 4). CCDT by-laws No 3, *supra* note 52 does not state a number, or mention powers of attendance, etc., but

in the CCDT or at its meetings seems to have been intended by the CDM as a means of introducing a governmental perspective into CCDT recommendations. Therefore, even during its independent non-profit phase, the CCDT's Board membership was subject to significant government control.

Removal of certain directors occurred during the government phase. In 2003, the CDM accepted the consulting agency KPMG/BearingPoint's suggestion that the CDM consider for replacement certain CCDT directors, including the existing Chair, Dr. Philip Belitsky, due to CDM "performance expectations."¹⁰⁴ The CCDT's reported response to the recommendation entailed the prompt resignation of Dr. Belitsky, who was replaced in 2004 by British Columbia's ex-Deputy Minister of Health, Ms. Leah Hollins.¹⁰⁵ This CDM-instigated replacement occurred in the initial government phase. Yet, in total, over 60% of the CCDT's original directors were replaced, most in the CCDT's first 5 years, including some in the non-profit period.¹⁰⁶ It is not

allows *ex officio* members to be appointed by the CCDT. Although in 2003, the consulting company KPMG/BearingPoint suggested replacing the CCDT's *ex officio* members with a government/stakeholder liaison group, the CDM chose to retain and expand with "[a]dditional *ex officio* members ... to ensure appropriate and full representation of jurisdictions and stakeholders" (*Summative Evaluation, supra* note 3 at 31). Former CCDT CEO Kimberly Young stated that "... as part of their *ex officio* capacity, a representative of Health Canada attended CCDT meetings ..." (*2008 Standing Committee Report, supra* note 52).

¹⁰⁴ KPMG/BearingPoint Recommendation 8 (which was not rejected by the CDM or the CCDT) requests "[t]hat the membership (size and required expertise) of the [CCDT] be re-considered. Further that the nomination and appointment processes for the Chair and members be articulated and carried out by the FPT, CDM, more closely aligning overall responsibility and accountability for the effective performance of the CCDT" (*Summative Evaluation, supra* note 3 at 112-13). Recommendation 10 (also accepted) was: "That the Chair of the [CCDT] be re-considered given the performance expectations and the required skill sets" (*ibid*).

¹⁰⁵ Notably, the CCDT reported this resignation as its "response" to the CDM's recommendation (*ibid* at 113). Elsewhere, the CCDT simply stated that the CCDT Chair resigned (at 21).

¹⁰⁶ For example, James Mohr left in 2005, after the non-profit conversion, while Dr. Chip Doig resigned in 2006. Leaving dates were deduced from the CCDT and other records. Mohr was listed as a founding director in CCDT by-laws No 1, *supra* note 52 at 8, and he was later a "first director" signatory" in the CCDT's February 2005 application for incorporation as a non-profit (at 1), although his name was mistakenly then replaced on page 2 by a new "first director" (Vivian McAlister). Mohr was not listed as a member after 2005 on team lists such as the CCDT, *2006 Annual Report*, while McAlister was listed (*supra* note 9 at 2). Dr

known if any other appointments or removals were prompted by the government. Thus, it is unclear if CDM control over individual directorial appointment and removal persisted during the independent non-profit phase.

However, a larger issue may be that ultimately, not only individual directors, but the entire CCDT was “replaced” by another non-profit and charity (the CBS), as the result of a government decision. Despite the CCDT’s apparent successes and its anticipation, in 2006-2007, of a second five-year mandate lasting until 2012, it was dissolved on March 31, 2008.¹⁰⁷ The reason for the transfer to CBS of the CCDT’s mandate, contribution agreement, Chair, and numerous CCDT directors is unclear. CBS’s CEO asserted that the transfer of mandate was “not a function grab by CBS.”¹⁰⁸ Judging by CCDT expectations of a second mandate, the transfer was not a CCDT decision. In fact, the decision to transfer the mandate to CBS was, like so many other decisions regarding the CCDT, probably made by the CDM.¹⁰⁹

Doig was also a founding member who was a signatory “first director” to the CCDT’s February 2005 non-profit application (*ibid* at 2); he was later listed as Chair of the CCDT Donations subcommittee in March 2006 in *SBINDD 2006*, *supra* note 21 at S7, but was not listed as a director in the CCDT Charity Application, *supra* note 56 at 2, or the CCDT, *2006 Annual Report*, *supra* note 9 at 2. Doig reported his resignation from the CCDT in an October 2006 article. See Christopher James Doig, “Is the Canadian Health Care System Ready for Donation After Cardiac Death? A Note of Caution”, 175 (2006) *Can Med Assoc J* 905 at 905.

¹⁰⁷ The CCDT, *2006 Annual Report*, *supra* note 9, states: “we have prepared an exciting and ambitious strategic plan for 2007 to 2012.” In March 2007, the CCDT also recommended continuing in its earlier capacity “in the next five-year period” (*2007 CCDT Summative Evaluation*, *supra* note 18 at 5). The CCDT deferred evaluating long-term effects of its recommendations, to its “next” five-year term (*ibid* at 48). Clearly, in 2006-7 CCDT directors did not believe that their work was nearing completion.

¹⁰⁸ See W Kondro, “National Organ Allocation Mechanism to be Sought” (2008) 179 *Can Med Assoc J* 640 [Kondro, “Allocation Mechanism”].

¹⁰⁹ “In October 2007, the deputy ministers of health for the provinces (except Quebec) and territories agreed in principle to a proposal that CCDT’s functions be transferred to the CBS and that the CBS assume responsibility for Canada’s organ and tissue donation system” (Sonya Norris, Library of Parliament: Parliamentary Information and Research Service, *Organ Donation and Transplantation in Canada*, (Ottawa: 25 June 2009) at 3, online: Library of Parliament <www2.parl.gc.ca/Content/LOP/ResearchPublications/prb0824-e.pdf> [Norris Report]).

Significantly, the CCDT's dissolution indicates that the CDM was, three years into the CCDT's non-profit period, able to compel the CCDT directors to seek revocation of their organization's charitable registration¹¹⁰ and corporate charter.¹¹¹ This seems at odds with the characteristics of an independent, arm's length non-profit. It was also unusual, since the CCDT was a charity with an unused capacity to fundraise to support itself. The CCDT's dissolution after the CDM's decision makes clear that substantial CDM control was maintained over CCDT membership throughout the CCDT's existence.

Government ratification of plans, subsidiary plans, and by-laws: In *Canadian Federation of Students*, Translink was required to create an overall transportation plan for government ratification. Similarly, the CCDT was required to create, for CDM ratification, a long-term work-plan for achieving the NCCOTDT targets. In fact, the CDM reportedly required the CCDT to correct its work-plan several times before accepting it.¹¹² Translink was also to prepare subsidiary plans, consistent with its overarching transportation plan, for government ratification. Somewhat similarly, the government created a subsidiary plan for the CCDT (i.e. a subset of the overall work-plan consisting of components, including the revision of brain death guidelines, selected as immediate CDM priorities), consistent with the overall CCDT work-plan.

The CDM-approved work-plan, and especially the CCDT's CDM-selected priority plan, substantially dictated the day-to-day activities of the CCDT. The priority work of the subsidiary plan required that the CCDT put all its other work-plan activities on hold, except for the tasks of revising brain death guidelines and conducting social marketing. In addition, the

¹¹⁰ The Minister could, under the *Income Tax Act*, RSC 1985, c 1 (5th Supp), ss 149.1(2) or (4.2), have unilaterally revoked the CCDT's charitable status for carrying on non-charitable business or failing to expend its annual funding disbursement quota or for wrong-doing involving gifts and false statements. However, the CCDT's charitable status revocation was recorded as "voluntary," a categorization that is not based on such failures. (Canada Revenue Agency, "Charities Listings", online: CRA <www.cra-arc.gc.ca/chrts-gvng/lstngs/menu-eng.html> [CRA, "Charities Listings"]). Therefore the revocation must have been initiated from within the CCDT.

¹¹¹ Under the *Canada Corporations Act*, RSC 1970, c C-32, s 32(1), a non-profit corporation may surrender its corporate charter if it can prove to the Minister of Industry's satisfaction that it possesses no assets or unresolved debts and that it has given public notice of the planned surrender in the *Canada Gazette*.

¹¹² See *Summative Evaluation*, *supra* note 3 at 20.

CDM was required to ratify the products of the CCDT's main and subsidiary plans, that is, the guidelines themselves, prior to their dissemination.

Finally, as in *Canadian Federation of Students*, where government was required to ratify the organization's taxation by-laws, there is evidence that the CDM required the CCDT to amend its by-laws on at least one occasion. In 2003, the CDM required that the CCDT update its internal by-laws "to comply with the *Memorandum of Understanding* and letter of agreement."¹¹³ In response, the CCDT updated its by-laws in April 2006, demonstrating government control over CCDT by-law creation during the non-profit period.¹¹⁴ There is no evidence that the CDM later ratified this CCDT choice of by-laws, although Health Canada presumably considered the change to comply with its Contribution Agreement. However, CDM ratification of CCDT work-plans and products certainly occurred, which is consistent with portrayal of the CCDT as a government entity.

Government history and agenda: Another factor considered in *Canadian Federation of Students* was whether Translink had an agenda or history as an entity independent of government. The fact that Translink did not contribute to its classification as a government entity. Unlike Translink, the CCDT had some history of being an entity independent of government, but it also had significant indicia of a government history and agenda. Following intense governmental study of the matter, three major reports were written,¹¹⁵ and a complex, collaborative *Memorandum of Understanding* was arranged by the Canadian government to pre-empt constitutional obstacles to a federal government secretariat operating in the provincial or territorial sphere of healthcare.¹¹⁶ During its initial governmental period, CCDT powers and responsibilities were delegated via the *Memorandum of Understanding*.

Thus, the CCDT functioned during its early history as a governmental secretariat, established to advise the CDM. In total, the CCDT operated as a governmental secretariat for approximately four of its nearly seven years. After the CCDT became a non-profit organization in mid-2005, a Letter of Agreement supplanted the *Memorandum of Understanding*, pursuant to a

¹¹³ *Ibid* at 112. The CDM "accepted" this KPMG/BearingPoint recommendation.

¹¹⁴ *Ibid*.

¹¹⁵ Advisory Committee, *Distribution Discussion Document*, *supra* note 7; 1999 *Standing Committee Report*, *supra* note 6; 1999 *NCCOTDT Strategy*, *supra* note 7.

¹¹⁶ See Health Canada, *Interim Funding*, *supra* note 8.

Health Canada Contribution Agreement.¹¹⁷ However, the CCDT's "basic reporting structure to the CDM remained unchanged" by non-profit incorporation.¹¹⁸

Indicia of the CCDT's government agenda are evident following the 2003 CDM-commissioned formative evaluation of the CCDT's structure and operations, conducted by KPMG/BearingPoint.¹¹⁹ Of KPMG/BearingPoint's 33 recommendations to the CDM,¹²⁰ 88% were followed by the CCDT, while only 12% were rejected based on CDM direction or approval.¹²¹ Notably, some of KPMG/BearingPoint's recommendations were followed even during the CCDT's non-profit phase.¹²²

Rejected suggestions included the recommendation that the CCDT restrict its advice to tissue banking, rather than address donation and transplantation issues more broadly. This recommendation appears to have been rejected due to the CDM's direction and priorities for the CCDT.¹²³

¹¹⁷ Don Parkinson, Health Canada, *Recipient Guide to Health Canada–Contribution Agreements* (2004), online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_contribution/agreement_accord/index-eng.php> [Health Canada, *Recipient Guide*]. The Guide defines a contribution agreement as "a conditional transfer of funds to an individual, organization or other level of government to reimburse some portion of the costs incurred in carrying out a worthy project that the Government of Canada wishes to support," stressing that under a contribution program, "Health Canada is not purchasing goods or services from a recipient." However, like a contract, "both Health Canada and recipients have responsibilities to ensure that funded projects are completed according to the agreement." A Health Canada program consultant monitors each project to "determine if the activities and expenditures are in line with the agreement and if objectives are being met."

¹¹⁸ *Summative Evaluation*, *supra* note 3 at 119.

¹¹⁹ *Ibid* at 32 (KPMG/BearingPoint's evaluation was made "at the request of the CDM because there were concerns about the role and operations of the CCDT" (*ibid*). The KPMG/BearingPoint recommendations and responses only appear to be available through their reporting in *ibid* at 29-31, 112-115.

¹²⁰ For clarity, none of KPMG/BearingPoint's recommendations dictated the content of clinical guidelines such as *SBINDD* or *BBFNDD*. The recommendations related to aspects of CCDT governance, structure, etc. .

¹²¹ *Ibid* at 31 (There were four recommendations that the CCDT or CDM did not accept that are listed at 31, 112-113).

¹²² For example, the CCDT's adoption of new by-laws in 2006 (CCDT by-laws No 3, *supra* note 52).

¹²³ *Ibid* ("This was not implemented and it was decided that for the remainder of its

KPMG/BearingPoint also recommended that the CCDT remain an unincorporated body, a suggestion that was reportedly rejected by Health Canada.¹²⁴ The CCDT's non-profit incorporation occurred in 2005. Of the other two rejected recommendations, one, involving reducing the number of *ex officio* government attendees, was rejected at the CDM's direction.¹²⁵ The other, which involved the CCDT's subcommittee structure, was postponed until the anticipated renewal of the CCDT's mandate.¹²⁶ The source of that decision was not disclosed.¹²⁷ These factors suggest that the CCDT adhered closely to the CDM's agenda.

As stated elsewhere, the CCDT was not delegated its governmental mandate and authority via an enabling statute. Of note, however, is the existence of CCDT indemnification legislation, enacted in Canada's Yukon Territory in 2002,¹²⁸ seemingly anticipated in the Northwest Territories,¹²⁹ and sug-

first mandate the CCDT would continue to focus on addressing donation and transplantation issues related to perfusable organs" at 31). The CCDT suggests that it alone made the decision to reject, noting that it chose instead to address "transplantation issues related to waitlists and organ allocation" (at 112, Recommendation 1). Yet the CCDT's function was to advise the CDM, on matters of priority to the CDM. KPMG/BearingPoint's recommendation would have conflicted with "priority instructions" that the CDM had selected for the CCDT as its first tasks: "[During the 2001-2004 period], the CDM selected certain priorities from the [CCDT's Work] Plan for the CCDT to address. All of them related to the topic of donation, essentially putting the work of the other committees on hold" (at 20). "Beginning with its first meeting in October of 2001, the [CCDT] ... devoted significant time to development of its work plan ... Some components of it (for example ... the Neurological Determination of Death component) were approved by the CDM at its December 2002 meeting, and the CCDT was mandated to pursue these initiatives" (at 16). To follow KPMG/BearingPoint's recommendation would have conflicted with these CDM priorities, suggesting that the CCDT's rejection of this recommendation was not made independently by the CCDT but was driven by CDM needs.

¹²⁴ *Ibid* at 31, 112. The CCDT or CDM also agreed.

¹²⁵ *Ibid* at 31 (Recommendation 12).

¹²⁶ *Ibid* at 31, Recommendation 16.

¹²⁷ *Ibid*.

¹²⁸ *Canadian Council for Donation and Transplantation Indemnification Act*, RSY 2002, c 24. In November 2001, Hansard cited the reasons supporting the need for indemnifying legislation in the Yukon: "People providing expert advice on health matters can be at risk of having legal action taken against them for the work that they do in good faith and to the best of their abilities"; "It is becoming a frequent and common requirement for governments to ensure that these individuals are not

personally at risk when they accept the responsibility to sit on an advisory group”; “In practical terms, indemnification of the CCDT means the government will pay for the legal expenses, including litigation costs and settlement costs, if legal action is taken against a member of the CCDT for work they have done in good faith for the [CCDT].” However, “the CCDT is required to purchase \$10 million of commercial insurance to draw on first if actions are taken against them. ... In the event that any indemnification would need to be paid out, an agreement is in place among all federal, provincial and territorial governments that will mean that the Yukon [would only pay] just under 0.1 per cent of the total.” (Yukon, Legislative Assembly, *Hansard* 30th Leg 2nd Sess online: Yukon Legislative Assembly <www.hansard.gov.yk.ca/30-legislature/session2/086_Nov_15_2001.html>). The second reading of the Bill passed. According to CBS Annual Reports for 2007-08 and 2008-09, the CBS, as the organization that took over the CCDT’s mandate, made a significant change to its insurance scheme in 2007–2008, which had previously involved a Bermudian captive insurance company, the Canadian Blood Services Insurance Company Ltd, founded in 1998. The company insured the CBS against blood-related losses of up to C\$250 million, of lesser relevance to CCDT matters. See CBS, *Annual Report* 2007-8 at 44, online: CBS <[www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/Annual+Reports/\\$file/07-08-CBS-Annual-Report-en.pdf](http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/resources/Annual+Reports/$file/07-08-CBS-Annual-Report-en.pdf)>. A significant change was the CBS’ establishment of a second captive insurance company, in British Columbia in May 2006 (at 48). As well as providing additional blood-related coverage (up to \$500 million more), this second insurance company also permitted indemnification of CBS members (who have included some former CCDT directors) against up to \$750 million in non-blood related losses, thus of potential relevance to the CCDT. CBS’ acquisition of this extra insurance coverage caused a net deficit to the CBS of \$8.9 million in 2007–2008 and a projected deficit of \$9.4 million in 2008–2009. Despite possessing this enhanced coverage, further risk assessments, factoring in the CBS’ new OTDT mandate, were commenced in 2007–2008 to assess the adequacy of the two captive insurance companies’ coverage. Reportedly, as of 2007–2008, no major claims had been made under either of the two CBS captive insurance programs (at 44, 45).

¹²⁹In the Northwest Territories, regulations create an exemption for the CCDT from ss 66-67.2 of the *Northwest Territories Financial Administration Act*, RSNWT 1988, c F-4 in *Contract of Indemnification Exemption Regulations*, NWT Reg 018-99. This exemption relates to aspects of indemnifying “an individual not an employee under the Public Service Act who serves at the request of government as a member of a board, agency, committee or council” or an entire “board, agency, committee or council that performs functions on behalf of government,” up to a maximum of \$500,000. The CCDT (along with the CBS and its second captive insurance company) is expressly listed among those to be indemnified (*ibid* s1). Although no indemnification legislation was passed in the Northwest Territories, the regulation suggests planned CCDT indemnification there, as in the Yukon, due

gested (but not pursued) in Canada's other provinces and territories,¹³⁰ for reasons that remain unclear.

Under the only existing CCDT indemnification legislation—that of the Yukon—the federal government agreed to assume financial responsibility for any litigation generated by CCDT “guidance” in that territory, to a maximum of \$10 million. This legislation was passed shortly after the CCDT’s establishment, before guideline-creation had commenced. Though not a statutory grant of governmental authority, such legislation suggests a high level of government support for the CCDT and its activities, through its protection of CCDT directors. None of the previous Canadian clinical groups that created brain death guidelines were protected by indemnifying legislation.

This legislation suggests that the government anticipated the possibility of litigation resulting from the CCDT’s (as yet unwritten) guidelines. It suggests that the government was willing to underwrite possible costs associated with the CCDT guidelines’ operationalization of the government’s plan to address OTDT shortages.¹³¹ This government protection of CCDT members through legislation may strengthen the understanding of the CCDT as animated by a government agenda.

to the CCDT’s performing “functions on behalf of government.”

¹³⁰ As part of an early Contribution Agreement approved (but unsigned) by the Treasury Board Secretariat on 11 April 2002, the [federal] Minister of Health was to “enter into an accord with the provincial and territorial Ministers of Health wherein FPT governments jointly indemnify the members of the [CCDT] and its working groups” (Health Canada, *Interim Funding*, *supra* note 8). However, at that time (2003), the Contribution Agreement was not finalized due to the accord being unsigned. The \$10.8-million Health Canada-CCDT Contribution Agreement was finally signed on 1 April 2005, remaining in effect until 31 March 2008 (Health Canada, *Final Audit*, *supra* note 9 at 1). According to the CCDT, the CDM had recommended in 2003: “[t]hat the CDM conclude a final review of the residual indemnification and determine the necessity for this provision and its inclusion in the FPT Accord. Further, that the CDM pursue the appropriateness of a Memorandum of Understanding and Letter of Agreement that could accomplish the objectives to be accomplished through the FPT Accord, hence replacing the need for the FPT Accord” (*Summative Evaluation*, *supra* note 3 at 112). Reportedly, the issue was addressed, seemingly without need for an FPT Accord, through the CCDT’s acquisition of insurance (*ibid*). No further mention of the CCDT indemnification accord appeared thereafter in Hansard or in provincial and territorial legislation.

¹³¹ Government may be sued in tort for its operational activity, but not for its policy-making (*Neilsen v Kamloops (City of)*, [1984] 2 SCR 2, 10 DLR (4th) 641).

Finally, perhaps the clearest indication of a government agenda was the CCDT's dissolution. As noted, after the CCDT's funding was withdrawn, it was open to the CCDT directors to fundraise, as permitted by the CCDT's charitable status, and to continue functioning as an "independent non-profit." However, after the CDM's agreement to dissolve the CCDT and to withdraw its funding, the CCDT's directors chose to discontinue operations. This suggests that the CCDT had no genuinely independent agenda as a non-profit organization and charity, once its CDM mandate and Health Canada funding were transferred to CBS.

Government control over day-to-day activities: The CCDT appears to have been subject to significant government control in its day-to-day activities. Control appeared to derive from two sources: the CDM (governing the CCDT's activities under its mandate) and, secondarily, Health Canada (governing the CCDT's use of Health Canada funds). The CCDT was subject to significant government monitoring, being required to report annually to the CDM on its activities and progress and subject to regular Health Canada financial audits. It is not known if the CDM liaison or *ex officio* members present at meetings played some role in monitoring CCDT activity. It is plausible that, in addition to injecting a governmental perspective into CCDT activities, the *ex officio* members and CDM liaison might, at least on an informal basis, have reported on CCDT progress to their respective government departments. Certainly nothing seems to have operated to prevent this.

CDM influence was a major theme throughout the CCDT's history and in government preparations prior to CCDT establishment. To recapitulate, following the 1999 Standing Committee's recommendation, the CDM directed the writing of the *1999 NCCOTDT Strategy*, which urged the CCDT's establishment and set the targeted OTDT increases and deadline. The CDM approved these goals and the *NCCOTDT Strategy*'s contents.¹³² Two years later, the CDM created the CCDT "to provide advice to the CDM."¹³³ The CDM suggested all of the CCDT's original board members for federal Ministerial appointment and was initially responsible for member renewal. After calling for a formative evaluation of the CCDT in 2003, to ensure optimal CCDT functioning, the CDM amended CCDT board membership based on performance expectations. The CDM also required that the CCDT respond to

¹³² *Summative Evaluation*, *supra* note 3 at 10.

¹³³ See Health Canada, *Final Audit*, *supra* note 9 at 1; *Summative Evaluation*, *supra* note 3 at 11.

recommendations of the CDM's choosing and reject the remaining recommendations.¹³⁴

Even during the CCDT's non-profit phase, the CDM required government representatives within the CCDT¹³⁵ and a CDM liaison. The two available sets of CCDT by-laws both indicate a requirement that *ex officio* members be sourced from various levels of government. The third set, operating after October 2006, also allowed the appointment of additional non-government *ex officio* members.¹³⁶ It is not known precisely what the content of the second set was on the matter of *ex officio* appointments or whether non-government members could also be included, but by the CCDT's own report in late 2006, government appointees were always required "for credibility with CDM." As noted elsewhere in this article, the content change of the second set of by-laws in April 2006 appears to have been instigated and permitted by government (Health Canada). The change to a third set must presumably also have complied with Health Canada's requirements for the CCDT to continue to qualify for the Contribution Agreement funds.

After the CDM re-considered the original CCDT Chair, he was replaced by a recent former CDM member. Having approved NCCOTDT targets, the CDM approved the CCDT's work-plan to meet these targets, set the CCDT's initial priority tasks, and then monitored CCDT progress via mandatory annual reports. The CDM effectively directed every part of the CCDT's guideline-production "advice cycle," from topic selection through approval¹³⁷ and uptake monitoring.¹³⁸

Finally, the CCDT was dissolved after a CDM agreement to transfer the CCDT's mandate and funding to CBS.¹³⁹ The voluntary revocation of the

¹³⁴ "[T]he CDM ... requested that the CCDT produce ... a response to the [KPMG/BearingPoint] formative evaluation by April 30, 2004" (*ibid* at 20).

¹³⁵ *Ibid* at 28.

¹³⁶ CCDT by-laws No 3, *supra* note 52 s 37.

¹³⁷ The CCDT reported that the *SBINDD* guidelines, at least, were submitted to the CDM for approval, and were subsequently disseminated as "knowledge products" or "consensus recommendations" to users (*Summative Evaluation, supra* note 3 at 21, 22, 25).

¹³⁸ *Ibid* at 19.

¹³⁹ According to Health Canada auditors, "dissolution of CCDT was first proposed in 2006" (Health Canada, *Final Audit, supra* note 9 at 5). The CDM agreed in principle to dissolve CCDT in October 2007 (Norris Report, *supra* note 109 at 3). Government transferred the CCDT's mandate to the CBS: "In October 2007, the

CCDT's charitable status indicates that the CDM retained sufficient influence over the CCDT's directors to prompt dissolution of the CCDT, in circumstances where loss of Health Canada funding may not have been fatal to the CCDT's continuation. These factors reveal a significant degree of CDM control over CCDT activities, even during the non-profit phase.

In *Canadian Federation of Students*, Translink was compared with universities and hospitals and concluded not to have operated with the same independence.¹⁴⁰ The CCDT members also lacked the academic freedom of funded academics in a university setting, the latter generally being free to choose their subject matter, hypotheses, and to report conclusions that are not pre-determined or influenced by third parties. In contrast, the general outcome of the CCDT guidelines was pre-determined by government: a large "sustained systematic increase" in transplantation-quality organs in a short time-frame, with brain death guidelines effectively specified as the means. After satisfying these government requirements, and after receiving the required input from the *ex officio* government representatives and CDM liaison, little academic freedom may have remained to the CCDT members for guideline-creation.¹⁴¹ Even less may have remained if the CDM required any corrections to guidelines before approving them. Thus, CCDT members' guideline-creation was significantly constrained by government, unlike typical academic freedom in the university context.

Health Canada's influence over CCDT purse strings was another recurrent theme during the CCDT's existence. Reportedly, Health Canada had

Deputy Ministers of Health for the provinces (except Quebec) agreed in principle to a proposal that the CCDT's functions be transferred to Canadian Blood Services (CBS) and that CBS assume responsibility for Canada's organ and tissue donation and transplantation system" (*ibid* at 3). An 8 October 2010 email from the CBS by (former CCDT CEO) Kimberly Young and (former CCDT director) Peter Nickerson also confirmed that the "[CBS] was given a mandate by the federal, provincial and territorial Deputy Ministers of Health (except Quebec) in 2008 to make recommendations on organ and tissue donation and transplantation (OTDT) in Canada," as the CCDT had been mandated previously. Email correspondence of Samantha Hayward (on behalf of Kimberly Young, Executive Director, CBS and Peter Nickerson, Executive Medical Director, CBS) with Jocelyn Downie (8 October 2010) regarding the CBS' Roundtable Discussion at Transplant Atlantic 2010, in Halifax, Nova Scotia, on 13-15 October 2010.

¹⁴⁰ *Canadian Federation of Students*, *supra* note 90 at para 20.

¹⁴¹ It is not clear from any available information whether government dictated the specific content of the CCDT guidelines.

long planned for the CCDT to operate as an “independent, arm’s length” agency.¹⁴² Although reasons for the non-profit conversion were never made known,¹⁴³ reports suggest that the non-profit conversion occurred with Health Canada’s support.¹⁴⁴ Non-profit status must have offered some significant benefit to government, offsetting the considerable time required and financial costs of the conversion,¹⁴⁵ since approximately 39% more Health Canada funding was needed during the CCDT’s non-profit phase to replace government resources.¹⁴⁶ In addition, the CCDT’s conversion to charitable

¹⁴² The CCDT reported: “Since its inception, it has been the intention that the CCDT would assume operations under a [Health Canada] contribution agreement as an independent and ‘arm’s length’ organization” (*Summative Evaluation, supra* note 3 at 15).

¹⁴³ It is also unclear what reason grounded the CCDT’s pursuit of charitable registration in addition to its non-profit status. See CCDT Charity Application, *supra* note 56. In the CCDT 2006 *Annual Report* (authored in November 2006 while the CCDT was a charity), the CCDT described itself as “a national, registered non-profit dedicated exclusively to the interests of the organ and tissue donation and transplantation system in Canada” (*supra* note 9 at 7). While CCDT by-laws No 3, *supra* note 52, required CCDT Directors to “take steps” enabling CCDT receipt of bequests, legacies, gifts, etc., no public fundraising activities were reported on CRA charitable returns (s 35). A single \$25 donation was reported on the CRA return for the 2007-ended fiscal year; returns are listed online and are accessible via the CRA, “Charities Listings”, *supra* note 110.

¹⁴⁴ *Summative Evaluation, supra* note 3 at 31. This listed all of KPMG/BearingPoint’s 33 recommendations, noting only four that the CCDT or the CDM did not accept, including Recommendation 3, that the CCDT remain unincorporated. Health Canada disagreed with this KPMG/BearingPoint recommendation and “[i]nstead, the CCDT became an incorporated non-profit and signed a Contribution Agreement with Health Canada in June 2005.”

¹⁴⁵ The CCDT’s new “non-governmental” structure was described by participants and stakeholders as “more effective” than the government structure, although it was not clarified at what it was more effective (*ibid* at 15, 21).

¹⁴⁶ “The major administrative change [of the CCDT to non-profit status] took significant time and energy in terms of hiring staff, locating office space and arranging for services previously provided in-house by Health Canada” (*ibid* at 21). Furthermore, “there were significant increases to ... operating costs associated with the CCDT’s transfer [to non-profit status] related to services that were previously provided in-kind within the government i.e. office space, information technology support, accounting and payroll services, human resources” (*ibid* at 55). Reported CCDT expenditures show that, between the last government year (2004-5) and the first non-profit year (2005-6), CCDT annual costs increased by C\$1,067,190 (i.e. 39%) (*ibid*).

status imposed some major disadvantages.¹⁴⁷ Thus, the CCDT's non-profit and charity status must have offered some compelling, balancing advantage, for which Health Canada was willing to spend more and risk temporarily slowing CCDT progress. One advantage suggested was that, as a non-profit, the CCDT's apparent objectivity and independence from government gave it greater credibility with practitioners, potentially enhancing uptake of the CCDT's guidelines.¹⁴⁸

Health Canada exercised financial control over the CCDT during its non-profit phase by funding the CCDT through the Contribution Agreement.¹⁴⁹ This arrangement allowed government to terminate the Agreement and reduce or remove the CCDT's funding at will. It seems unusual for a Contribution Agreement not to require a partial contribution from the recipient organization itself, yet this was the case, leaving the CCDT more dependent on its government funding.¹⁵⁰ Notably, the CCDT was not provided with an unconditional grant of funds to spend as it pleased, but with a conditional grant for the specific purpose of addressing certain "worthy project[s] the Government of Canada wishes to support."¹⁵¹ Evidence shows detailed Health Canada monitoring and control over the CCDT's day-to-day spending decisions.

¹⁴⁷ Charitable status restricted the activities in which the CCDT could legally engage, since Canadian charities are prohibited, under the federal *Income Tax Act*, RSC 1985, c 1, 5th Supp from pursuing, on more than an incidental basis, "political" (i.e. legislative or policy-oriented) activities (Canada Revenue Agency, "Policy Statement: Political Activities", CPS-022, 2 September 2003, at 6.1-6.2, online: CRA <www.cra-arc.gc.ca/chrts-gvng/chrts/policy/cps/cps-022-eng.html>).

¹⁴⁸ 2007 *CCDT Summative Evaluation*, *supra* note 18 at 5.

¹⁴⁹ *Summative Evaluation*, *supra* note 3 at 12.

¹⁵⁰ This sole funding conflicts with the now-archived Treasury Board Secretariat "Policy on Transfer Payments" governing Contribution Agreements, operating during the relevant time period (from 2000 until late 2008). Under s 7.13.2 of the Policy, there was an expectation that a funding recipient would contribute some of its own funds towards the total project costs; s 7.13.1 stated that, before approving a contribution over \$100,000 for a project, the potential recipient must submit a statement indicating its other sources of possible funding. Finally, under ss 7.8.2, 7.8.3, there was also an expectation that the government's contribution funding would be repaid by the recipient organization, although non-profit corporations unable to generate the necessary revenues for repayment could be exempted. See Treasury Board of Canada Secretariat, *Archived [2008-10-01] - Policy on Transfer Payments*, online: TBS <www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=12257>.

¹⁵¹ Health Canada, *Recipient Guide*, *supra* note 117.

Specifically, the Contribution Agreement funding was subject to terms agreed to in advance, regular interim progress checks during receipt of funds, and a final audit before the release of the last funding instalment to the CCDT.¹⁵² These audits judged overall CCDT compliance with the government Contribution Agreement, and suggest government attempts to control CCDT use of these funds.

Yet, overall, Health Canada may have exercised imperfect control over CCDT spending. Health Canada's regular audits noted instances of apparent CCDT funding misallocation (e.g. CCDT use of funds for overseas travel, and excessive hospitality budgets).¹⁵³ It also failed to prevent CCDT payments made to certain CCDT "members" (elsewhere implied to be directors¹⁵⁴), including large "honoraria,"¹⁵⁵ which the recipients reportedly per-

¹⁵² *Ibid.*

¹⁵³ Despite several financial transgressions noted on the Health Canada, *Final Audit*, *supra* note 9 at 8, the CCDT was described as being in compliance with the Contribution Agreement.

¹⁵⁴ For instance, the CCDT's application for charitable status with the CRA, while the CCDT was a non-profit, provides information that, in combination with other information, implies that CCDT directors were receiving honoraria (CCDT Charity Application, *supra* note 56 at Q18). From as early as 2001 until late 2006, the CCDT by-laws permitted only CCDT directors to receive honoraria and benefits (CCDT by-laws No 1, *supra* note 52 s 3.14; CCDT by-laws No 3, *supra* note 52 s 15). Under s 36 of CCDT by-laws No 3, the CEO was to be the CCDT's "only direct employee." These statements reveal that the honoraria and travel benefits reported as paid in the 2006 charitable application must have gone to CCDT directors, since no other individuals were permitted under CCDT by-laws to receive honoraria (*Summative Evaluation*, *supra* note 3 at 17; Health Canada, *Interim Funding*, *supra* note 8). Previous mention of the "honoraria issue" (although not stated as involving CCDT directors) appeared in 2003 in KPMG/BearingPoint's Recommendation 13, which was reported as having been addressed by the "honorarium policy" Health Canada developed pursuant to the CCDT's 2005 Contribution Agreement (*Summative Evaluation* at 113).

¹⁵⁵ Health Canada, *Interim Funding*, *supra* note 8 at 113 indicated that CCDT "members" received honoraria, and expressed concerns that "[CCDT] members perceive the payment of honoraria as compensation. ... The misunderstanding between honoraria and compensation may also impact Health Canada's [future] arm's length relationship to the [CCDT]." Despite these concerns, Health Canada did not prohibit the awarding of honoraria, but set high "maximum" honorarium limits in the CCDT's Contribution Agreement in 2005 (*ibid.*). While a non-profit, the CCDT also reported in late 2006 that "[CCDT] members are paid honoraria," although it left unclear whether the "members" described included CCDT

ceived as salaried “compensation.” The honorarium issue generated considerable Health Canada concern in the 2003 audit as a threat to the CCDT’s (planned) arms’ length status from government.¹⁵⁶ Yet, despite its concern, Health Canada permitted the CCDT practice of awarding honoraria to continue during the non-profit phase. Presumably, Health Canada could have prevented continuation of this behaviour via the Agreement, but did not, for reasons that remain unclear. Instead, it agreed to very large maximum honorarium amounts in the 2005 Contribution Agreement, seemingly jeopardizing the CCDT’s arm’s length status.¹⁵⁷ Another example of Health Canada’s imperfect control involved the CCDT’s awarding of “severance pay” to its remaining “employees” in 2008.¹⁵⁸ This was considered an avoidable and wasteful expense by Health Canada.

Health Canada concluded in 2009 that the CCDT had satisfied the terms of its Contribution Agreement. Yet, even after the CCDT’s dissolution, Health Canada auditing of CCDT expenses continued and extended to the management of the transfer of CCDT’s assets to CBS.¹⁵⁹ This indicates the persistence of Health Canada’s influence well beyond the CCDT’s initial

directors, forum participants, or others (*ibid* at 17). The CCDT’s charitable status application, made in the non-profit period in 2006, also indicated that CCDT directors continued to receive honoraria (CCDT Charity Application, *supra* note 56). In apparent contradiction, the CRA information returns for this same (2007-ended) time period and thereafter reported that CCDT directors received no compensation by honorarium, salary, or benefits. In this and subsequent years, these same CRA returns reported yearly payment of large honoraria, exceeding C\$119,000 per annum in some years, to unspecified individuals at the CCDT (CRA, “Charities Listings”, *supra* note 110).

¹⁵⁶ See Health Canada, *Recipient Guide*, *supra* note 117 (“[u]nder a ... contribution program, Health Canada is not purchasing goods or services from a recipient.” In light of this, salaried compensation for work performed could conflict with this requirement, while honoraria might not.

¹⁵⁷ See *Summative Evaluation*, *supra* note 3 at 113.

¹⁵⁸ See Health Canada, *Final Audit*, *supra* note 9 at 4-5. Severance pay was seemingly not reported however in the 2009-ended CRA return for the CCDT at line C9, which stated that no expenses were incurred “for the compensation of employees during the [2009-ended] fiscal period” (CRA, “Charities Listings”, *supra* note 110). Therefore the amount of the severance pay remains unknown.

¹⁵⁹ Health Canada, Management Response and Action Plan (MRAP): Audit of the Management of Contribution Agreement with the Canadian Council for Donation and Transplantation and the Canadian Blood Services, (17 December 2009), online: HC <www.hc-sc.gc.ca/ahc-asc/pubs/_audit-verif/2009-22/mrap-rdpa-22-eng.php>.

government phase. To paraphrase what was said of Translink, to the extent that Health Canada may not have exercised 100% control over the CCDT, government control over the CCDT was shared with the CDM, which exercised much more extensive control over CCDT operations.¹⁶⁰ Together, these factors suggest that substantial government control was exercised over the CCDT's day-to-day activities, by both the CDM and Health Canada.

Based on these indicia, it seems that there was substantial governmental control over the CCDT. On one hand, the CCDT may not have been an agent of government, as was BC Transit, designated by legislation and subject to regulations governing its affairs. On the other hand, the CCDT appears to have been subject to sufficient governmental control to characterize it as a government entity, not unlike Translink in *Canadian Federation of Students*. Government appointment and removal of members, government ratification of CCDT plans and work products, government control over day-to-day activities, and the CCDT's seeming lack of an agenda independent of government all suggest that the CCDT may qualify as "government." Thus, the CCDT may satisfy the first branch of the *Eldridge* test, as a part of the "fabric of government," making all of the CCDT's activities subject to the *Charter*.

A recent Ontario lower court decision, *Canadian Blood Services v Freeman*, examined whether the *Charter* applied to the activities of the CBS, the organization that eventually took over the CCDT's mandate.¹⁶¹ *Freeman* involved an HIV-negative, homosexual man who argued that he had been discriminated against under section 15 of the *Charter* by being rejected as a potential blood donor. However, Mr. Freeman's argument failed when the court concluded that, based on a lack of governmental control over the CBS, the CBS was a private corporation to which the *Charter* was inapplicable.¹⁶²

Although there are similarities between the CBS and the CCDT,¹⁶³ CBS may be distinguished in several important respects from the CCDT. First, the

¹⁶⁰ *Canadian Federation of Students*, *supra* note 90 at para 20.

¹⁶¹ 2010 ONSC 4885, 217 CRR (2d) 153 [*Freeman*].

¹⁶² *Ibid* at para 343 (the critical factor was the lack of governmental control built into CBS' governance framework).

¹⁶³ *Ibid* at para 305. Both the CCDT and the CBS were independent non-profit organizations and charities which claimed to operate at arms' length to government. Both were created via FPT Memoranda of Understanding, and the government was the sole funding source. No enabling legislation was ever created for either organization, although for the CBS (but not the CCDT) such legislation

Freeman court emphasized the importance of the original *Memorandum of Understanding* which, from the beginning, created the CBS as a non-profit intended to operate at arm's length from government.¹⁶⁴ In contrast, the CCDT was first created as a government secretariat and was only years later converted to an "arm's length" non-profit, suggesting a more governmental history and character.

Second, *Freeman* emphasized that the ministerial right to remove CBS members was never exercised, implying that the requisite "government control" over the CBS was not in evidence: "Although there is a mechanism whereby the Ministers of Health ... can remove one or all of the [CBS] Board members, this has never happened."¹⁶⁵ In contrast, during the government phase, the CCDT Chair (and possibly some of the other directors) was re-considered for replacement by the CDM and the Chair was replaced, followed by government replacement of the entire CCDT with the CBS.

Third, evidence suggests that, unlike at the CBS, the "arm's length" relationship between government and the CCDT may have been flawed (e.g. by honorarium payments that reportedly raised independence concerns but which may have continued).¹⁶⁶ Fourth, the impugned act in *Freeman* was the application of an existing Health Canada screening policy, rejecting Mr. Freeman as a donor. The court concluded that, in rejecting him, the CBS was not "performing a particular government policy or program" sufficient to make CBS "government." In contrast, the impugned CCDT activity was the drafting of guidelines dangerous to some patients. That is, the CCDT did not simply mechanically apply an existing government instrument but created one at government direction, with government-specified subject matter, form, and results, to operationalize a government plan. This may be more likely to qualify as "performing a particular government policy or program." Taken together, these factors suggest that the CCDT had significantly greater governmental character than the CBS. In addition, it remains to be seen how the *Freeman* case may fare upon appeal.

was recommended. According to the court, the CBS' Board of Directors was staffed by provincial government ministers, while at the CCDT, this is not known to have been the case.

¹⁶⁴ Compare *ibid* at para 353.

¹⁶⁵ *Ibid*.

¹⁶⁶ See also *ibid* at para 371.

In 2010, a report by the Professional Institute of the Public Service Commission of Canada expressed concern over the vast scale of the federal government's contracting out services that could be "more effectively and cheaply provided in house," creating, in effect, a "shadow public service."¹⁶⁷ In line with this trend, the CCDT's non-profit status may have effectively disguised the governmental source of its brain death guidelines, while, in the process, perhaps enhancing their uptake.

2. Are the CCDT Guidelines "Government Activity"?

Were the preceding argument to fail, the CCDT guidelines might still attract *Charter* review by satisfying the second branch of the *Eldridge* test. By satisfying this branch, the CCDT guidelines, though not the CCDT's other activities, would constitute "government activity" for the purposes of the *Charter*. Such an argument might succeed, if an express delegation of governmental legislative authority to the CCDT can be identified. This possibility is explored below.

The second branch of the test laid out in *Eldridge* has been employed less often than the first and therefore offers fewer jurisprudential examples. Unfortunately, the Court in *Eldridge* provided few indicia to guide the identification of activities as governmental in nature.¹⁶⁸ A relatively recent case that proceeded on the basis of the second branch is *Sagen v Vancouver Olympic Organizing Committee for the 2010 Olympic and Paralympic Winter Games*.¹⁶⁹ In that case, the court found that an International Olympic Committee decision not to include women's ski jumping as an Olympic event, where the events were staged by the Vancouver Olympic Organizing Committee, was not a governmental activity to which the *Charter* applies.

In so finding, the court reiterated that performance of a public function is insufficient to bring an activity within the ambit of the *Charter*. Instead, the

¹⁶⁷ Professional Institute of the Public Service Commission of Canada, "The Shadow Public Service: Number of Outsourced Employees Explodes" (2010) 36:4 Communications Magazine, online: PIPSC <www.pipsc.ca/portal/page/portal/website/news/magazine/autumn2010/8>.

¹⁶⁸ However, the Court noted what would not identify such activity: "the mere fact that an entity performs a public function or that an activity may be described as public in nature will not be sufficient to bring it within the purview of government" (*Eldridge*, *supra* note 83 at para 43). Instead, governmental activity must involve carrying out a government policy or program.

¹⁶⁹ 2009 BCCA 522, 313 DLR (4th) 393.

Sagen court suggested that “it is necessary to look not only at the activities or function of the entity itself but also to the nature or function of the specific act or decision of the entity that is said to infringe a *Charter* right.”¹⁷⁰ On this basis, the Committee’s decision not to include women’s ski jumping did not qualify as government activity. Although the Vancouver Olympic Organizing Committee was a non-governmental body controlled in minute detail in its day-to-day activities, it was controlled by another private body, with no governmental influence over events or the practical staging of the events.¹⁷¹ To be said to engage in government activity, a body must be carrying out a government policy or program, and there must be evidence of, or the potential for, governmental control.

In comparison, the government funded the CCDT and delegated the authority to create OTDT guidelines through a *Memorandum of Understanding* and Letter of Agreement, the content of which may be deduced from other reports. The CCDT’s OTDT guideline creation activities (including brain death guideline revision) were specifically envisaged in the Standing Committee report, while OTDT-related guideline-creation was planned in the NCCOTDT blueprint. The CCDT’s nine-point mandate, drawn up under the Health Canada Contribution Agreement, included drafting practice guidelines and advising the CDM on the creation of guidelines, standards, and best practices for OTDT improvement.¹⁷² In addition, the CDM identified brain

¹⁷⁰ *Ibid* at para 49.

¹⁷¹ *Ibid* at paras 15, 45, 65.

¹⁷² According to the 2006 *Summative Evaluation*, *supra* note 3 at 12 [emphasis added]: “the CCDT Terms of Reference (June 7 2001) identified the following nine tasks:

1. Provide advice on a coordinated FPT strategy on organ and tissue donation and transplantation as well as advice on the development of high quality provincial/ territorial strategies;
2. Provide advice on, and a forum for, members to discuss opportunities for the *enhancement of standards, clinical practice guidelines and best practices*;
3. Provide a forum for members to discuss issues including: information sharing; provincial/ territorial initiatives related to donation and transplantation; and ethical issues related to donation and transplantation;
4. Consult with relevant health care organizations as required for the purposes of formulating advice only;
5. *Recommend practice guidelines based on an assessment of best practices*;

death determination guidelines as one of the CCDT's two priorities in the CCDT work-plan. The CDM and Health Canada appear to have significantly contributed to the resulting guidelines, both by participating at CCDT meetings and by approving the resulting guidelines. After dissemination, the CDM also maintained an interest in the guidelines' fate within Canada's medical community, requiring the CCDT to monitor guideline uptake.¹⁷³ These indicia suggest that the CCDT, in amending brain death guidelines pursuant to the CDM's instructions, carried out a government policy or program. As previously discussed, the CCDT was controlled in its day-to-day operations in minute detail by the CDM. The guidelines may, therefore, be found to qualify as "governmental activity."

In creating its guidelines, the CCDT exercised government powers delegated through the *Memorandum of Understanding*. The products of delegated governmental legislative activity may be subject to the *Charter*, as noted in *Dolphin Delivery*:

It would seem that the *Charter* would apply to many forms of delegated legislation, regulations, orders-in-council, possibly municipal bylaws, and bylaws and regulations of other creatures of Parliament and the Legislatures. It is not suggested that this list is exhaustive.¹⁷⁴

Thus the CCDT guidelines might be considered subordinate legislation, aiding in the interpretation of primary legislation.¹⁷⁵ Subordinate legislation

6. Provide advice on program and system linkages and interoperability with respect to: information management systems; and educational resources for interdisciplinary professionals involved in donation and transplantation processes;

7. Provide advice on social marketing strategies and their implementation;

8. Monitor, for the purposes of providing advice in accordance with its mandate only, the implementation of a FPT strategy and identify areas of emerging interests; and

9. Monitor, for the purposes of providing advice in accordance with its mandate only, donation and transplant outcomes, both quantitative and qualitative, measured against international and the Canadian experience; and on the outcomes of the FPT strategy, measured against target goals established by the provinces/territories."

¹⁷³ Summative Evaluation, *ibid* at 19.

¹⁷⁴ *Dolphin Delivery*, *supra* note 80 at para 39.

¹⁷⁵ See David Philip Jones & Anne S de Villars, *Principles of Administrative Law*, 5th

represents a growing segment of legislative activity, not all of which receives full Parliamentary scrutiny.¹⁷⁶ This has led some to comment that: “some legislative enactments should be regarded as so important that they should be debated openly in Parliament before enactment, [and] ... should not be contained in subordinate legislation.”¹⁷⁷ The CCDT guidelines add much-needed flesh to the bones of the provincial and territorial tissue gift statutes, by spelling out the procedures for death determination. Yet, when should such soft law, that is, guidelines and policies, be considered legislative activity or law for *Charter* purposes, and when should it be viewed merely as an administrative aid to statutory interpretation?

The question has received somewhat ambiguous Supreme Court treatment to date.¹⁷⁸ Much of the legislative/administrative distinction has turned on whether the soft law in question was binding in nature: legislative activity is indicated by binding guidelines, while administrative activity is suggested by voluntary guidelines. Based on this and other indicia, the Supreme Court in *Little Sisters* refused to recognize a manual of guidelines, used by Customs officers in decisions regarding allegedly obscene gay and lesbian artistic materials, as “law” for *Charter* remediation purposes. Instead, the Court

ed (Toronto: Carswell, 2009) at 104-05. Subordinate legislation may encompass: “ordinances, regulations, rules, codes, by-laws, ... directives and policies,” and “Parliament or a legislature may authorize virtually anyone to make subordinate legislation.” Conceivably, guidelines aiding in the interpretation of statutes, such as the CCDT guidelines, might also fit within this category (Jackson & Jackson, *supra* note 44 at 325). The authors note that “[d]elegated [or subordinate] legislation constitutes a large and ever-increasing proportion of all government legislative decisions.”

¹⁷⁶ *Ibid* (“an enormous volume of [subordinate] legislation (much of it technical) is ... not subjected to the full parliamentary legislative process” at 325).

¹⁷⁷ Jones & de Villars, *supra* note 175 at 108–09.

¹⁷⁸ See Gerald Heckman, “Judicial Review of Soft Law Instruments” (2010) 52 Sup Ct L Rev (2d) 52 at 56-57. As Heckman notes, in past SCC cases such as *Eldridge*, *supra* note 83 and *New Brunswick (Minister of Health and Community Services) v G(J)*, [1999] 3 SCR 46, 177 DLR (4th) 124 [*JG* cited to SCR], as well as *Canadian Federation of Students*, *supra* note 90 at para 72, such policies were held to be “law,” to which the *Charter* applied, while in other cases, such as *Little Sisters Book and Art Emporium v Canada (Minister of Justice)*, 2000 SCC 69, [2000] 2 SCR 1120 [*Little Sisters*], such soft law was deemed to be purely “administrative” guidance. Some authors question how meaningful a distinction there is between administrative policies and legislative policies having the same effect. See e.g. Gerald Heckman, “Judicial Review of Soft Law Instruments” (2010) 52 Sup Ct L Rev (2d) 52 at 57.

held these guidelines to be merely administrative aids for statutory interpretation.¹⁷⁹

Later, the Court in *Canadian Federation of Students* clarified that “non-law” administrative aids are those intended for internal use by a decision maker and are usually accessible only within the government entity applying them, rather than being made publicly available.¹⁸⁰ The Court noted that such guidelines are often informal in nature, requiring no express statutory authority for their creation, and are not intended to establish individual rights, obligations, or entitlements. Conversely, legislative government policies, authorized by statute, contain a general norm or standard intended to be binding, and are “sufficiently accessible and precise.”¹⁸¹

The CCDT guidelines exhibit features from both sides of the administrative/legislative dichotomy. First, although they assist in interpreting statutes, the CCDT guidelines were not authorized by statute, as the CCDT had no enabling statute. Any guideline-making authority appears to have been delegated by the *Memorandum of Understanding*. In addition, while the guidelines contain general norms and standards, they are voluntary, absent uptake by healthcare institutions capable of enforcing them. As noted above, the guidelines have been adopted by hospitals in Alberta and Atlantic Canada.

On the issue of sufficient accessibility and precision, the CCDT guidelines appear to be more precise than the vague comparative manual at issue in *Little Sisters*.¹⁸² They resemble, instead, the policies addressed in *Canadian Federation of Students*. Similar to administrative guidelines, however, the CCDT guidelines could be said to be employed for internal use or “indoor management” purposes. Unlike the administrative guidelines in *Little Sisters*, however, which were only used within the government agency that created them, the CCDT guidelines are used only outside the organization that created them, in healthcare settings.

In contrast to the guidelines in *Little Sisters*, the CCDT guidelines are available to the general public—either online via the CMA InfoBase or via government or through the published medical literature. This seems more

¹⁷⁹ *Little Sisters*, *ibid* at para 85.

¹⁸⁰ *Canadian Federation of Students*, *supra* note 90 at para 63.

¹⁸¹ *Ibid*.

¹⁸² *Little Sisters*, *supra* note 178 (the manual was described as “a rough and ready border screening procedure” at para 80).

akin to the situation in *Canadian Federation of Students*, where the guidelines were accessible to any member of the general public who cared to inquire. However, the argument that the CCDT guidelines are publicly accessible assumes that members of the public have sufficient knowledge of health-care and medical science to locate and understand the guidelines. In practice, these considerations limit the guidelines' public accessibility.

Finally, there is the question as to whether the CCDT guidelines establish individual rights, obligations or entitlements. Unlike purely administrative guidelines, the CCDT guidelines do not per se create patient rights but do have an effect on patients' rights and entitlements at a particular point in the biological continuum from birth to bodily decay. Upon a physician's declaration of a patient's death, the patient ceases to possess legal rights (e.g. to own property, make decisions), the patient's succession or estate opens, and the patient is thereafter considered simply a cadaver.¹⁸³ In Canada, the brain death guidelines that preceded those of the CCDT established a patient's legal rights as (potentially) extending to a later point in the biological continuum than under the CCDT guidelines. Arguably, the CCDT guidelines deal with individual rights, obligations or entitlements, establishing the point at which they divest within the biological continuum of functions, but it is not clear whether this will favour characterizing the guidelines as "law."

It remains for a reviewing court to decide how best to characterize the CCDT guidelines within the spectrum of governmental soft law activity. The implications for remedies of a finding that the guidelines are administrative rather than subordinate legislation or legislative rules is revisited in a later section.

Whether or not the guidelines can be shown to qualify as law remains in some doubt. However, it is probable that even if the CCDT itself cannot be shown to be governmental, the CCDT guidelines could qualify as government activity under the second branch of the *Eldridge* test, and attract *Charter* scrutiny. Additional support for the proposition that the CCDT guidelines constitute government activity may be derived from the federal government's recognition of the CCDT guidelines as Government of Canada publications. The federal government's electronic library of "current and archived Government of Canada publications," the Depository Services Program, lists the

¹⁸³ A human corpse is, however, accorded more respectful treatment than other inanimate matter.

CCDT guidelines and makes them “available to the Canadian public.”¹⁸⁴ Specifically, the *SBINDD* guidelines (created while the CCDT was a government body) and the *BBFNDD* guidelines (created while the CCDT was a non-profit) are listed as “Government of Canada Publications,” attributed to Health Canada.¹⁸⁵ This supports the characterization of the CCDT guidelines as government activity.

III. *Charter* Rights Infringements Under the CCDT Guidelines

A. *Are Charter Rights Infringed by the CCDT Guidelines?*

Having concluded that the CCDT guidelines are probably susceptible to *Charter* scrutiny, the next issue is whether the guidelines risk infringing *Charter* rights. Since the different versions of the guidelines interact and may be in use simultaneously, all invite discussion. A number of *Charter* rights may be infringed by the CCDT guidelines. For instance, the right to freedom of conscience and religion under section 2(a) may be infringed due to the lack of opportunities for expression of religious beliefs regarding the declaration of death under the guidelines.¹⁸⁶ There may also be an infringement of a patients’ section 12 right not to be subjected to cruel and unusual treatment or punishment, since some CCDT recommendations could lead to patients

¹⁸⁴ Government of Canada, “Terms Of Reference Of The Depository Services Program Library Advisory Committee (DSP-LAC)”, online: Depository Services Program <publications.gc.ca/site/eng/depositoryLibraries/dsp-lac/termsOfReference.html> (DSP acts as the Government of Canada’s information safety net, collecting current and archival government publications and making them widely available to the Canadian public).

¹⁸⁵ *SBINDD*, *supra* note 1, and *BBFNDD*, *supra* note 20, were identical in content to *SBINDD 2006*, *supra* note 21, and *BBFNDD 2008*, *supra* note 35, respectively, the latter two being published in academic journals. The DSP’s listing of *SBINDD* suggests that *SBINDD 2006* is also the product of government, based on the shared content. The DSP also lists several CCDT Annual Reports, including one written in late 2006, while the CCDT was a non-profit and charity, as “Government of Canada Publications,” adding weight to earlier arguments that the CCDT itself was government.

¹⁸⁶ See Samantha Weyrauch, “Acceptance of Whole-Brain Death Criteria for Determination of Death: A Comparative Analysis of the United States and Japan” (1999) 17:1 UCLA Pac Basin LJ 91 at 119-22 (for religious reasons, many traditional Buddhist, Shinto, and Confucian followers may not accept brain death as death, preferring a cardiopulmonary criterion).

with reversible conditions being declared dead and subjected to organ harvesting.¹⁸⁷

While any of the above arguments could potentially ground a *Charter* challenge to the guidelines, this paper will focus on the argument that aspects of the CCDT guidelines infringe section 7 of the *Charter*: the “right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with principles of fundamental justice.” Case law suggests that, for constitutional protection to be triggered under section 7, there must be governmental interference with an “interest of fundamental importance”¹⁸⁸ to an individual, generating a “serious and profound effect” on him.¹⁸⁹ To qualify as an infringement, state interference must also have occurred in a way that is inconsistent with the “principles of fundamental justice.” The procedural entitlements these principles might entail are discussed below.

In general, to trigger protection of the right to security of the person, there must have been a governmental restriction or compulsion of individual choices of a “fundamentally intimate and personal nature.”¹⁹⁰ As the Supreme Court ruled in *Blencoe v British Columbia (Human Rights Commission)*, a section 7 deprivation must affect more than mere reputation, dignity,

¹⁸⁷ It does not seem to be possible to advance an argument based on *Charter*, *supra* note 5, s 15 equality rights (e.g. of inter-regional equality) regarding the CCDT guidelines’ effects (e.g. the use of a brainstem criterion under the CCDT guidelines, versus use of a whole-brain criterion by those not adopting CCDT guidelines: see *SBINDD*). Here, the inequality (i.e. some patients being declared dead based on such factors as a brainstem criterion while others are declared dead using a whole-brain criterion) is “external” to the law itself, resulting from private activity by physicians or hospitals in choosing to adopt or reject the CCDT guidelines. This may preclude an argument that the guidelines deny equal legal benefit, protection, or equality before and under the law via s 15(1): “Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.” However, this inequality may contribute to the “manifest unfairness” of the CCDT guidelines’ operation, as discussed later.

¹⁸⁸ *Blencoe v British Columbia (Human Rights Commission)*, 2000 SCC 44 at para 82, [2000] 2 SCR 307 [*Blencoe*].

¹⁸⁹ *Ibid* at para 81.

¹⁹⁰ *Ibid* at para 83 (“It is only ... exceptional cases where the state interferes in profoundly intimate and personal choices that ... could trigger the s 7 security of the person interest”).

anxiety or stigma.¹⁹¹ Such deprivation may occur either through physical or psychological means, according to *Rodriguez v British Columbia (AG)*:

Section 7 is ... implicated when the State restricts individuals' security of the person by interfering with, or removing from them control over, their physical or mental integrity ... There is no question, then, that personal autonomy, ... control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person ...¹⁹²

Threats to security of the person may have a prospective quality. Mere exposure to, or the risk of, security of the person violations can trigger protection.¹⁹³ Nonetheless, David Mullan writes that there exists “a very narrow window of opportunity for operation of s.7,” in which “it will take very extreme circumstances to trigger s.7 protection through the security of the person route.”¹⁹⁴ So what then has qualified as an “extreme circumstance” sufficient to trigger security of the person protection in past jurisprudence? In *Morgentaler*, the Supreme Court held that requiring a woman to seek a (potentially non-existent) committee's permission to terminate her unwanted pregnancy constituted a profound interference with physical and psychological security of the person.¹⁹⁵ In the influential Ontario Court of Appeal deci-

¹⁹¹ *Ibid* at para 81.

¹⁹² According to the majority in *Rodriguez v British Columbia (AG)*, [1993] 3 SCR 519 at 588, 82 BCLR (2d) 273 [*Rodriguez*], quoting Justice Lamer's judgment in the earlier case of *Reference re ss 193 and 195.1(1)(c) of the Criminal Code (Man)*, [1990] 1 SCR 1123 at para 68, 4 WWR 481.

¹⁹³ See *Singh v Canada (Minister of Employment and Immigration)*, [1985] 1 SCR 177, 17 DLR (4th) 422 [*Singh* cited to SCR] (“‘security of the person’ must encompass freedom from the threat of physical punishment or suffering as well as freedom from such punishment itself” at 207). See also *R v Morgentaler*, [1988] 1 SCR 30, 44 DLR (4th) 385 [*Morgentaler* cited to SCR] (Justice Wilson reiterated the same view, clarifying that “... the fact of exposure [to the security of the person threat] is enough to violate security of the person” at 162).

¹⁹⁴ David J Mullan, *Administrative Law* (Toronto: Irwin Law, 2001) at 200-01.

¹⁹⁵ *Morgentaler*, *supra* note 193 at 56, 65. Chief Justice Dickson stated: “The case-law leads me to the conclusion that state interference with bodily integrity and serious state-imposed psychological stress, at least in the criminal law context, constitute a breach of security of the person. It is not necessary in this case to determine whether the right extends further, to protect ... interests unrelated to criminal justice” (*ibid*). Since *Morgentaler*, other SCC cases have revealed that state-imposed physical and psychological stress can also trigger s 7 security of the person protection in non-criminal contexts, e.g. in immigration, and child

sion in *Fleming v Reid*, forcing involuntarily admitted, mentally ill patients to endure unwanted psychoactive drugs contrary to their competent advance directives, was similarly found to infringe security of the person.¹⁹⁶ In *New Brunswick (Minister of Health and Community Services) v JG*, a state procedure brought against an unrepresented litigant, for her children's removal, was deemed by the Supreme Court a "gross intrusion" into parental autonomy, triggering protection for the parent's psychological security of the person rights.¹⁹⁷ Proceedings for the removal from Canada of individuals who face potentially life-threatening consequences have also triggered security of the person protection.¹⁹⁸

The government-created CCDT guidelines appear to generate significant state interference with the "fundamentally intimate and personal" interest of brain-injured patients in avoiding the premature declaration of death. Inevitably, the point at which death is declared has profound physical and psychological implications for a patient, and deep emotional, spiritual, and cultural ramifications for family and friends. A premature declaration of death therefore seems to have the requisite "serious and profound effect" on a patient by interfering with "interests of fundamental importance" to the patient. These interests include a patient's interest in not being subjected to physical or psy-

protection. As stated in *Blencoe*, *supra* note 188 at para 45: "there is no longer any doubt that s 7 of the *Charter* is not confined to the penal context."

¹⁹⁶ (1991), 82 DLR (4th) 298, 4 OR (3d) 74 (CA) [*Fleming* cited to DLR]. The court stated: "The common law right to bodily integrity and personal autonomy is so entrenched in traditions of our law as to be ranked as fundamental and deserving of the highest order of protection. Indeed, ... the common law right to determine what shall be done with one's own body and the constitutional right to security of the person, both of which are founded on the belief in the dignity and autonomy of each individual, can be treated as coextensive" (at 312). See also *Starson v Swayze*, 2003 SCC 32 at para 75, 1 SCR 722 (a majority of the SCC mentioned the *Fleming* result with some approval, stating: "The right to refuse unwanted medical treatment is fundamental to a person's dignity and autonomy").

¹⁹⁷ *JG*, *supra* note 178 at 78.

¹⁹⁸ See e.g. *United States of America v Burns*, 2001 SCC 7 at para 59, 1 SCR 283 [*Burns*] (state proceedings to extradite two individuals accused of murder to a country employing the death penalty were found to affect liberty and security of the person rights). See also *Suresh v Canada (Minister of Citizenship and Immigration)*, 2002 SCC 1 at para 129, 1 SCR 3 [*Suresh*] (the Court held that deporting a refugee to face a substantial risk of torture infringed his s 7 life, liberty and security of the person rights, subject to exceptions reflecting a need to balance this interest against concern for Canadian security).

chological suffering, in having his bodily integrity respected, and in retaining the legal status of a living member of the human community, at least for as long as those patients assessed under earlier guidelines. These important section 7 interests, with which the CCDT guidelines may interfere, exceed *Blencoe's de minimus* threshold.

Although numerous aspects of the CCDT guidelines may infringe patients' section 7 rights, only selected examples with serious potential effects will be discussed here in depth.¹⁹⁹ These examples are the CCDT's imposition of a brainstem criterion of death; the CCDT's change in the treatment of barbiturate-intoxicated patients; the simplification of testing for high-risk patients; and the removal of recommended wait times in testing. The first example makes it possible to declare some deaths significantly earlier than under previous brain death guidelines, while the other listed examples increase the risk of a premature, "false positive" declaration of death. All of these changes make it possible to systematically hasten the declaration of death, which is the point at which consenting donors become eligible for organ harvesting.

The brainstem criterion of death: The first concerning recommendation is the CCDT's imposition of a brainstem criterion of death. This requires that only the brainstem—that is, the lower part of the brain responsible for breath-

¹⁹⁹ Additional and no less significant section 7 concerns exist with other CCDT guideline recommendations. For instance, tests for brain death were originally divided into (non-technical) "clinical" and (technical) "supplemental" or "confirmatory" tests, the latter being in addition to the clinical tests. However, the CCDT guidelines have increased the reliance placed on non-clinical tests. *BBFNDD 2008*, *supra* note 35 states that ancillary testing is the response "required when there are factors confounding" assessment (at 143). In the past, with potentially transient confounding factors, the affected patient was not to be tested until the confounding factor had resolved or been corrected; this no longer appears to be required by the guidelines. While *BBFNDD 2008* reiterates that in brain death assessment "clinical criteria have primacy" (at 141), and that "[n]eurological determination of death remains principally and fundamentally a clinical determination" (at 143), it clarifies that "the term 'ancillary' should be understood as an alternative to the clinical determination, that otherwise, for any reason, cannot be conducted" (at 142). Since technical tests can now seemingly replace clinical tests for any reason, in theory, under very extreme circumstances, technical tests could become the sole criterion used to determine death. The CCDT also specified a particular type of brain blood flow testing, as discussed later in this paper.

ing,²⁰⁰ wakefulness²⁰¹ and certain other reflexes—need be shown to be permanently non-functional for brain death to be declared. Significantly, the CCDT’s criterion contains no requirement for non-functionality of the brain’s cortex, responsible for conscious awareness, voluntary movement, sensation (e.g. pain), and communication.²⁰² In contrast, the whole-brain criterion of death, recommended in Canadian guidelines since 1968, requires that not only the brainstem, but also the cortex, be shown to be permanently non-functional. Thus, the brainstem criterion requires demonstration of far less brain damage before death may be declared. Accordingly, under a brainstem criterion, some deaths could be declared considerably earlier than under a whole-brain criterion.²⁰³

All versions of the CCDT guidelines recommend a brainstem death criterion. In *SBINDD 2006*, this was phrased as “the irreversible loss of the capacity for consciousness combined with the irreversible loss of all brainstem functions ... including the capacity to breathe.”²⁰⁴ This may be interpreted as producing a brainstem criterion because consciousness is understood to comprise two components: wakefulness (controlled by a functioning brainstem)

²⁰⁰ See Allan Siegel & Hreday N Sapru, *Essential Neuroscience* (New York: Lippincott Williams & Wilkins, 2006) at 403 (the “pre-Bötzing complex” within the ventral respiratory group of neurons of the brainstem is the structure thought to trigger breathing rhythms).

²⁰¹ See S Laureys et al, “Coma” in Robert Stickgold & Matthew Walker, eds, *The Neuroscience of Sleep*, (London: Academic Press, 2009) 146 (“Consciousness is a multifaceted concept that has two dimensions: arousal or wakefulness (i.e., the level of consciousness), and awareness (i.e., the content of consciousness)” at 146).

²⁰² See MF Bear, BW Connors & MA Paradiso, *Neuroscience: Exploring the Brain*, 3d ed (New York: Lippincott, Williams & Wilkins, 2007) at 185.

²⁰³ See *Singh*, *supra* note 193 at 207 (the mere risk of exposure to security of the person threats may be sufficient for *Charter* protection). See also the reasons of Wilson J in *Morgentaler*, *supra* note 193 at 162. How much earlier death could be declared would depend on the nature of the patient’s other injuries and the life support (e.g. ventilator support) provided to him. However, potentially, if damage to the cortex (and to the patient’s body) are nil or minimal, but the brainstem is totally destroyed, the patient could seemingly be declared dead months to years earlier under a brainstem criterion than under a whole-brain criterion.

²⁰⁴ *Supra* note 21 at S3. In contrast, the “whole-brain” death criterion requires permanent loss of function of the entire brain including, but not limited to, the brainstem.

and awareness (generated by a functioning cortex).²⁰⁵ Thus, the “irreversible loss of the capacity for consciousness” may be the product of either loss of cortical function (loss of “awareness”) or loss of brainstem function (loss of “wakefulness”). Under the CCDT guidelines, the minimum brain damage that may prompt a declaration of death is brainstem destruction.

SBINDD 2006 adds the confirmatory detail that “spinal reflexes and motor responses confined to spinal distribution may persist” in brain death.²⁰⁶ Here, the words “motor responses” can refer neither to spinal motor reflexes (since these are mentioned separately), nor to brainstem motor reflexes (since the brainstem must be dead), and must, it seems, therefore refer to *cortical* motor responses. Thus, voluntary motor activity, generated by the cortex and affecting spinal distribution—that is, affecting the entire body—is allowed to persist in the CCDT’s version of brain death, indicating a brainstem criterion of death. Notably, *BBFNDD*’s definition of neurological death contains no details regarding the presence or absence of cortical function, also indicating that it refers to a brainstem death criterion.

CCDT authors have confirmed in medical literature that a brainstem criterion was the intended result.²⁰⁷ Since all CCDT guideline versions recommend a brainstem criterion, and since the CCDT reportedly did an effective job of achieving some informal adoption of the guidelines well before their journal publication, a brainstem criterion may be in some use in Canada. Although the guidelines’ adoption was described by 2006 as only “checkerboard,”²⁰⁸ this in itself suggests a potential for serious unfairness in brain

²⁰⁵ See Laureys et al, *supra* note 201 at 146.

²⁰⁶ *Supra* note 21 at S2.

²⁰⁷ See G Bryan Young et al, “Brief Review: The Role of Ancillary Tests in the Neurological Determination of Death” (2006) 53:6 Can J Anaesth 620 at 622. “In Canada we accept the clinical criteria for brain death (essentially brainstem death) ... [a]ll of the clinical criteria for brain death are met with irreversible, total destruction of the brainstem. This is confirmed in the recently adopted [CCDT] Canadian guidelines for the neurological determination of death” (*ibid* at 620-21). Misleadingly, elsewhere, the CCDT has claimed that Canada’s brain death criterion is an amalgam of both whole-brain and brainstem criteria. For instance, *BBFNDD* argues that the CCDT definition of brain death “include[s] both the whole brain death concepts as well as ... brainstem death” (*supra* note 20 at 6). Compare *SBINDD*, *supra* note 1 at 30: “Distinctions between brainstem death and whole-brain death are unclear in Canada.”

²⁰⁸ Wayne Kondro, “Fragmented Organ Donation Programs Hinder Progress” (2006) 175 Can Med Assoc J 1043 at 1044 [Kondro, “Fragmented Organ Donation”].

death declaration, since some regions of Canada may use a brainstem criterion, while others retain a whole-brain criterion.

To date, only the UK has employed a brainstem criterion of death. Almost all other nations employ a whole-brain criterion. Brain death expert James Bernat has clarified the reason the US President's Commission (of which he was a co-author) rejected brainstem death:

the brainstem formulation [of death] does not require commensurate damage to the [cortex]. It therefore leaves open the possibility of misdiagnosis of death because of a pathological process that appears to destroy brainstem activities but that permits some form of residual conscious awareness that cannot easily be detected. It thus lacks the fail-safe feature of whole-brain death.²⁰⁹

In other words, in Bernat's view, and as noted by the CCDT in a literature review it provided to *SBINDD* participants, under a brainstem criterion there remains a possibility that a patient declared brainstem-dead might only be in a "super locked-in" state.²¹⁰ Such a patient would be totally paralyzed and unable to communicate but, due to a functional cortex, might still possess "some form of residual conscious awareness."

The concept of a super locked-in state is a slightly more extreme form of the well-known neurological diagnosis, the "locked-in state."²¹¹ Patients who are locked-in—such as Jean-Dominique Bauby, the author of *The Diving Bell and the Butterfly*²¹²—are almost totally paralyzed due to brainstem damage, except for some residual voluntary movement, usually involving the eyes.²¹³ If known to caregivers, this movement ability can allow the affected patient to communicate, by blinking, for example. Due to a functional cortex, locked-in patients can experience normal cortical functions, including cogni-

²⁰⁹ James L. Bernat, "The Whole-Brain Concept of Death Remains Optimal Public Policy" (2006) 34 *JL Med & Ethics* 35 at 39.

²¹⁰ CCDT, *Literature Review Brain Death*, *supra* note 15 at 6.

²¹¹ Also termed "cerebromedullospinal disconnection."

²¹² Jean-Dominique Bauby, *The Diving-Bell and the Butterfly*, translated by Jeremy Leggatt (London: Harper Perennial, 2008).

²¹³ The anterior part of the pons is the brainstem structure damaged in locked-in syndrome.

tion and pain-sensitivity.²¹⁴ In Bernat's predicted super locked-in state, such a patient would experience a total paralysis of voluntary movement.

While the CCDT has argued that a super locked-in state can be discounted as a purely theoretical construct,²¹⁵ evidence suggests otherwise.²¹⁶ Among ordinary locked-in patients, residual movement abilities may fade over time, eventually creating the total paralysis of a super locked-in state.²¹⁷ If such paralysis occurs in a severe brainstem injury, the patient may be rendered unconscious and unable to breathe, permitting a diagnosis of brainstem death. Yet, while the brainstem injury may eliminate the patient's wakefulness, rendering him unconscious, without cortical destruction, it may not eliminate his awareness (e.g. of pain).²¹⁸ Such a patient, with an intact cortex, could be aware and sensate, though unconscious and paralyzed. Reportedly, some brainstem-dead patients may display cardiovascular and hormonal

²¹⁴ See Peter McCullagh, *Conscious in a Vegetative State? A Critique of the PVS Concept* (London: Kluwer Academic Publishers, 2004) at 6.

²¹⁵ CCDT, *Literature Review Brain Death*, *supra* note 15 at 7.

²¹⁶ McCullagh, *supra* note 214 at 156. The CCDT's claim is contradicted by McCullagh's reference to a 1979 study, which identified 12 patients in a super locked-in state (termed a "total locked-in" state by McCullagh, describing the same state of complete paralysis) (*ibid*). McCullagh also argues that even the incompletely paralyzed "locked-in" syndrome is challenging to diagnose, being easily mistaken for the (unconscious) persistent vegetative state (at 157). See also Damian Cruse et al, "Bedside Detection of Awareness in the Vegetative State: A Cohort Study" (2011) 378 *Lancet* 2088 (among vegetative state patients previously understood to be permanently lacking awareness (and intermittently awake), 19% were actually found to be aware and responsive to verbal instructions, and thus possibly locked in, rather than in a persistent vegetative state). In addition, numerous reports exist of conscious, locked-in patients having been misdiagnosed for years as persistent vegetative state patients. See "Julia Tavalara, 68: Poet and Author Noted for Defying Severe Paralysis", *Los Angeles Times* (21 December 2003), online: Los Angeles Times <articles.latimes.com>; Kate Connolly, "Trapped In His Own Body for 23 years—the Coma Victim who Screamed Unheard", *The Guardian* (23 November 2009), online: Guardian Unlimited <www.guardian.co.uk>. Therefore, it would seem entirely possible for super locked-in patients, if they exist, to be similarly misdiagnosed.

²¹⁷ See McCullagh, *supra* note 214 at 157.

²¹⁸ Since, as noted earlier, "consciousness" comprises both "wakefulness," due to the brainstem's reticular ascending activating system, and "awareness," due to the cortex, a human being may lose consciousness through damage to either (or both) structures, causing loss of either (or both) of these two components of consciousness.

stress responses suggestive of pain during unanaesthetised organ harvesting; however, this remains unsettled.²¹⁹ The possibility that a patient with a destroyed brainstem might simply be in a super locked-in state may therefore not be an easily discounted theoretical concern. In fact, the CCDT appears to acknowledge this state as a realistic possibility in *BBFNDD*'s fifth recommendation, which seems to imply that such patients cannot be declared neurologically dead.²²⁰ It is not clear that Canadians would welcome the CCDT's sudden shift to a brainstem criterion of death. According to a 2005 CCDT survey, 71% of Canada's public does not believe that "whole brain-dead" patients are truly dead, so as many Canadians might object to the more radical brainstem criterion's application to themselves or their loved ones.²²¹ It is unclear whether a causal relationship exists between the belief that brain death is not death and chronically low Canadian organ donor rates.²²² If one exists,

²¹⁹ See Shewmon, *supra* note 2 at 139; Mohamed M Ghoneim, ed, *Awareness During Anesthesia*, (Oxford: Butterworth Heinemann Boston, 2001) at 78 (in surgery on living patients, changes in heart rate, blood pressure, sweating or tear production are considered by some to signal when a patient is inadequately anesthetized and aware of pain, despite being unconscious (i.e. non-wakeful)); P J Young & B F Matta, "Anaesthesia for Organ Donation in the Brainstem-Dead—Why Bother?" (2000) 55 *Anaesthesia* 105 at 106 (however, it is not known whether similar observations during organ harvest in some brainstem-dead donors might indicate pain. Some authors therefore recommend anaesthesia for brainstem-dead donors out of caution); B Poulton & M Garfield, "The Implications of Anaesthetizing the Brainstem Dead" (2000) 55 *Anaesthesia* 695 (the authors suggest that the practice of anaesthetizing the brainstem-dead remains controversial).

²²⁰ *Supra* note 20 at 6. A "key consideration" in Recommendation 5 is that "[in] cases of complete and irreversible loss of brainstem function due to mechanisms other than terminal elevation of intracranial pressure [e.g. brainstem stroke], ... brain blood flow to [cortical] regions may be present thus negating the determination of death by neurological criteria" (*ibid*). This passage recognizes that, in some cases of brainstem destruction, brain blood flow to the cortex may continue to maintain cortical neural function. Such "complete" brainstem damage, including the pons, could generate a "locked-in" or "super locked-in" state, in which the patient's cortical functions (e.g. pain awareness) could be normal. Significantly, Recommendation 5 acknowledges that such a patient should not be declared brain-dead, despite satisfying all elements of *BBFNDD*'s definition of neurological death.

²²¹ See CCDT, *Public Awareness Report*, *supra* note 46 at 8, 33.

²²² *Ibid*. This 2005 CCDT public survey suggested public suspicion (among 71% of those surveyed) that brain death is not actually death, and (in 22%) that organs may be acquired through premature brain death declaration. The possible link between the significant level of disbelief in brain death as death and low organ

were the public to learn of the CCDT's shift to a criterion that permits earlier declaration of death, low donation rates might be further depressed.

The CCDT's recommendation of a brainstem death criterion marks a major shift from the whole-brain criterion, employed since 1968, and stands in stark contrast to the incremental changes made to Canada's brain death guidelines in preceding decades. It would be illuminating to know why the CCDT felt that a brainstem criterion, which has been adopted by only one other nation, was justifiable. The CCDT provided no satisfactory explanation, leaving room only for speculation.²²³ In a 2003 literature review preceding the guidelines, the CCDT merely claimed that "the similarities between the two models of [brain death] determination [i.e. the brainstem and whole-brain criteria] appear more striking than the differences."²²⁴ This implies that the functions of the human cortex—associated with consciousness, thought, voluntary actions, pain perception, memory, and personality—are of negligible importance in assessing the life of a human being. Some Canadians might disagree.

Certain concerns raised in this paper were mentioned by the CCDT prior to its creation of the guidelines, though they were not resolved. For instance, in 2003, the CCDT noted the need to correct, exclude, or wait for confounding factors to dissipate before declaring death.²²⁵ It recommended, however,

donor rates was not explored. If such a link exists, this may mean that major alterations in how early brain death can be declared could, if discovered, further weaken public trust in both declarations of brain death and the ethics of organ procurement, thereby reducing donation rates.

²²³ See CCDT, *Literature Review Brain Death*, *supra* note 15 at 7. One hint may lie in the CCDT's quoting of brain-death architect James Bernat: "the criteria for brain death may ultimately move in the direction of accepting a brainstem formulation [of death] ... this shift in criteria might be facilitated by the development of new medical technologies capable of isolating brainstem activities." The quotation was not supported by a citation, making it difficult to verify. However, Bernat's other writings staunchly defended the whole-brain criterion, based on the concern regarding detecting super locked-in patients. This suggests that Bernat's comment regarding a future change in criterion was probably contingent on the development of technologies able to make this distinction, —which has not occurred to date.

²²⁴ *Ibid* at 25.

²²⁵ *Ibid* at 16-17. Regarding hypothermia or drug intoxication, the CCDT noted that "[c]onfounding clinical conditions such as hypothermia, drug intoxication or drug therapy must be either treated, excluded or allowed to dissipate before [neurological determination of death]" (CCDT, *Executive Summary: A Review of the Literature on the Determination of Brain Death* (Edmonton: CCDT, 2003),

proceeding despite these factors.²²⁶ In addition, in *BBFNDD*, the CCDT appeared to acknowledge the potential for inappropriately declaring dead a patient with an isolated brainstem injury. Despite this potential, the CCDT did not withdraw its earlier support for a brainstem criterion. It gave no reasons for proceeding despite such concerns.

Another CCDT claim was that, unlike the CCDT guidelines,²²⁷ previous brain death guidelines had not been evidence-based.²²⁸ This claim is disingenuous, however, as the evidence must be able to demonstrate that particular brain death guidelines are effective (i.e. they incorrectly declare few dead patients to be “alive”) and safe (i.e. they declare as “dead” only those who are dead). Such evidence is extremely elusive. In terms of objective data, only two relatively small studies exist correlating brain death with cardiac death.²²⁹ Thus the CCDT guidelines are no more evidence-based than earlier guidelines; in fact, they are arguably less so, since they conflict with well-

online: CCDT <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Brain-Death-Short-Lit-Review.pdf> [CCDT, *Short Review*]. Nonetheless, that same year, *SBINDD* allowed brain death testing without requiring confounding conditions to be treated, excluded or to dissipate, as long as a technological test is done, to compensate for the confounder’s interference with clinical testing.

²²⁶ See *SBINDD 2006*, *supra* note 21 at Recommendation A6 (it recommended performing a technical test in such cases, but these tests might be affected by the confounding variable too).

²²⁷ See CCDT, *Short Review*, *supra* note 225 at 3 (“A key objective of the [*SBINDD*] forum ... is to develop an evidence-based, ‘made-in-Canada’ guideline for the diagnosis of brain death”).

²²⁸ *Ibid* at 4-6 lists areas where evidence is lacking: “there is no literature to suggest evidence that evaluation by two physicians is preferable or superior to that of a single clinician”; “a literature review could not establish a firm basis for recommended [wait] interval times”; “there is no scientific corroboration for [a 24-hour wait period between tests in hypoxic-ischemic brain injuries]”; “no evidence-based source for any particular temperature threshold recommendation could be identified”; “there is little if any evidence to support many of the age-related recommendations.” See also *SBINDD*, *supra* note 1 at 7: “the current evidence base for the [earlier] [brain death] guidelines is inadequate.”

²²⁹ See National Institutes of Neurological and Communicative Disorders and Stroke, “An Appraisal of the Criteria of Cerebral Death” (1977) 237 *JAMA* 982-86; US President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (Washington, DC: Government Printing Office, 1981).

established scientific evidence regarding confounding factors, as discussed below.

With no completely satisfactory explanation being put forth, it is unclear why the CCDT felt that the move to a brainstem criterion was appropriate. The fact remains that the brainstem criterion makes it possible to declare brain death in a patient potentially weeks, or more, sooner than under a whole-brain criterion. By making many more organs available sooner, and in a more transplantable state, the brainstem criterion would have offered greater potential for CCDT targets to be achieved. While unpalatable, this explanation satisfies Occam's razor as the simplest hypothesis consistent with known information.

A brainstem criterion could declare dead some patients who are only super locked-in. With damaged brainstems, but intact cortices, such patients might retain pain-awareness, but could be declared brain-dead under CCDT standards, making them eligible for (unanaesthetised) organ harvesting. The CCDT's recommendation of a brainstem criterion may therefore infringe patients' rights to life and to physical and psychological security of the person.²³⁰

Barbiturate-affected patients: The second concern involves two aspects of the CCDT's brain death assessment of barbiturate-intoxicated patients. In earlier guidelines, barbiturate intoxication at any dosage was considered a confounder (i.e. a factor preventing an accurate diagnosis of brain death) requiring postponement of brain death testing. This was due to the potential for barbiturate intoxication to mimic brain death in several ways: barbiturate intoxication may result in coma, blunted neurological responses, and extremely shallow breathing, although these symptoms may be completely reversible with the passage of time. Under earlier guidelines, developed since 1968, a lengthy wait period (potentially of several days) was required for barbiturate clearance from the patient's system, before attempting a brain death assessment.²³¹

²³⁰ See Sam Shemie et al, "Organ Donor Management in Canada: Recommendations of the Forum of Medical Management to Optimize Donor Organ Potential" (2006) 174:6 Can Med Assoc J S13 (the CCDT's 2006 companion practice guideline on organ donor management—"Medical Management for Donor Organ Potential"—does not recommend anesthesia in organ harvesting).

²³¹ See Canadian Congress of Neurological Sciences, *A CMA Position: Guidelines for the Diagnosis of Brain Death* (1987) 136:2 Can Med Assoc J 200A at 200B (for

The CCDT recommendation in *SBINDD* appears to retain the classification of barbiturates as a confounder to be avoided at higher doses (i.e. in “significant intoxications”), but it abandons it at the lower (i.e. “therapeutic”) dosages of “anti-convulsants, sedatives, and analgesics.”²³² Clinically, barbiturates are used as all three.²³³ This recommendation implies that lower barbiturate doses will no longer be considered to confound brain death diagnosis. Adding confusion, elsewhere in *SBINDD*, a “Key Consideration” suggests that, even at higher dosages, barbiturate intoxication may no longer confound brain death declaration, as long as brain blood flow is tested.²³⁴

Problems exist with the recommendation that patients with low, therapeutic dosages of barbiturates be treated differently than those given high dosages. First, with barbiturates, specifically, there may be difficulty in defining what constitutes a therapeutic dose. As drugs, barbiturates have a particularly narrow therapeutic-to-toxic ratio, meaning that the dosage difference between a therapeutic dose and a life-threatening overdose may be small.²³⁵ The relative effect of any barbiturate also depends on the particular barbiturate, on other drugs in the patient’s system, on the patient’s age and size, and on concurrent medical conditions, making characterization of a therapeutic dose a highly individual matter.²³⁶

The level of barbiturate (and other interacting drugs) in a patient’s system may also be unknown. While the abuse of barbiturates as recreational drugs has declined in recent decades, it may be making a comeback among

example, the 1987 “Guidelines for the diagnosis of brain death” specify that “[d]rug intoxication (particularly of barbiturates, sedatives and hypnotics) ... must be excluded” for the brain’s loss of function to be considered irreversible).

²³² *SBINDD 2006*, *supra* note 21 at S3, Recommendation A7.

²³³ See R M Schears, “Barbiturates” in Judith Tintinalli et al, eds, *Tintinalli’s Emergency Medicine: A Comprehensive Study Guide* (New York: McGraw-Hill, 2011) at Introduction.

²³⁴ *Supra* note 1 at 14 (a “Key Consideration” in Recommendation A.6 states: “Existing evidence, although not firmly established, suggests that ... under the circumstances of high dose barbiturate therapy ... brain death can be confirmed by the demonstration of absent intracranial blood flow”).

²³⁵ Also termed its “therapeutic index” or “therapeutic ratio.” See Susan Coupey, “Barbiturates” (1997) 18:8 *Pediatrics in Review* 260 (“Barbiturates are dangerous drugs with a narrow therapeutic index between the dose required for sedation and the dose that will cause coma and death” at 260).

²³⁶ Schears, *supra* note 233 at Pharmacology.

younger substance abusers.²³⁷ Reportedly, some may use barbiturates in combination with (or to mask symptoms of) simultaneous stimulant use.²³⁸ Barbiturates have also been taken in overdose by suicidal individuals, producing an unknown dosage in the patient's system. These factors can make it difficult to determine what dosage of barbiturates exists in a given patient.

This CCDT recommendation is also noteworthy in the context of brain death testing, since barbiturates are commonly used therapeutically (but in high doses) to treat traumatic brain injury, induce therapeutic coma, lower brain metabolism, protect brain tissues from hypoxic damage, and reduce intracranial pressure.²³⁹ Such usage blurs the distinction between higher doses and therapeutic doses. This CCDT recommendation might therefore affect a significant proportion of traumatic brain injury patients assessed for brain death.

SBINDD's recommendations regarding barbiturates are also troubling because, by permitting testing while this confounder is present, a physician may mistakenly and prematurely declare a patient dead. *BBFNDD* added a further change: it not only permitted testing high-dose barbiturate patients, but it also simplified the brain death assessment process for these patients. *BBFNDD*'s Recommendation 9 stipulates that, if a barbiturate-treated patient has a flat electroencephalogram (EEG) trace, no apnoea test of breathing is required, unless "there is uncertainty surrounding the depth or level of barbiturate-induced coma."²⁴⁰ However, it is only by means of an apnoea test that "uncertainty"²⁴¹ regarding the depth of a patient's coma can be identified, in-

²³⁷ Coupey, *supra* note 235 at 260.

²³⁸ *Ibid.*

²³⁹ See Mary Ann Liebert, "The Use of Barbiturates in the Control of Intracranial Hypertension" (1996) 13:11 *Journal of Neurotrauma* 711 at 711. But see J C Orban & C Ichai, "Hierarchical Strategy for Treating Elevated Intracranial Pressure in Severe Traumatic Brain Injury" (2007) 26 *Annales françaises d'anesthésie et de réanimation* 440 at 440 (some now argue that barbiturates are not the optimal treatment for raised intracranial pressure).

²⁴⁰ See *BBFNDD*, *supra* note 20 at 8.

²⁴¹ Comatose patients' symptoms may outwardly appear somewhat similar. Apnoea testing is therefore essential to determining whether a patient's coma is so profound that the Pre-Bötzinger complex within the brainstem is totally non-functional, qualifying the patient as being (at least) brainstem-dead. Recommendation 9 omits the one vital test by which to assess this (*ibid.*).

roducing the element of a Catch-22 into the recommendation.²⁴²

This change in the treatment of barbiturate patients also conflicts with the repeated CCDT assertion, in both *BBFNDD* and *SBINDD*, that EEG is an unreliable indicator of brain death.²⁴³ It is known that barbiturate treatment of brain injuries, specifically, may temporarily produce a flat-line EEG,²⁴⁴ broadening Recommendation 9's application. Recommendation 9 also contradicts the earlier *SBINDD 2006* "Key Consideration" that in high-dose barbiturate patients, a brain blood flow test is required for death declaration. An EEG tests brain electrical activity, rather than brain blood flow.²⁴⁵

²⁴²In Recommendation 9, the default rule is that all flat-EEG, high-barbiturate patients are exempt from apnea testing unless the precondition of uncertainty regarding coma depth is present. The Recommendation incorrectly implies that some certainty of brain death exists in most flat-EEG, high-barbiturate patients. However, uncertainty as to coma depth (i.e. uncertainty as to whether a coma is so deep it qualifies as brain death) can only be established by doing an apnea test, since this test is the only way to establish whether brainstem breathing reflexes persist. Because uncertainty actually exists, an apnea test should always be done in these patients, yet this approach would render Recommendation 9 meaningless. If physicians do not know there is any uncertainty, the default rule of no apnea testing will operate automatically, so that uncertainty about coma depth is never established and so on. By creating a requirement to justify testing, instead of a requirement to test, Recommendation 9 effectively ensures that flat-EEG, high-barbiturate patient will not have to undergo apnea testing.

²⁴³*Ibid* at 1. These same guidelines advise that EEG is "no longer supported" as a reliable indicator of brain death. The CCDT recommendation against reliance on EEG appears in *SBINDD*, *supra* note 1 at 32, 35, 37. CCDT co-authors state that the EEG "is vulnerable to confounders" and "may be flat or iso-electric in massive barbiturate overdose or deep anesthesia, conditions that are completely reversible. Thus there is a "double dissociation" in that EEG activity may be absent without brain death, either from surviving sub-cortical neurons or completely reversible conditions (false positives) and ... present in patients who meet the criteria for brain death (false negatives) ... At best EEG is mildly confirmatory [of brain death], at worst it is misleading or irrelevant." (Young et al, *supra* note 207 at 622. See also *SBINDD 2006*, *supra* note 21 at S9 (regarding the confounders: "The EEG is significantly affected by hypothermia, drug administration, and metabolic disturbances, thus diminishing its clinical utility").

²⁴⁴See David D'Argenio, *Advanced Methods of Pharmacokinetic and Pharmacodynamic Systems*, vol 1 (New York: Plenum Press, 1991) at 80-81.

²⁴⁵Yet even were a brain blood flow test required, this test too could be confounded by barbiturates. Brain blood flow (as measured by the proxy of brain glucose metabolism) may be reduced by 47%-67% by barbiturates. See McCullagh, *supra*

In *BBFNDD*, the CCDT effectively recommends replacing evidence from a reliable but time-consuming clinical test (the apnoea test) with a technological test (the EEG) that the CCDT itself repeatedly declares unreliable. Significantly, no prior set of Canadian guidelines has created exemptions from apnoea testing,²⁴⁶ since this test is an important indicator of brainstem reflex functioning. This functioning is acknowledged by the CCDT as an essential component of *BBFNDD*'s definition of death.²⁴⁷ Omitting the apnoea test leaves no way to assess breathing function. The CCDT's simplified assessment carries a risk of premature declaration of death, as patients may simply be suffering from reversible barbiturate reactions.²⁴⁸ This CCDT change may therefore again infringe patients' section 7 rights to life and security of the person.

“High-risk” patients: Another CCDT recommendation specifically targets the most vulnerable brain-injured patients. According to *BBFNDD*'s Recommendation 8,²⁴⁹ patients at “excessive risk” of death due to their hemodynamic or respiratory instability warrant different treatment in testing. As with the concern detailed above, this treatment involves a simplified test that omits apnoea testing. Specifically, Recommendation 8 advises replacing the apnoea test with an ancillary test²⁵⁰ for brain blood flow—CT angiography—if

note 214 at 122.

²⁴⁶ Recommendation 8 in *BBFNDD*, *supra* note 20 at 8 also recommended omission of apnoea testing for one other patient group, patients who are extremely frail and unstable in terms of their respiratory or hemodynamic status.

²⁴⁷ *Ibid* at 11.

²⁴⁸ This guideline therefore creates a significant risk of false positive diagnoses of brain death. Barbiturates may produce reversible symptoms, much like brain death: respiratory depression, central nervous system depression, reduced cardiac output, and lack of temperature regulation, resulting in a cold, apnoeic patient with low blood pressure, who appears neurologically unresponsive (Schears, *supra* note 233 at Clinical Features, Treatment).

²⁴⁹ *BBFNDD 2008*, *supra* note 35 at 144.

²⁵⁰ The CCDT favoured a particular type of ancillary test assessing “brain blood flow” to brain tissues. There are two possible such tests: tests which record the flow of blood in major blood vessels within the brain (i.e. CT and 4-vessel angiography) and tests of actual “perfusion” of brain tissues with blood (HMPAO or radionuclide scintigraphy). Although in theory, both tests should assess how much blood continues to nourish brain tissues, in reality, brain perfusion tests are more sensitive at detecting whether viable brain tissue actually remains. This is because even when the (tested) major blood vessels are devoid of blood flow, some flow may persist through abnormal blood vessel connections (“collateral linkages”) in

the declaring physician believes the apnoea test poses “excessive risk” due to a patient’s respiratory or hemodynamic instability. There are several problems with this. One problem is that the brain blood flow testing through CT angiography could itself pose a risk of causing death in patients. Brain blood flow testing, using CT angiography as the CCDT recommends, involves injected contrast chemicals that may damage organs, possibly triggering an unstable patient’s death.²⁵¹

Yet brain blood flow tests cannot substitute for apnoea testing. As noted earlier, apnoea testing is the only way to test a key element of (either brainstem or whole-brain) death: the brainstem’s breathing reflex.²⁵² If a decision has been made to assess an unstable patient for brain death, his instability

the brain, continuing to nourish brain tissues. “The presence of tissue perfusion/uptake in the absence of demonstrable brain blood flow may arise in the remote circumstance of unexpected collateral blood flow, or flow detection below the lower limits of [the CT angiography] test” (see *BBFNDD*, *supra* note 20 at 3). CT angiography also poses some risks of tissue damage due to contrast media, while scintigraphy poses no comparable risks. See Manraj K S Heran, Navraj S Heran & Sam D Shemie, “A Review of Ancillary Tests in Evaluating Brain Death” (2008) 35 *Can J Neurol Sci* 409 at 414. While the CCDT states that CT angiography and scintigraphy are “rated equally,” elsewhere it makes clear that CT angiography, the less sensitive and more damaging test for viable brain tissue, is given priority (*BBFNDD*, *supra* note 20 at 4). Without explanation, the CCDT states that: “CT angiography is recommended as a preferred test” (*ibid*). This point was directly contradicted by a CCDT-commissioned paper to which *BBFNDD* specifically refers readers for guidance (*ibid*), which concluded that: “[Among] the preferred ancillary [tests], ... HMPAO ... radionuclide angiography [is] considered the first-line study. When this is not available or is equivocal, 4-vessel angiography ... can be performed” (Manraj Kanwal Singh Heran & Navraj Singh Heran, “Potential Ancillary Tests in the Evaluation of Brain Death: The Value of Cerebral Blood Flow Assessment” (10 October 2006) at 11, online: Canadian Blood Services <www.organsandtissues.ca/s/wp-content/uploads/2011/11/Potential-Ancillary-Tests.pdf>). Similarly, CCDT forum Chair Sam Shemie and the above authors stated in another paper that: “[o]ther options [than CT angiography] are preferred,” for reasons of patient safety in testing and transportation, expertise, cost and availability (Heran, Heran & Shemie at 414). Thus, *BBFNDD* preferentially recommends use of the less sensitive, more indirect and more harmful procedure for assessing the blood supply to brain tissues.

²⁵¹ *Ibid*.

²⁵² See Siegel & Sapru, *supra* note 200 (the Pre-Bötzing complex within the brainstem is thought to be responsible for producing this reflex).

seems insufficient reason to replace apnoea testing²⁵³ with brain blood flow testing.²⁵⁴ Without apnoea testing, blood flow tests may erroneously declare some patients dead using evidence of interrupted blood flow. Brain blood flow may initially be absent during testing, due to brain swelling, suggesting “brain death” but could later resume, as swelling subsides. A brain blood flow test would provide no direct indication of whether the brainstem reflex that triggers breathing remains functional. If it remains functional but untested, the patient is not, by the CCDT’s own definition, brainstem-dead. Such a patient with restored brain blood flow and (untested but) intact brainstem breathing reflexes could be in a persistent vegetative state.

Performing only a brain blood flow test and no apnoea test on very frail patients might over-assess the number of patients declared “brain-dead” and thereby infringe their rights to life and security of the person. While the wording “excessive risk” in Recommendation 8 suggests concern for patients’ safety, its potential effects suggest the reverse.

Wait time removal: The final concern involves the CCDT’s removal of recommended wait times between re-testing. Traditionally, brain death assessments have required two sequential tests of a patient’s responsiveness. The CCDT now makes it possible for two doctors to simultaneously assess and immediately declare a patient dead, with no intervening wait period. *SBINDD 2006* added the confusing suggestion that if “sequential” testing by a single physician is performed, patients should be recorded as dead when the first test indicates death, rather than awaiting a second result.²⁵⁵ This recommendation would effectively make a second, sequential test superfluous,

²⁵³ Yet Ari R Joffe et al, “A 10-Month-Old Infant With Reversible Findings of Brain Death” (2009) 41 *Pediatric Neurology* 378 at 379, warned of the risk that apnoea testing might also kill a very frail or unstable patient. However, having defined “neurological death” to require evidence of lack of breathing reflexes, as the CCDT has done (*BBFNDD*, *supra* note 20 at 11), it seems that a physician’s only choice should be to either wait for the patient to stabilize or deteriorate further, or to perform the apnoea test as an essential test of brainstem functioning. Replacing the apnoea test with a test of other patient characteristics is not an acceptable alternative.

²⁵⁴ Both of these tests take time to perform and require transporting the patient to the imaging department where angiography is performed. Transportation may also pose risks to unstable patients. See *SBINDD*, *supra* note 1 at 31.

²⁵⁵ *SBINDD 2006*, *supra* note 21 at S10. Only babies under 30 days old are required to be repeat-tested at a different time (S4).

since life support could be withdrawn and organs legally harvested after the first test suggests brain death.²⁵⁶

This CCDT recommendation significantly changes the established procedure for determining death, which has always included an assessment of the irreversibility of a patient's condition. Under prior guidelines, irreversibility was estimated (albeit imperfectly) by requiring re-testing after wait periods of (originally) at least 24 hours, or under later guidelines, as few as two hours. Unfortunately, simultaneous re-testing without wait periods, or accepting the first test suggesting death, prevents detection of transient, reversible conditions that mimic brain death, such as hypothermia (discussed below) or drug effects.

Some argue that, for certain brain trauma patients, initial loss of brain blood flow and neurological unresponsiveness may spontaneously resolve after 48 hours.²⁵⁷ Patients with other neurological conditions, such as Alzheimer's disease, may exhibit cyclic symptoms, again suggesting a need for multiple, sequential tests. As Jennett noted "[a]n important safeguard against mistakenly suspecting brain death is to allow enough time to elapse [in brain death testing]."²⁵⁸ The CCDT's recommendations mean that the irreversibility of a patient's condition is not actually assessed. Thus, some patients could be incorrectly declared dead due to the CCDT's removal of recommended wait times. In contrast, sequential assessments, separated by a wait period, may find some patients alive upon a second test.

The CCDT's founding director Sam Shemie's comments regarding a recent brain death misdiagnosis in Edmonton, Alberta, appear to illustrate this very problem.²⁵⁹ This misdiagnosis appears to have occurred with the use by

²⁵⁶ In such cases, the requirement to declare brain death would seem to be reduced to a single test by a single physician, with no wait period in the testing. This could hasten the declaration of death, making organs available from donors hours or days earlier than previously.

²⁵⁷ Coimbra argues that when some minor flow remains, "suppressed neurological functions remain recoverable ... for up to 48h ... This phenomenon is known as ischemic penumbra" (CG Coimbra, "Implications of Ischemic Penumbra for the Diagnosis of Brain Death" (1999) 32 *Brazilian Journal of Medical and Biological Research* 1479 at 1480).

²⁵⁸ B Jennett, "Brain Death" (1981) 53:11 *British Journal of Anaesthesia* 1111 at 1117.

²⁵⁹ T Blackwell, "Theory on Life Support: Debate Grows Over When Brain Dead Really Means Dead", *National Post* (4 February 2010) online: NP

two paediatric intensivists of the CCDT guidelines, which had been adopted by the hospital, on a 10 month-old baby.²⁶⁰ As permitted by *SBINDD 2006*, only one brain death determination test was performed simultaneously by the two physicians before death was declared.²⁶¹ Ironically, given the CCDT's role in removing wait times, Shemie stated that, had 24-hour wait times been employed by the declaring physicians, permitting reversal of the alleged confounding factor of the infant patient's hypothermia, this misdiagnosis could have been avoided.²⁶²

<www.nationalpost.com> [Blackwell, "Life Support"]; Joffe et al, *supra* note 253 at 378-79.

²⁶⁰ The CCDT reported in 2006 that Edmonton hospitals had made changes to their institutional rules based on the CCDT guidelines. See *Summative Evaluation*, *supra* note 3 at 39, 42. Physicians at Stollery Children's Hospital where the baby died implied that the CCDT guidelines were employed in the case: "[The baby] fulfilled all criteria for brain death according to the [*SBINDD 2006*] recommendations" and "According to [*SBINDD*] Canadian consensus guidelines, this first examination was compatible with brain death" (Joffe et al, *supra*, note 253 at 378-79).

²⁶¹ As permitted by Recommendations A9 and B1 of *SBINDD*, *supra* note 1.

²⁶² "Dr. Shemie, however, said that ... [t]he problem was that the baby was subjected to 24 hours of hypothermia ... which can also mimic brain death. Had the doctors waited another 24 hours before testing for brain death to avoid that 'confounding factor,' there would have been no [misdiagnosis], he [Shemie] argued" (Blackwell, "Life Support", *supra* note 259). Yet *SBINDD*, co-authored by Shemie, removed minimum wait time requirements for all patients over 30 days old, requiring 24-hour minimum wait times only for those less than 30 days old (*supra* note 1 at Recommendation A9 at S4). *SBINDD* also recommended that "the legal time of death be marked by the first determination of death" (*ibid* at Recommendation B1, reversed by *BBFNDD*). Hence, under *SBINDD* Recommendations A9 and B1, the 10-month-old baby could legally be declared brain-dead after the first examination, by two physicians testing concurrently (i.e. zero wait time). This appears from Joffe et al, *supra* note 253 to be what occurred. In seeming contrast to Shemie's statement implying that the problem involved an insufficient pre-test warming period to correct the confounding factor of hypothermia, according to Joffe et al (at 378), when first tested, the baby had in fact been re-warmed to 36.2° Celsius (an acceptable non-hypothermic temperature for *SBINDD* Recommendations A3 and A9). Citing the *SBINDD* guidelines, Joffe et al suggested that these guidelines "may require revision for infants, to more clearly define a time interval between examinations and to incorporate consideration of confounding sedative drug effects [e.g. barbiturates]" (at 378). Under *SBINDD*, "therapeutic" barbiturate dosages were not deemed a confounding variable that would either preclude brain death determination

However, in fact, another Edmonton physician, Dr. Ari Joffe, reported no hypothermia, but noted another potentially influential variable: the baby had received a therapeutic dose of the barbiturate phenobarbital—as permitted by the CCDT guidelines but not previous guidelines—just five hours before the misdiagnosis.²⁶³ As recognized by earlier guidelines, the creation of wait times is an important means of addressing confounding factors. Without wait times to address the possibility of reversible conditions, such as hypothermia or barbiturate intoxication, there remains a potential for patients to erroneously be declared dead under the CCDT guidelines. This suggests the possibility of infringement of rights to life and security of the person.

The above CCDT recommendations suggest governmental interference with “matters of a fundamentally intimate and personal nature” in patients’ lives, invoking section 7 of the *Charter*. There appears to be a real possibility that several CCDT recommendations could be found to infringe patients’ rights to life and security of the person. It remains to be determined whether such infringements accord with the principles of fundamental justice.

B. Are the Section 7 Deprivations “In Accordance with the Principles of Fundamental Justice”?

If the suspected section 7 infringements can be shown to have occurred “in accordance with the principles of fundamental justice,” they comply with the *Charter*.²⁶⁴ It must be determined whether this is the case for each of the possible section 7 infringements mentioned above.

(*SBINDD* Recommendation A2) or require an ancillary brain blood flow test to complete the declaration (*SBINDD* Recommendation A6). Thus, according to *SBINDD*, there were no confounding factors, so the baby could be declared brain-dead after the first examination by two physicians, with no minimum re-testing wait time, and no brain blood flow test. This declaration could not have occurred under earlier brain death guidelines. Four hours before the first actual brain death examination, the physicians performed a computed tomography scan on the baby’s head, but it was not reported whether this scan investigated or found brain blood flow; no brain blood flow test was reported closer to the brain death exam although several were done after the baby resumed breathing (*ibid* at 378-79). It appears that the declaring physicians correctly applied *SBINDD*, resulting in a legal declaration of death after the first examination.

²⁶³ *Ibid.*

²⁶⁴ See *Morgentaler*, *supra* note 193 at 56, Dickson CJ & Lamer J (“Parliament could [legitimately] choose to infringe security of the person if it did so in a manner

Just what procedural fairness entitlements the principles of fundamental justice might entail in this context is not entirely clear. The jurisprudence indicates that the procedures required are not fixed and immutable, but determined by the individual context of a case: “[c]ertain procedural protections might be constitutionally mandated in one context but not in another.”²⁶⁵ Procedural fairness expectations under section 7 must also be balanced against fairness and efficiency considerations.²⁶⁶ According to the Supreme Court in *Reference re BC Motor Vehicle Act*, “the principles of fundamental justice are found in the basic tenets and principles, not only of our judicial process, but also of the other components of our legal system.”²⁶⁷ However, the Court stressed that these principles must be “more than vague generalizations as to what our society considers to be ethical or moral [and] capable of being identified with some precision.”²⁶⁸

Regarding the sources of these principles, the *Suresh* Court stated: “The inquiry into the principles of fundamental justice is informed not only by Canadian experience and jurisprudence but also by international law, including *jus cogens*.”²⁶⁹ Justice Wilson, dissenting in *Thomson Newspapers*, adopted the Court’s view in *Motor Vehicle* that sections 8-14 of the *Charter* provide guidance as to the content of the principles of fundamental justice. She believed these sections reflect “presumptions of the common law developed over time” or included in international human rights conventions that contribute to a justice system “based on a belief in ‘the dignity and worth of the human person.’”²⁷⁰

While it is unclear exactly what procedural entitlements a court might require in a challenge to the CCDT guidelines, case law contains indications as

consistent with the principles of fundamental justice”).

²⁶⁵ *R v Lyons*, [1987] 2 SCR 309 at para 85, 61, CR (3d) 1.

²⁶⁶ *R v Jones*, [1986] 2 SCR 284 at para 41, 31, DLR (4th) 569.

²⁶⁷ [1985] 2 SCR 486 at para 64, 24 DLR (4th) 536 [*BC Motor Vehicle Reference*].

²⁶⁸ *Rodriguez*, *supra* note 192 at 591 (according to the majority).

²⁶⁹ *Supra* note 198 at para 46. See also *Burns*, *supra* note 198 (“[International law] takes into account Canada’s international obligations and values as expressed in the various sources of international human rights law—declarations, covenants, conventions, judicial and quasi-judicial decisions of international tribunals, [and] customary norms” at paras 79-81).

²⁷⁰ *Thomson Newspapers Ltd v Canada* (Director of Investigation and Research, Restrictive Trade Practices Commission), [1990] 1 SCR 425 at 462, 67 DLR (4th) 161 [*Thomson Newspapers cited to SCR*].

to what will be considered unacceptable. A line of Supreme Court jurisprudence has indicated repeatedly that arbitrariness or unfairness will not satisfy the principles of fundamental justice. In *Rodriguez*, the Supreme Court suggested that a law or policy that is either arbitrary or unfair will offend the principles of fundamental justice.²⁷¹ Four of the seven justices in *Morgentaler* viewed a “manifestly unfair” law as similarly offensive,²⁷² which the Supreme Court in *Chaoulli* later interpreted as based on arbitrariness.²⁷³

In *R v Malmo-Levine and R v Caine*, in which liberty was at stake, it was argued that “law that is arbitrary or irrational will infringe section 7.”²⁷⁴ Other section 7 rights, to life and security of the person, appear no less important than the right to liberty and warrant similar protection. In *Chaoulli*, the Court specified that, to avoid being arbitrary, the limit on section 7 rights “requires not only a theoretical connection between the limit and the legislative goal, but a real connection on the facts.”²⁷⁵ Thus, where life and security of the person rights are affected, as by the CCDT guidelines, arbitrariness, unfairness, or irrationality may offend fundamental justice.

Proportionality also appears to be essential to fundamental justice. The Supreme Court stated in *Suresh*, a case involving deportation to possible torture, that:

The notion of proportionality is fundamental to our constitutional system. Thus we must ask whether the government’s proposed response is reasonable in relation to the threat. ... [S]ome responses are so extreme that they are *per se* disproportionate to any legitimate government interest ...²⁷⁶

As noted by Justice LaForest in *Thomson Newspapers*, community interests may play a role in shaping the content of fundamental justice when a

²⁷¹ The *Rodriguez* Court stated that “the blanket prohibition on assisted suicide is not arbitrary or unfair. The prohibition relates to the state’s interest in protecting the vulnerable and is reflective of fundamental values at play in our society. Section 241(b) therefore does not infringe s 7 of the Charter” (*supra* note 192 at 522).

²⁷² See *Morgentaler*, *supra* note 193 at 72, 110, 114, 119.

²⁷³ *Chaoulli v Quebec (AG)*, 2005 SCC 35 at paras 132-33, [2005] 1 SCR 791, 254 DLR (4th) 744 [*Chaoulli*] (reasons of McLachlin CJC, Major J, and Bastarache J).

²⁷⁴ 2003 SCC 74 at para 135, [2003] 3 SCR 571.

²⁷⁵ *Chaoulli*, *supra* note 273 at para 131.

²⁷⁶ *Supra* note 198 at para 47.

“just accommodation” is sought, through “delicate balancing” of the interests of individuals and of the state, taking into account the context in which legal measures operate, so as to benefit the community as a whole.²⁷⁷ A similar contextualization occurred in *Burns*, where the co-accused in a US homicide case argued that their unconditional extradition to face the death penalty would “shock the Canadian conscience,” due to their young age and Canadian nationality,²⁷⁸ violating the principles of fundamental justice. The Court agreed:

The “shocks the conscience” language signals the possibility that ... a particular treatment or punishment may sufficiently violate our sense of fundamental justice as to tilt the balance against extradition.²⁷⁹

A similar standard might be applied to the deprivation of section 7 rights generated by the CCDT guidelines. Overall, it appears that a law that is arbitrary, irrational, unfair, or that employs means disproportionate to the law’s ends—shocking the Canadian conscience—may offend fundamental justice.

The first CCDT concern discussed, the recommendation of a brainstem criterion of death, seems highly unlikely to satisfy the principles of fundamental justice, due to disproportionality between the means employed and the ends attained. The CCDT’s admittedly worthy goal was to increase the availability and viability of organs urgently needed by those on transplant wait-lists. In Canada, every year, 10–30% of those awaiting an organ die.²⁸⁰

²⁷⁷ In *Thomson Newspapers*, *supra* note 270 at para 180, LaForest J wrote regarding the content of s 7 that: “A community’s interests is one of the factors that must be taken into account in defining the principles of fundamental justice.” Specifically, he argued that legal practices should “seek to achieve a just accommodation between interests of individuals and those of the state, both of which play a part in assessing whether a particular law violates the principles of fundamental justice,” adding at para 181, that “in assessing whether a measure violates the principles of fundamental justice,” the specific context in which it operates must be kept steadily in mind (para 176). Overall, he suggested that legal measures are the product of a “delicate balancing” of state and individual interests, whereby “the community as a whole benefits” (paras 176, 208).

²⁷⁸ *Burns*, *supra* note 198 at para 17.

²⁷⁹ *Ibid* at para 69.

²⁸⁰ See Sam D Shemie, Christopher Doig & Philip Belitsky, “Advancing Toward a Modern Death: The Path From Severe Brain Injury to Neurological Determination of Death” (2003) 168 *Can Med Assoc J* 993 at 993. In 2007, only 2188 of 4195 Canadians on organ waitlists, or 52%, received transplants; the relative proportion

With the aging of Canada's population, this demand-supply deficit has continued to grow.

Yet, a government strategy to overcome a 10–30% deficit in Canada's organ supply through a major redefinition of brain death seems an extreme, disproportionate measure, which does not appear to be justified by recent scientific developments. The brainstem criterion of death has been rejected by other nations, including the US, due to its perceived risks. The possibility that a super locked-in organ donor might suffer after being mistakenly declared dead makes this a radical guideline change. In addition, the fact that the lives of both donors and non-donors are at risk of being curtailed by these guidelines also suggests a disproportionate effect. The possible negative effect of the CCDT recommendation on many brain-injured patients seems disproportionate to the benefits gained by organ recipients.²⁸¹ Therefore, the Supreme Court's observation in *Suresh* that "some [means] are so extreme that they are per se disproportionate to any legitimate government interest" also seems a valid criticism of the CCDT's adoption of brainstem death. Applying the standard enunciated in *Burns*, the CCDT's approach to increasing organ donation by radically redefining brain death criteria might well "shock the Canadian conscience," thereby violating the principles of fundamental justice.

According to the Supreme Court in *Chaoulli*, to avoid being arbitrary, a limit must show more than a purely theoretical connection between the impugned limit and the legislative goal, including "a real connection on the facts." Sustainability was an important element of the CCDT's scheme to improve Canada's transplant system. With the health of the baby-boomer generation declining and threatening to place increasing demands on finite healthcare resources, attempts to curb healthcare system costs were needed. The government may have hoped to rein in some costs by improving transplant access. Yet, the link between infringement of section 7 rights and making healthcare sustainable is more imagined than real. Only in kidney disease is transplantation known to reduce subsequent healthcare costs, by obviating

of the other 48%, who either died or continued waiting, was unstated (Kondro, "Allocation Mechanism", *supra* note 108 at 640).

²⁸¹ In fact, "less than 10-15 per cent of ... suitable donors become actual donors"(Adrian W Gelb & Kerri M Robertson, "Anaesthetic Management of the Brain Dead for Organ Donation" (1990) 37 Can J Anaesth 806 at 806). Among willing organ donors, some unmatched or unsuitable organs may also be rejected after donation.

the need for subsequent dialysis.²⁸² For other organs, such as hearts, arguments regarding cost savings lack support.²⁸³ Without “a real connection on the facts” then, the section 7 violation appears to be arbitrary.

Other fairness considerations also suggest that the principles of fundamental justice have not been satisfied. For instance, there has been no public notice of a major change in the death criterion to the donor and patient populations. Moreover, as urgent as the need for transplantable organs may be, it cannot outweigh the importance of the need to respect the lives, dignity, and bodily integrity of patients assessed for brain death. It has been recognized in Canada and internationally that a declaring physician’s primary loyalty and responsibility is to the patient being assessed for death, not the organ recipient.²⁸⁴ To protect patients being assessed for brain death, physician conflicts

²⁸² According to the 1999 *Standing Committee Report*, *supra* note 6 ch 3(B)(1)(c), “\$19,500 for ... hospital costs [is] associated with a kidney transplant versus ... \$50,000 per year for maintaining an individual on dialysis.”

²⁸³ *Ibid.* The report cited one-time transplant costs of “\$111,120 for heart and lung combined or just lung alone, \$82,400 for liver, and \$75,220 for heart” and remarked that “[with respect to these] other types of transplants, witnesses noted that no life-sustaining alternatives equivalent to dialysis exist,” against which to offset these transplantation costs. Costs of re-transplantation, complications, or treatment for the side effects of anti-rejection drugs may also add to the healthcare system costs of transplantation. After transplantation, recipients must pay five hundred dollars per month for anti-rejection drugs for the rest of their lives.

²⁸⁴ The 2006 World Medical Association *Declaration of Geneva* states: “The health of my patient will be my first consideration” (online: WMA <www.wma.net/en/30publications/10policies/g1/index.html>). Notably, dying patients create no special exceptions. The 2006 World Medical Association *Declaration of Venice on Terminal Illness* describes the duty of physicians caring for terminal patients thus: “to protect the best interests of their patients. There shall be no exception to this principle even in the case of incurable disease” (online: WMA <www.wma.net/en/30publications/10policies/i2/>). Thus, even when a patient is terminally ill, his or her interests have primacy over physician or third-party interests. The 2006 WMA *Statement on Human Organ Donation and Transplantation* also declares: “The primary obligation of physicians is to their individual patients, whether they are potential donors or recipients of transplanted organs ... Nevertheless ... the physician’s responsibility for the well-being of a patient who needs a transplant does not justify unethical or illegal procurement of organs” (online: WMA <www.wma.net/en/30publications/10policies/t7/>). The 2006 WMA *Declaration of Venice*, Principle 1, emphasizes that a physician declaring death in these patients should maintain the primary focus on the dying patient’s best interests rather than on secondary interests (such as organ donation). Also confirming the primacy of the needs of the patient being assessed for death,

of interest with organ transplantation are expressly disallowed in Canadian tissue gift legislation.²⁸⁵ Hastening the declaration of death in severely disabled patients who are unable to speak for themselves, in order to supply others with organs, would reverse this priority and instrumentalize donors as raw materials for the benefit of others. This is inconsistent with respect for the dignity and worth of the human person.

Notably, for four of the Supreme Court justices in *Morgentaler*, one factor that contributed to the striking down of the anti-abortion law was the recognition that “[u]nfair functioning of the law could be caused by external factors which do not relate to the law itself.”²⁸⁶ In *Morgentaler*, pregnant women experienced difficulty in accessing abortions, in part due to hospitals’ failure to create therapeutic abortion committees. The resulting inequality of access was judged “manifestly unfair” to Canadian women.

Similarly, some report an incomplete or “checkerboard” adoption of the CCDT guidelines among Canadian hospitals and jurisdictions.²⁸⁷ This generates the inequitable result that, in some Canadian regions or hospitals, use of the CCDT’s brainstem criterion of death may be required, while in others, a whole-brain criterion might still be used.²⁸⁸ As in *Morgentaler*, external factors, rather than the law itself, have created this gross regional disparity in access to appropriate medical treatment, contributing to the “manifest unfair-

over the needs of would-be organ recipients, the 2006 WMA *Declaration of Sydney on the Determination of Death and the Recovery of Organs* requires death to be declared by a physician who is not in a conflict of interest through involvement in transplanting that patient’s organs (online: <www.wma.net/en/30publications/10policies/d2/index.html>).

²⁸⁵ With the exception of the Northwest Territories and Nunavut, Canada’s provincial tissue gift acts expressly disallow physicians associated with an organ’s transplant from declaring a donor’s death. For example, Nova Scotia’s *Human Tissue Gift Act*, *supra* note 14, s 8(2) states: “No physician who has had any association with the proposed [organ] recipient that might influence his judgment, shall take any part in the determination of the fact of death of the [organ] donor.”

²⁸⁶ *Morgentaler*, *supra* note 193 at 65.

²⁸⁷ See Kondro, “Fragmented Organ Donation”, *supra* note 208; *Summative Evaluation*, *supra* note 3 at viii, para 3 (reported that by late 2006, adoption of CCDT guidelines had occurred in a piecemeal fashion, i.e. “practitioner by practitioner, organization by organization and province by province,” rather than on the desired national scale).

²⁸⁸ For example, in Atlantic Canada, all the hospitals that perform transplants have reportedly adopted the CCDT guidelines (*ibid* at 40, 42).

ness” of the CCDT guidelines’ operation, and offending principles of fundamental justice.

The second concern discussed also seems unlikely to satisfy fundamental justice requirements. The CCDT recommendation affects barbiturate-intoxicated patients, which may form a large segment of those assessed for brain death, including many traumatic brain injury patients, some recreational drug users, accidental overdose victims, those who have attempted suicide, and others. Under *BBFNDD*, these patients may not only undergo brain death assessment while affected by barbiturates (which previously confounded testing), but they may also now undergo a significantly simplified test for brain death.²⁸⁹ In this simplified process, no apnoea test is done for some and an EEG, labeled as unreliable elsewhere in the CCDT guidelines, may replace the CCDT’s earlier recommendation of a brain blood flow test. With the exception of high-risk patients, discussed above, no other patients are assessed in this way. From a patient-safety perspective, the recommendation suggests irrationality and unfairness, implying that it violates the principles of fundamental justice.

This recommendation also appears scientifically arbitrary. Under *BBFNDD*, barbiturate-intoxicated patients are given a significantly different, much simpler assessment than all other patients, without clear, scientific reason. The treatment of barbiturate patients also differs markedly between earlier (*SBINDD*) and later (*BBFNDD*) guidelines, again without reference to a scientific basis for the change.²⁹⁰ According to current medical literature, barbiturates can create reversible, death-like states at dosages that may qualify as therapeutic. Thus, barbiturate-intoxicated patients require greater safeguards in death determination to prevent misdiagnoses. The CCDT’s recommendation therefore seems to be an arbitrary change, lacking scientific support, and contradicting claims that the CCDT guidelines are evidence-based.²⁹¹ While this CCDT recommendation may not affect all patients as-

²⁸⁹ *SBINDD* versions of the CCDT guidelines contain no such recommendations to exclude apnoea testing.

²⁹⁰ See *BBFNDD*, *supra* note 20 at 8. Testing of high-dose, barbiturate-affected patients (and use of a simplified brain death assessment with no apnoea test) was allowed only in the *BBFNDD* versions of the CCDT guidelines, but not in the earlier *SBINDD* guidelines, which only permitted testing with low or therapeutic barbiturate dosages and required an apnoea test for all patients.

²⁹¹ The 1999 NCCOTDT *Strategy* stated its commitment to “evidence-based decision-making” in its plan to improve Canadian OTDT through CCDT efforts (*supra* note 7 at 6). As justification for replacing earlier Canadian brain death guidelines

essed for brain death, based on the frequency of barbiturate use in head injury and other patients, it may affect a significant proportion. The guidelines' apparent willingness to subject this sub-group of Canadian patients to less thorough testing, possibly to increase organ supply, seems sufficient to "shock the Canadian conscience."

A similar concern attends the third issue discussed. This recommendation specifically targets the most vulnerable patients assessed for brain death: those so frail that brain death tests alone might kill them. Out of concern for their frailty and respect for their lives and dignity, it might be expected that the guidelines would recommend delaying testing in these patients, to await their stabilization or natural demise. Instead, the CCDT recommends simplifying the brain death assessment. This recommendation does not appear to be supported by existing medical knowledge. Since the simplified test may kill or over-assess the death rate in this patient group, this recommendation appears irrational, unfair, and scientifically arbitrary. As with the previous recommendation regarding barbiturate-treated patients, the CCDT's apparent willingness to subject such a vulnerable group of patients to a less rigorous standard of assessment does not suggest respect for patients' dignity and worth. The recommendation therefore appears to violate the principles of fundamental justice.

The final concern involves the effective removal of recommended wait times. This recommendation fails to consider the existence of reversible death-like states, such as hypothermia, which must be excluded before a diagnosis of brain death is medically justified. As noted above, some physicians also believe that, for up to 48 hours after brain trauma, a temporary "ischemic penumbra" may exist in the brain, due to raised intra-cranial pressure limiting brain blood flow. This may be clinically indistinguishable from brain death, but is reversible, making recovery possible for some. Without wait times, such cases cannot be detected.

with the CCDT guidelines, the CCDT argued that previous Canadian brain death guidelines were not evidence-based, thereby implying that its guidelines would be. See CCDT, *Literature Review Brain Death*, *supra* note 15 at iii, 12, 15-16, 19, 25. However, a CCDT survey respondent revealed a low opinion of the CCDT guidelines' evidence basis: "organ donation doesn't have a lot of high level of evidence, medically speaking ... [so] we have to live with expert opinion ... That's one of the problems that critics of the CCDT have, that most of what's been produced is expert panel recommendations—there is not a lot of science or high level of evidence behind those recommendations ... the level of evidence is low" (*Summative Evaluation*, *supra* note 3 at 43).

Wait-time removal leaves the vital irreversibility component of death untested, making declaration of death medically unjustified. An element of irrationality is also introduced by the recommendation to declare death based on the first sequential test result. Early in the CCDT's history, it was declared that the CCDT would be sensitive to the need to protect the safety and the best interests of patients being assessed.²⁹² However, if an important part of diagnostic confidence requires "allowing sufficient time to elapse" before declaration of death, then recommendations discouraging physicians from allowing for such time appear to abandon patient safety considerations. This CCDT suggestion also appears to defy scientific support and rationality, violating fundamental justice.

In summary, on grounds of arbitrariness, irrationality, unfairness, disproportionality, and a standard shocking to the Canadian conscience, each of the section 7 deprivations discussed in the preceding section appears to violate the principles of fundamental justice, suggesting infringement of section 7.

C. Could the Suspected Section 7 Infringements be Justified under Section 1 of the Charter?

Section 1 of the *Charter* allows a prima facie infringing state activity to be upheld on public policy grounds, as a "reasonable limit, prescribed by law and demonstrably justified in a free and democratic society." Unlike the demonstration of a section 7 deprivation, the burden of proof of justification

²⁹² In 2001, Federal Health Minister Allan Rock, upon unveiling the plan to increase organ donation through CCDT efforts, stated: "Our priority is to protect the health and safety of all Canadians" ("Canadian government launches \$20 million, 5-year plan to increase donors", *Transplant News* (12 May 2001), online: All Business <www.allbusiness.com/health-care-social-assistance/ambulatory-health-services/783295-1.html>). Presumably, he meant to include Canadians tested for death. Similarly, the goals agreed to by the CDM in approving CCDT creation included a commitment "[t]o preserve, protect and improve the health of Canadians" (*Summative Evaluation*, *supra* note 3 at 10). See also *SBINDD*, *supra* note 1 at 7 ("[CCDT] recommendations [for brain death determination] must be in the best interests of patients with severe brain injury"). Kimberly Young, the CCDT's former CEO also stated: "According to the CCDT vision ... all donation should be compassionate, safe and efficient" (*2008 Standing Committee Report*, *supra* note 52 at 5). Yet in contrast, the 1999 NCCOTDT *Strategy* was committed to "meet the highest quality and safety standards," but only for "Canadians in need [of transplants]" (*supra* note 7 at 5). Finally, *BBFNDD* stated that it was intended to reflect "the needs of medical practitioners," rather than patients of either type (*supra* note 20 at 1).

under section 1 falls to the state.²⁹³ The majority of the Court in the *BC Motor Vehicles Reference* argued that it would take “exceptional conditions” such as “natural disasters, the outbreak of war, epidemics and the like” to justify infringement of section 7 rights.²⁹⁴ Two ideas support this view:

First, the rights protected by s. 7 ... are very significant and cannot ordinarily be overridden by competing social interests. Second, rarely will a violation of the principles of fundamental justice ... be upheld as a reasonable limit demonstrably justified in a free and democratic society.²⁹⁵

Mullan notes that, accordingly, “it is difficult to find examples of a section 1 justification actually succeeding” in upholding a section 7 deprivation.²⁹⁶ Yet for greater certainty, the CCDT guidelines must be examined for the possibility that some of the above infringements might be upheld under section 1. The legal test by which this question is answered is the *Oakes* test, which asks: whether the *Charter* infringement involved a goal that was “pressing and substantial”; whether the claimed infringement was “rationally connected” with that goal; whether the infringement impaired “as little as possible” the right infringed; and, finally, whether the means used were proportionate to the ends sought by the infringing activity.²⁹⁷ A failure at any branch of the *Oakes* test means that the impugned government activity cannot be saved under section 1.

Under the first branch of the *Oakes* test, the goal of the CCDT guidelines was to improve Canada’s relatively dismal rate of organ donation in order to save more lives, an objective that does appear pressing and substantial. As noted earlier, 10-30% of those on Canadian wait lists die while awaiting a transplant. In Canada’s increasingly aging, obese, and sedentary society, the need for transplantable organs is likely to grow. With a transplant, many patients can live longer, more comfortable and fulfilling lives. These facts warrant concern and attention.

²⁹³ This was noted by the majority in *R v Mills*, [1999] 3 SCR 668 at para 66, 180 DLR (4th) 1.

²⁹⁴ *BC Motor Vehicle Reference*, *supra* note 267 at para 85.

²⁹⁵ *JG*, *supra* note 178 at 92.

²⁹⁶ Mullan, *supra* note 194 at 205.

²⁹⁷ The test first appeared in *R v Oakes*, [1986] 1 SCR 103 at 138–39, 26 DLR (4th) 200. It was later amended, the modified result appearing in *R v Laba*, [1994] 3 SCR 965 at 1006, 120 DLR (4th) 175 [*Laba*].

With donation rates hovering around 14 donors per million population, some have described Canadian organ donation as being “in crisis.”²⁹⁸ Yet, is this crisis equivalent to the outbreak of war, an epidemic, or a natural disaster? Canada’s federal government clearly thought that increasing organ donation was both important and urgent.²⁹⁹ The 1999 NCCOTDT blueprint for CCDT establishment suggested that the content of guidelines to be drafted by the CCDT was of “national concern.”³⁰⁰ Following Parliamentary discussions from 1995-1999, improving organ donation was deemed such a high priority as to warrant a *Memorandum of Understanding* among all levels of government to overcome constitutional obstacles. Though the government may not have perceived donation rates as equivalent to such extreme threats as war or epidemic, it is likely that the CCDT guidelines would pass as sufficiently pressing and substantial for the purposes of the first branch of the *Oakes* test.

²⁹⁸ Various reports noted “the donation crisis” of the late 1990s in Canada. See e.g. 1999 NCCOTDT *Strategy*, *supra* note 7 at 3; *Summative Evaluation*, *supra* note 3 at 9. While donation rates have increased slightly each year, these small increases are outpaced by growth in Canada’s population and in rates of organ transplant needs. According to Health Canada, *Government Response*, *supra* note 6, “[d]onation rates have leveled off at 14.5 [donors per million] at a time when the need for transplants has increased by 50 per cent.” In the US, despite much higher donation rates of 21 per million, a 2006 report suggests that organ shortages are so severe that “it is important to explore any scientifically credible and ethically acceptable proposal that might increase the organ supply. This may, of necessity, require a reexamination of the sources of organs and strategies for their acquisition that were rejected in the past at a time when the crisis was less acute” (James F Childress & Catharyn T Liverman, eds, *Organ Donation: Opportunities for Action* (Washington, DC: National Academies Press, 2006) at 141).

²⁹⁹ The 1999 *Standing Committee Report*, *supra* note 6 ch 6 stated that “Canada is currently facing a serious situation with respect to organ and tissue donation and transplantation. ... [E]xtremely low donor numbers have resulted in ever-expanding waiting lists.” The same report mentions the “need for immediate action,” requiring the committee to work “at an accelerated pace” (ch 1). While such wording suggests urgency, it implies nothing so extreme as that required to deal with war, the outbreak of epidemics, or natural disaster.

³⁰⁰ 1999 NCCOTDT *Strategy*, *supra* note 7 at 26. However, in the 1999 *Standing Committee Report*, there was no mention of “national concern” or “national emergency” as a constitutional basis for the proposed federal plan to address the OTDT crisis by creating the CCDT (*supra* note 6 ch 2(E)(1)). The *Report* mentioned only the federal government’s “general powers ... criminal law, spending, and peace, order and good government,” and “the need for a national perspective” (ch 3).

The second branch of the *Oakes* test asks whether the goal in question was “rationally connected” to the impugned action. Here, the action taken in response to the goal described above was the CCDT’s creation of a set of guidelines that redefine the point at which brain death can be declared. Is there a rational connection between the issuance of the guidelines, and the goal of increasing national organ donation rates and viability? Clearly, there is a rational connection because the declaration of brain death marks the point at which it becomes legal to harvest a consenting patient’s organs and tissues.³⁰¹ The earlier brain death can be declared, the sooner organs can be harvested, and the more successful a transplant may be. As stated in a paper co-authored by the CCDT forum chair and a *BBFNDD* contributor, “[e]arlier determination of brain death may ... allow for avoidance of protracted stays in the ICU, and potentially expedite organ donation before tissue viability becomes a concern.”³⁰²

Past efforts to increase donor rates through marketing and education have consistently failed to meet the growing Canadian demand for transplantable organs. Unfortunately, approaches based on donor choice and autonomy face resistance due to strongly held religious or personal values, and possibly due to public fears by some of a conflict of interest between organ donation and death declaration.³⁰³ Under the CCDT approach, some deaths could be declared significantly earlier than under previous guidelines, making a greater number of viable organs available sooner.³⁰⁴ This suggests a rational connection between the CCDT guidelines’ infringement on brain-injured patients’ section 7 rights and the goal of increasing organ supplies.

³⁰¹ Most of the organs harvested for transplant in Canada in 2009 were from brain-dead donors. In 2006 some Canadian provinces began harvesting from “donation after cardiac death” donors. However, these amounted to fewer than 10% of organs harvested for transplant in 2008. See CIHI, *Keeping Pace with Demand*, *supra* note 29.

³⁰² Heran, Heran & Shemie, *supra* note 250 at 411.

³⁰³ According to a 2005 CCDT survey of Canadian public attitudes to OTDT, nearly one-quarter of those surveyed (22%) believed that doctors might declare death prematurely to obtain organs. Although not a majority opinion, this nevertheless indicates the presence of some public concern (CCDT, *Public Awareness Report*, *supra* note 46 at 7).

³⁰⁴ This is especially the case with the use of a brainstem criterion of death, where death might be declared months or years sooner than under a whole-brain criterion. The other CCDT recommendations might allow patients to be declared dead hours or days sooner than under past guidelines.

The connection, though rational, is not without complications. The CCDT's approach might backfire if it became publicly known that the CCDT had dramatically altered the criteria for brain death declaration with the goal of increasing organ supplies. This could negatively affect public trust in organ donation, possibly causing organ donor consent rates to drop. Some also speculate that if organs did become significantly more available, physicians might simply relax current eligibility requirements and offer transplants to less sick patients.³⁰⁵ Thus, the organ demand-supply gap might still persist. Despite this difficulty, it is probable that the CCDT brain death guidelines would still pass as "rationally connected" to the government objective of improving both organ supply and transplant viability.

Under the third branch of the *Oakes* test, can it be said that the CCDT brain death guidelines have impaired patients' security of the person rights only minimally? Such a finding seems highly unlikely. The CCDT might argue that these guideline changes are minimally impairing since they declare dead some severely neurologically damaged people—many of them close to death—only slightly sooner than previous guidelines. Wayne Kondro, in 2006, also reported that brain death accounts for just 1.4% of Canadian deaths.³⁰⁶ In terms of the numbers affected by the guidelines, then, altering brain death guidelines to permit an earlier declaration of death might seem to constitute a minimal encroachment on the rights to life or security of the person.³⁰⁷ Yet, this view breeds disrespect for patients with severe disabilities who are assessed for death. It also ignores the fact that the CCDT recommendations infringe a fundamental, highly-valued, and sensitive right in Canadian society.

In *Fleming*, the Ontario Court of Appeal stated that the right to bodily integrity, which the court deemed co-extensive with the section 7 right to security of the person, is "ranked as fundamental and deserving of the highest order of protection," based on "the belief in the dignity and autonomy of each individual."³⁰⁸ This right is of such overriding importance in Canadian society that even infringing actions with a beneficent or therapeutic intent—such as

³⁰⁵ See Childress & Liverman, *supra* note 298 ("the patients who would gain access to transplantation as a result of an increased organ supply may differ systematically from patients who currently receive a transplant" at 34).

³⁰⁶ Kondro, "Fragmented Organ Donation", *supra* note 208 at 1044.

³⁰⁷ Prior Canadian guidelines were altered to declare patients dead slightly sooner (e.g. reducing wait times from 24 to 2 hours, or by allowing spinal reflexes to persist), but these changes were more incremental.

³⁰⁸ *Fleming*, *supra* note 196 at 312.

the administration of psychoactive drugs by medical staff to cure an individual's serious mental illness, as in *Fleming*—may be deemed to unacceptably infringe rights under section 7 of the *Charter* and may not be upheld under section 1. In *Fleming*, the important individual and societal value of curing severe mental illness, such as schizophrenia, did not outweigh the importance of individual security of the person.

It would seem that infringing actions occurring in a medical context with a beneficent, therapeutic intention to cure a third party's serious illness are even less likely to be upheld under section 1 than the infringement at issue in *Fleming*. The individual and societal benefits of providing more people with viable organ transplants, while meritorious, cannot outweigh the importance of life and security of the person to individuals assessed for brain death. The CCDT brain death guidelines apply to all patients assessed for brain death, whether they are consenting organ donors or not, implicating the rights of more individuals than necessary to increase organ supplies. This, too, suggests insufficient tailoring of the section 7 infringement. It therefore seems doubtful that a court would view the CCDT guidelines' impairment of security of the person as "minimal."

For greater certainty, the final branch of the *Oakes* test will also be examined. This branch asks whether the infringement has "deleterious effects which are proportional to both their salutary effects and the importance of the [Parliamentary] objective."³⁰⁹ Here, the objective sought was a sustainable OTDT system that would resolve Canada's organ donation crisis by increasing donation rates to 25 donors per million within 5 years of CCDT establishment, making larger supplies of transplantation-quality organs and tissues available.³¹⁰ The intended salutary effect was that more successful organ transplants might be performed in Canada, providing years of productive, comfortable life to many needy patients each year, with possible, but as yet unclear, economic benefits.

In addition, as the organ donation agency Trillium Gift of Life's website has argued, organ transplants do not just save lives, they save "productive lives."³¹¹ Patients with organ failure represent a significant cost for govern-

³⁰⁹ As expressed by the court in outlining the *Oakes* test, in *Laba*, *supra* note 297 at 1006.

³¹⁰ 1999 NCCOTDT *Strategy*, *supra* note 7 at 7 ("rais[e] donor levels [from 14 donors per million] to 25 [donors per million] in 5 years" *ibid*).

³¹¹ Trillium Gift of Life, "Frequently Asked Questions", online: TGL <www.gift

ments due to welfare and disability payments, as well as home-care and healthcare system costs for hospitalization, drugs, and interim treatments, such as dialysis. Despite its advantages, however, organ transplantation is no panacea. The benefits of organ donation must ultimately be weighed against the high economic and other costs of transplantation surgery, lifelong anti-rejection drugs, re-transplantation, and treatment of serious side-effects, including cancer, graft-versus-host disease, and chronic fatigue. A complete economic cost-benefit assessment of all types of organ transplantation would be extremely complex. Perhaps because of this, no such assessment has been performed in Canada or other industrialized nations.³¹²

In terms of costs, the potential deleterious effects of the guidelines include the very serious possibility of prematurely declaring a patient dead. While this may offer the advantage of shorter and less expensive hospital ICU stays and more numerous and successful organ transplants, these advantages cannot outweigh the incalculable negative effect of premature death on patients and their families. These risks may affect a significant proportion of patients—both donors and non-donors alike—making the range of persons affected by the infringement broader than necessary to achieve Parliamentary goals.³¹³

While the CCDT recommendations may offer major advantages to some in the cost-benefit calculation, these benefits accrue only to individuals in the relatively healthier, and more powerful group (patients awaiting an organ transplant) at a very high cost to the more vulnerable group (the severely disabled who are assessed for brain death). While both groups are vulnerable, those awaiting organs are less so in that they can typically communicate their wishes and defend their interests. Here, the benefits of greater organ availability for a more dominant group should not lead a court to discount the guidelines' harsh effect on more vulnerable, brain-injured patients.

Nor is it clear that Parliament's goal is achievable simply by increasing organ supplies, since an increased organ supply might simply increase trans-

oflife.on.ca/en/faq.htm> at "How does donation help other people?"

³¹² In Canada, each kidney donation may save \$104,000 per patient in dialysis and other healthcare costs over a twenty-year period. See James F Whiting et al, "Cost-Effectiveness of Organ Donation: Evaluating Investment into Donor Action and Other Donor Initiatives" (2004) 4 *Am J Transplant* 569 at 569. However, it is less clear whether there are cost savings associated with other organ transplants.

³¹³ The guidelines may be applied to declare the death of any patient, whether a donor or not.

plant recommendations to overly frail patients, increasing costs but producing no real gains in these patients' lifespans. The erosion of safeguards encourages disrespect for the lives of severely disabled individuals and could also negatively affect public trust in organ donation if it becomes publicly known.

After weighing these deleterious and salutary effects in the context of the federal government's objective, the proportionality required under the final branch of the *Oakes* test appears to be lacking. The potential negative effect of the CCDT guidelines on the rights of all Canadians—including vulnerable brain-injured individuals—outweighs the societal and individual benefits to be gained from increased organ availability. To conclude, it seems unlikely that the impugned CCDT recommendations could be saved under section 1 of the *Charter* as a reasonable governmental policy choice. If the recommendations are found to be contrary to the *Charter*, a court must strike the guidelines down, according to section 52(1) of the *Constitution*.³¹⁴ However, if, as discussed previously, the guidelines are administrative aids to statutory interpretation this course of action may not be open to a court.³¹⁵

D. Alternative Legal and Disciplinary Responses to the CCDT Guidelines

If the CCDT guidelines cannot be characterized as law for the purposes of section 52, the guidelines could be remedied on a case-by-case basis under section 24 of the *Charter*. Of concern is the fact that a section 24 case-by-case approach leaves the CCDT guidelines “on the books,” where they can continue to affect patients for years to come.³¹⁶ This approach would also be unfortunate, because of the difficulty of finding a suitable plaintiff to challenge the guidelines: a plaintiff who has been misdiagnosed as brain-dead, who is known to have been diagnosed under the CCDT guidelines (or under hospital guidelines based on them), and who has also survived the subsequent withdrawal of life support (or evaded organ harvesting). In addition, the plaintiff (or the plaintiff's family) must be willing to undertake legal ac-

³¹⁴ being Schedule B to the *Canada Act, 1982* (UK), 1982, c 11 s 52(1).

³¹⁵ While unlikely, the CCDT guidelines possess some features that might characterize them as “law” that would enable them to be struck down as inconsistent with the Constitution and therefore “of no force and effect.”

³¹⁶ It is, however, possible that a successful s 24 ruling might have a chilling effect on future physician use of the CCDT guidelines, if the results of the ruling were widely known to physicians.

tion despite the major cost and effort involved.³¹⁷ Finding such a plaintiff poses an enormous obstacle to case-by-case challenge under section 24. A potential challenger might however, exist in the family of the Alberta baby discussed earlier.³¹⁸

Because of the difficulties posed by section 24, several alternative legal responses to the CCDT guidelines' use or dissemination warrant comment. Several potential legal approaches may apply to physicians who applied or disseminated the CCDT guidelines, including the civil law of negligence and College disciplinary penalties.

The civil remedy based on the tort of negligence faces numerous obstacles. First, if a patient is mistakenly declared dead under the CCDT guidelines and is later found to be alive (with a clinical outcome similar to that upon admission), it may be difficult to prove that there is a harm to be compensated through tort: the patient may already be in much the same position as before the misdiagnosis. In other cases, it could be difficult to show causation of the patient's injury, or later death, by the earlier brain death misdiagnosis and the associated temporary withdrawal of care. Finally, patients whose misdiagnoses are never discovered, and who succumbed to treatment cessation or organ harvest, clearly cannot bring an action to recover in negligence.³¹⁹

Not all physicians who declare brain death may be neurologists, so non-neurologists must also be considered. In the US, at least, many hospitals al-

³¹⁷ To date, two other Canadian patients are known to have survived brain death misdiagnoses (one of them long-term). However, these survivors did not pursue a remedy in court and so details such as the guidelines used are unknown. See Tom Blackwell, "Who says Doctors Know Best? Families do not Have Final say in Pulling Plug", *National Post* (11 December 2006).

³¹⁸ Had the Edmonton hospital operated according to prior (CNCG) guidelines, the baby would not have been tested so shortly after barbiturate administration (which the CNCG strictly excluded). In addition, for an infant, a full 24-hour wait period would have been required between tests, and given his hypoxic aetiology, a wait period of over 24 hours would have been possible. Thus the baby's life support and aggressive care would have continued during the 15 hours he was believed dead, which might have led to his survival.

³¹⁹ Neither patients nor their families can bring an action because none will have knowledge that there was ever a misdiagnosis. Even physicians may remain unaware of a misdiagnosis, if organs are harvested or life support withdrawn before signs of life (e.g. breathing attempts) reappear.

low non-neurologists and junior physicians to declare brain death,³²⁰ so this group may be sizable. In a negligence action, a non-neurologist would be held to the standard of a reasonable medical practitioner of his or her type, whose behaviour was “in accordance with the conduct of a prudent and diligent doctor in the same circumstances.”³²¹ However, courts do not possess detailed medical expertise; to construct the relevant standard of care and assess whether a physician’s behaviour complied with reasonable medical expectations, a court may defer to indicia of the norms of professional practice.³²² These norms might include the CMA InfoBase guidelines that produced the harm, leading a court to find no liability.³²³ Due to their dissemination by the CMA and their adoption by some hospitals, the CCDT guidelines might be viewed by a court as an element of standard medical practice, the complexity and scientific content of which are beyond the ordinary understanding and experience of a judge and jury.

³²⁰ See David J Powner, Michael MS Hernandez & Terry E Rives, “Variability Among Hospital Policies for Determining Brain Death in Adults” (2004) 32:6 Crit Care Med 1284 at 1285 (no neurologist was required by 62% of 140 US hospitals studied). Similarly, in a second study, “a surprisingly low rate of involvement of neurologists or neurosurgeons” was the reality in brain death determinations at 41 top US hospitals (David M Greer et al, “Variability of Brain Death Determination Guidelines in Leading US Neurologic Institutions” (2008) 70 Neurology 284 at 287).

³²¹ *ter Neuzen v Korn*, [1995] 3 SCR 674 at para 33, 127 DLR (4th) 577 [*ter Neuzen*]. Thus a family physician would be held to the standard of a reasonably prudent and diligent family physician.

³²² “It is generally accepted that when a doctor acts in accordance with a recognized and respectable practice of the profession, he or she will not be found to be negligent. This is because courts do not ordinarily have the expertise to tell professionals that they are not behaving appropriately in their field ... [T]he medical profession is assumed to have adopted procedures which are in the best interests of patients and are not inherently negligent” (*ibid* at para 38). Yet the court noted that “there are certain situations where [a] standard practice itself may be found to be negligent. However, this will only be the case where a standard practice is ‘fraught with obvious risks’ such that anyone is capable of finding it negligent ... ” (at para 41).

³²³ The Supreme Court held that “where a procedure involves difficult or uncertain questions of medical treatment or complex, scientific or highly technical matters that are beyond the ordinary experience and understanding of a judge and jury, it will not be open to find a standard medical practice negligent” (*ter Neuzen*, *supra* note 321 at para 51). Where the CCDT guidelines’ adoption is presently only “checkerboard” and there is evidence of some variability in practice, it is unclear if the CCDT guidelines qualify as standard practice.

Given the complex neurological content of the guidelines, it may be unreasonable for a court to expect non-neurologists to recognize the flaws in the CCDT guidelines and reject their use. It is only if the guidelines are “fraught with obvious risks” that even a layperson can understand that this would be expected. Brain death tests involve difficult, highly technical knowledge, with which even non-specialist physicians may be unfamiliar. Without this specialized knowledge, physicians are likely to rely on the guidelines. A non-neurologist’s use of the guidelines may therefore neither produce a finding of civil liability in negligence, nor meet the higher evidentiary standard of criminal negligence.³²⁴ A complaint could, however, be initiated against a physician by a member of the public to trigger a College disciplinary hearing.³²⁵

In the case of the misdiagnosed Edmonton baby mentioned earlier, death was declared by two paediatric intensivists. These specialist physicians, who are not usually neurologists, are trained in intensive care of the critically ill. The intensivists here applied the CCDT guidelines correctly in regard to concurrent testing by two physicians, with no minimum wait interval, as permitted by *SBINDD* for all patients over 30 days old,³²⁶ and they declared death after the first examination, as recommended by *SBINDD*.³²⁷ Although a computed tomography test was done four hours before the first brain death test, it was not reported if brain blood flow was part of this test. However, based on *SBINDD* stipulations, no ancillary blood flow test was required since no confounding factors (such as hypothermia) existed.³²⁸ The boy’s therapeutic intoxication with barbiturates and sedatives was not considered by *SBINDD* to be a confounding factor precluding diagnosis or requiring ancillary blood flow testing.³²⁹ Overall, given the boy’s serious initial injury, it is unclear whether he would have lived but for the application of the *SBINDD* guidelines and the ensuing 15 hours without aggressive medical intervention. Because they simply followed guidelines that were not fraught with obvious

³²⁴ *Criminal Code*, RSC 1985, c C-46, ss 219, 220.

³²⁵ *Medical Act*, SNS 1995-96, c 10, s 48 allows a complaint to be made to the College by “any official body corporate or organization” or “any other person.”

³²⁶ *SBINDD*, *supra* note 1 at Recommendation A9.

³²⁷ *Ibid* at Recommendation B1.

³²⁸ Joffe et al, *supra* note 253 at 378 reported a core temperature of 36.2° Celsius when the baby was first tested; *SBINDD* neonatal temperature requirements required the patient be at least 36° Celsius when tested, while requirements for those over 1 year of age were 34°C (*SBINDD*, *supra* note 1 at Recommendations A3, A9).

³²⁹ *Ibid* at Recommendations A2, A6.

risks, it appears that no liability in negligence should apply to the two intensivists who applied the guidelines in declaring the baby's death.

In contrast, neurologists applying the guidelines would be held to the higher standard of the "reasonable specialist" in neurology. Like all physicians, neurologists owe a fiduciary duty to safeguard the lives of the patients they assess for brain death, putting these patients' welfare above the interests of those awaiting organs. It would seem that a reasonable neurologist could be expected to note the guidelines' inconsistencies and risks, and to reject them as dangerous for patients in their care. However, although a reasonable neurologist should recognize that the CCDT guidelines are flawed and risky, the *ter Neuzen* test will not give rise to liability if the risks are not obvious to a layperson, which seems doubtful, or if the CCDT guidelines are considered standard practice, which also remains uncertain.³³⁰ Accordingly, it is unclear how a court may rule in a hypothetical future case involving neurologists. Conceivably, if the guidelines are not deemed "standard practice," employing them might leave a neurologist vulnerable to a finding of civil liability in negligence.

The CMA actively promotes the use of its InfoBase guidelines by Canadian physicians to further "ongoing improvement in the quality of care for Canadians." Reportedly, the InfoBase was planned as a "comprehensive, one-stop source" of guidelines for physicians.³³¹ Based on the number of patients potentially affected, one might predict the potential for civil liability among CMA decision makers who chose to disseminate the CCDT guidelines to users via the InfoBase.³³² At the moment, however, this remains unclear.

³³⁰ See *Flora v Ontario Health Insurance Plan*, 2008 ONCA 538, 295 DLR (4th) 309, a case seeking reimbursement for out-of-country medical expenses involving the interpretation of a standard in a regulation. The court concluded that evidence of medical procedure as practised in the jurisdiction (of the reimbursement decision) was the appropriate standard to be adopted. In contrast, the CCDT guidelines do not yet represent medicine as practised in Canada; adoption is sporadic and the CCDT earlier noted in 2003 that the CNEG guidelines reflected Canadian medical practice (CCDT, *Literature Review Brain Death*, *supra* note 15).

³³¹ Becky Skidmore, "New and Improved: CMA's Guidelines InfoBase Now at Physicians' Fingertips" (2000) 162:9 Can Med Assoc J 1342 at 1342.

³³² As noted earlier, the CMA issued a policy in 2000 to move away from issuing brain death guidelines specifically, preferring to subsequently "defer to affiliated societies" on the matter of brain death. This deferral was facilitated by the CMA's

Considering the CMA's objectives to improve quality of care for human lives, the CMA set surprisingly low criteria for InfoBase inclusion. A CMA InfoBase authors' Guideline, created collaboratively with the Royal College of Physicians and Surgeons to assist InfoBase authors, recommended, *inter alia*, that authors cite their evidentiary basis, its strength and date, and consider ethical issues throughout the guideline creation process.³³³ These seem to be reasonable, minimal core standards that all clinical guidelines should satisfy before being applied to patients. Yet, surprisingly, in contrast to the InfoBase authors' *Guideline*, the CMA InfoBase "inclusion criteria"³³⁴ do not require such minimal ethical and scientific standards. This suggests a kind of wilful blindness to InfoBase guideline content by the CMA.

Instead, the only InfoBase inclusion criterion of a scientific nature is the need for "evidence" of "a literature search" during the guideline-creation process. This is an exceedingly low standard that most health-related organizations would be hard-pressed to fail, making it likely that almost any guidelines submitted to the CMA InfoBase would be considered acceptable. This seems at odds with the InfoBase objective "to provide leadership and to promote the highest standard of health and healthcare for Canadians."³³⁵

Unfortunately, the CCDT guidelines may be part of a broader trend in clinical practice guidelines. Recent authors have lamented the lack of a Canadian source of clinical practice guidelines free from potential conflicting

June 2006 agreement with the CCDT to disseminate its guidelines.

³³³ CMA, *Guidelines for Canadian Clinical Practice*, online: CMA <prismadmin.cma.ca/index.php?ci_id=54703&la_id=1>. Thus there was no requirement to show a scientific basis for any part of the CCDT guidelines, nor to consider ethical matters such as conflicts of interest. Guideline 1 also stipulates that "the goal of clinical practice guidelines should be to improve the quality of health care," while Guideline 7 recommends that practice guidelines "should be developed in collaboration with representatives of those groups who will be affected ... including patients." The CMA appears to have trusted guideline authors to submit safe, ethical, evidence-based guidelines.

³³⁴ The CMA InfoBase's inclusion criteria are: "... be produced in Canada by a medical or health organization, professional society, government agency or expert panel ... ; have been developed or reviewed in the last five years; and have evidence that a literature search was performed during guideline development", CMA, "Submit a Guideline", online: CMA <prismadmin.cma.ca/index.php?ci_id=54685&la_id=1>.

³³⁵ CMA, "Guidelines", *supra* note 39 at Introduction.

interests, such as pharmaceutical company commercial interests.³³⁶ As illustrated in the CCDT's case, conflicting interests may put patient safety at risk. The CMA's undemanding standard for InfoBase inclusion facilitates this trend. Overall, the CMA's passive stance towards ensuring the scientific and ethical merits of its guidelines stands in sharp contrast to its active encouragement of InfoBase use as a means to high-quality, evidence-based care. These observations demand resolution.

Potential College disciplinary penalties may include consequences to licensing or practice. Such consequences may prompt future CMA decision makers to consider more carefully their inclusion criteria and the practice guidelines they disseminate. A final option involves the College disciplinary committee's ability to craft "such other disposition as it deems appropriate."³³⁷ Here, the College could require the withdrawal of CCDT guidelines from the InfoBase and their replacement with earlier, safer guidelines, such as the 1999 Canadian Neurocritical Care Group guidelines, which are more consistent with scientific knowledge on brain death and free from the risk of damaging conflicts of interest.

Conclusion

The determination of death is an issue of fundamental importance to all Canadians. In addition to having direct implications for organ donation and transplantation, the accurate determination of death by the appropriate clinical and technical procedures is a key component of law, associated with many important social conventions and legal decisions in the lives of Canadians. It is important that changes in the guidelines for brain death determination reflect changes in scientific knowledge. It is equally essential that such guidelines respect the *Charter*.

This article has considered whether the *Charter* might be applied to the recent CCDT brain death guidelines, and, if so, whether these guidelines might survive *Charter* scrutiny. As a government agency to which the *Charter* applies, or as a body that performed governmental activity, the CCDT pursued a novel and creative approach to correcting Canada's intractable low

³³⁶ See e.g. Roger Collier, "The Centralized Approach to Guidelines Development" (2011) 183 Can Med Assoc J 299 at 299; Roger Collier, "Clinical Guideline Writers Often Conflicted" (2011) 183 Can Med Assoc J E139 at E139; Roger Collier, "Clinical Practice Guidelines as Marketing Tools" (2011) 183 Can Med Assoc J E141 at E141.

³³⁷ *Medical Act*, *supra* note 325 at s66(2)(e)(i)(G).

organ donation rates. It did so by substantially redefining aspects of the brain death assessment process recommended to Canadian physicians. Some benefits may have flowed from this approach in the form of major regional increases and modest national increases in donor organ and tissue supplies. Nova Scotia, for example, reported a tripling of tissue donations between 2001 and 2005, which the CCDT claimed was due to local adoption of its guidelines.

Although the government may have had valid concerns regarding low organ donation and healthcare sustainability, its attempts at a solution were pursued in an inappropriately one-sided manner. No attempts were made to canvas opinion (especially from the patients, families, and healthcare providers most affected) regarding a possible redefinition of brain death. This is unacceptable in light of historical commitments to ensuring that donor interests have primacy over recipient interests. Public notice of the CCDT changes was not made, even after the fact, which is surprising in light of the magnitude of the changes. There were also no attempts to engage with the public to assess how changes to brain death definitions (proposed by OTDT professionals with conflicting interests) may affect, and perhaps erode, trust in organ donation. Nor were there efforts to assess whether performing a greater number of expensive organ transplants—other than kidney transplants—is capable of generating long-term cost-savings and greater healthcare sustainability.

Unfortunately, the CCDT's recommendations not only dramatically redefined the criterion by which brain death is declared, allowing death to be declared significantly earlier than under past guidelines, but have also removed or weakened important methodological safeguards used in declaring death. While physicians declaring death owe a fiduciary duty to protect the patients they assess, their workplace rules, if based on the CCDT guidelines, may confuse and conflict with this duty. The CCDT changes potentially jeopardize the lives of patients assessed for brain death, infringing rights to life and security of the person under section 7 of the *Charter*. In so doing, they show fundamental disrespect for and instrumentalization of those with neurological injuries. Despite the possible societal benefits to be derived from the guidelines, their infringing recommendations should not be upheld under section 1 of the *Charter*.

The CCDT guidelines appear susceptible to a future *Charter* challenge. It remains to be seen, however, how a court might rule. Striking down the guidelines—though desirable—may not be an option. Yet, if left to stand, future guidelines may build upon the CCDT's foundation, by recommending

still more dramatic changes and further erosion of the rights of patients at their most vulnerable. These serious effects demand immediate replacement of the guidelines. Health Minister Allan Rock, while unveiling the CCDT-based plan to increase organ supplies, stated the following in 2001: “Our priority is to protect the health and safety of all Canadians.”³³⁸ Accordingly, efforts are needed to make brain death guidelines protective of rights to life and security of the person of those undergoing brain death testing. Future brain death determination guidelines must respect the *Charter* as the supreme law protecting *all* those living on Canadian soil, regardless of how close they may appear to death.

³³⁸ Transplant News “Canadian government launches \$20 million, 5-year plan to increase donors” (12 May 2001), online: Transplant News <www.trannews.com>.

LES CONSEILLERS EN GÉNÉTIQUE ET LES PROFESSIONS MÉDICALES ET INFIRMIÈRES AU QUÉBEC : DES FRONTIÈRES BROUILLÉES ?

*Ma'n H Zawati**

In recent decades, genetic counsellors have come to play an indispensable role in the field of medical genetics. In part because this discipline is often executed within a multidisciplinary team in a hospital setting, genetic counsellors are deprived of the protection granted to other professionals by the *Professional Code* of Quebec. Most notably, Quebec law does not recognize acts exclusive to the profession and the use of title reserved to practising genetic counsellors. The related legal consequences are considerable. Understanding these consequences requires a study of the professional interaction between genetic counsellors, physicians, and nurses. This article first presents a review of the normative framework applicable to the practice of genetic counsellors. Second, it identifies the situations in which the genetic counsellor is at risk of infringing on the practice of physicians and nurses and the potential legal consequences that may result. Finally, the article suggests legislative and organisational solutions to these legal challenges. In particular, the legislative solution adopted by France, which recog-

Depuis quelques décennies, les conseillers en génétique jouent un rôle de plus en plus important dans le domaine de la génétique médicale. Leur apport ainsi que l'importance de leur rôle sont aujourd'hui incontestables. La pratique du conseil génétique, qui s'effectue bien souvent au sein d'une équipe multidisciplinaire dans un centre hospitalier, est cependant privée de la protection octroyée par le *Code des professions* du Québec aux autres professionnels, dont celle ayant trait au titre et à l'exclusivité des actes. Les conséquences juridiques qui en découlent ne sont pas négligeables. Une étude de l'interaction professionnelle entre le conseiller en génétique, les médecins et les infirmières s'avère donc nécessaire. Cet article présente tout d'abord un examen de l'encadrement normatif entourant le rôle du conseiller en génétique. Les situations dans lesquelles le conseiller en génétique risque d'empiéter sur les pratiques médicale et infirmière sont par la suite cernées afin de déterminer les conséquences juridiques susceptibles d'émerger. Finalement, des pistes de solutions d'ordres législatif et organisationnel sont

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Citation: Ma'n H Zawati, "Les conseillers en génétique et les professions médicales et infirmières au Québec : des frontières brouillées ?" (2012) 6:1 MJLH 137.

Référence : Ma'n H Zawati, « Les conseillers en génétique et les professions médicales et infirmières au Québec : des frontières brouillées ? » (2012) 6 : 1 RDSM 137.

nizes the genetic counsellor's professional status in its laws, provides useful guidance for reform in Quebec.

proposées. À cet égard, cet article présente la solution législative retenue par la France, qui prévoit la reconnaissance du statut professionnel du conseiller en génétique ainsi que la protection de son titre et de l'exclusivité de ses actes, comme un exemple intéressant qui pourrait être transposé au contexte québécois.

Introduction	140
I. Le rôle et les tâches professionnelles du conseiller en génétique	144
<i>A. Le conseiller en génétique et l'absence d'une définition uniforme</i>	144
<i>B. Les tâches professionnelles du conseiller en génétique au Québec</i>	149
1. L'étape préliminaire : réception des demandes de consultation et triage	149
2. L'étape de la préconsultation : obtention de l'information médicale pertinente au cas en espèce	150
3. L'étape de la consultation	152
<i>a. L'anamnèse</i>	152
<i>b. L'évaluation des risques</i>	152
<i>c. La coordination des examens génétiques et diagnostiques</i>	154
4. L'étape de l'après-consultation	154
II. Les conseillers en génétique et les professions médicales et infirmières : y a-t-il un risque d'empiètement ?	155
<i>A. Les tâches du conseiller en génétique et le rôle du médecin généticien</i>	155
1. L'évaluation des risques : une forme de diagnostic médical ?	157
2. La contribution à l'établissement d'un diagnostic : faire indirectement ce que l'on ne peut faire directement	161
<i>B. Les conseillers en génétique bénéficient-ils d'actes partagés avec les médecins ?</i>	163

C. <i>Le conseil génétique est-il un acte médical délégué ?</i>	164
1. Le principe de la délégation de l'acte médical	164
2. L'absence de délégation de l'acte médical dans le cas du conseiller en génétique	167
3. Responsabilité du médecin déléguant dans une situation d'absence de délégation de l'acte médical	168
4. Responsabilité du médecin traitant dans une situation d'absence de délégation de l'acte médical	169
D. <i>Le conseil génétique et la pratique infirmière</i>	170
1. Les tâches du conseiller en génétique : une forme d'évaluation de l'état de santé d'une personne conformément à l'article 36 de la <i>Loi sur les infirmières et infirmiers</i> du Québec ?	170
2. Actes infirmiers partagés et délégués : le conseiller en génétique est-il habilité ?	173
E. <i>Les conséquences juridiques pour le conseiller en génétique suite à de tels empiètements : la responsabilité pénale</i>	174
III. Piste de solutions : le cas de la France	177
A. <i>L'encadrement juridique des conseillers en génétique en France</i>	177
1. Le <i>Code de la santé publique</i> et la reconnaissance de la profession de conseiller en génétique	177
2. Les règles professionnelles régissant la profession du conseiller en génétique	179
B. <i>La transposition de l'expérience française au Québec : est-ce possible ?</i>	181
1. Solutions législatives	181
2. Solutions organisationnelles	184
Conclusion	186

Introduction

Depuis maintenant quelques décennies, l'utilisation de la génétique dans le milieu médical ne cesse d'augmenter¹. En effet, cette science de l'hérédité nous offre désormais des explications ainsi que des solutions à de nombreux problèmes médicaux. Ceci s'explique par les nombreuses découvertes émanant du séquençage d'au moins 98% du génome humain en 2003² et par les diverses associations posées par des scientifiques entre certains génotypes et phénotypes³. Aujourd'hui, afin de mieux prévenir, contrôler et traiter certaines maladies chroniques, les recherches en génétique humaine explorent le génome humain et ses nombreuses interactions avec l'environnement et les modes de vie des individus à travers un prisme populationnel⁴.

Ces avancements ainsi que l'impact de la génétique sur la profession médicale ont mené à sa reconnaissance en tant que spécialisation au Québec en 1997⁵. Auparavant, ceux exerçant dans ce domaine médical étaient, entre

¹ Alexander Morgan Capron, « Tort Liability in Genetic Counseling » (1979) 79 Colum L Rev 618 à la p 620 ; Jon Weil, « Genetic Counselling in the Era of Genomic Medicine » (2002) 3 EMBO Reports 590 à la p 591.

² Francis S Collins, Michael Morgan et Aristides Patrinos, « The Human Genome Project: Lessons from Large-Scale Biology » (2003) 300 Science 286 à la p 287.

³ Vivian G Cheung et Richard S Spielman, « Genetics of human gene expression: mapping DNA variants that influence gene expression » (2009) 10 Nature Reviews Genetics 595 à la p 598 ; Benjamin S. Wilfond et al, « Ethical Issues in Conducting Behavioral Genetics Research: The Case of Smoking Prevention Trials among Adolescents » (2002-2003) 6 J Health Care L & Pol'y 73 à la p 74. Dans la recherche en pharmacogénomique, le but ultime des chercheurs est d'adapter un traitement au bagage génétique du patient, soit par l'étude de l'influence qu'a un médicament sur des gènes spécifiques, mieux connu comme étant l'analyse du génotype vers le phénotype, ou bien encore par la recherche de gènes qui influencent le métabolisme du médicament en question, connu comme étant l'analyse du phénotype vers le génotype. Voir Santé Canada, « Pharmacogénomique », en ligne : Santé Canada <www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/pharma-fra.php>.

⁴ Bartha Maria Knoppers, Ma'n H Abdul-Rahman (Zawati) et Karine Bédard, « Genomic Databases and International Collaboration » (2007) 18 King's Law Journal 291 à la p 292 ; Helen Swede, Carol L Stone et Alyssa R Norwood, « National Population-Based Biobanks for Genetics Research » (2007) 9 Genetics in Medicine 141.

⁵ Fédération des médecins spécialistes du Québec, « Association des médecins généticiens du Québec », en ligne : FMSQ <www.fmsq.org/fr/la-fmsq>

autres, des pédiatres, des neurologues et des obstétriciens-gynécologues⁶. Ce double rôle joué par ces praticiens était facilité par la conception selon laquelle le rôle du généticien est davantage de conseiller ses patients⁷. Aujourd'hui, le médecin spécialisé en génétique se charge principalement

de l'investigation, du diagnostic et de la prise en charge des personnes qui présentent des erreurs innées du métabolisme, des anomalies chromosomiques et des dysmorphismes. Il est aussi le spécialiste du conseil génétique, des tests de dépistage prénatal et de la tératologie⁸.

Cela dit, le conseil génétique ne relève plus exclusivement du champ de pratique des généticiens. Pendant un certain temps, il a été prodigué par des infirmières amenées à évaluer l'état de santé d'un patient, à identifier une condition génétique anormale et à déterminer l'intervention requise⁹. Aujourd'hui, le conseil génétique est aussi offert par des conseillers en génétique¹⁰.

Les conseillers en génétique ont fait leurs débuts aux États-Unis dans les années soixante-dix¹¹. Ils se chargent principalement de conseiller les

/organisation/associations/association-des-medecins-geneticien-du-quebec>
[FMSQ].

⁶ Voir *Liss v Watters*, 2010 QCCS 3309 au para 15, 77 CCLT (3^e) 19, inf par 2012 QCCA 257 ; Ann P Walker, « The Practice of Genetic Counseling » dans Wendy R Uhlmann, Jane L Schuette et Beverly M Yashar, dir, *A Guide to Genetic Counseling*, 2^e éd, Hoboken (New Jersey), Wiley-Blackwell, 2009, 1 à la p 17.

⁷ Sylvie Presseault, *La responsabilité du médecin en génétique*, essai de LL. M., Université de Sherbrooke, 1997 [non publié] à la p 62 [Presseault] ; Elizabeth Petty, « The Medical Genetics Evaluation » dans Uhlmann, Schuette et Yashar, *ibid* aux pp 251-82.

⁸ FMSQ, *supra* note 5.

⁹ Association des infirmières et infirmiers du Canada, « La profession infirmière et la génétique : sommes-nous prêts? », *Zoom sur les soins infirmiers : enjeux et tendances dans la profession infirmière au Canada*, n° 20 (mai 2005) 1 à la p 2.

¹⁰ Sans nommer les travailleurs sociaux et toutes les personnes qui sont « specifically trained to be effective communicators and who act as links between the medical specialists and the general public ». Voir par ex Mona Sidarous et Estelle Lamothe, « Norms and Standards of Practice in Genetic Counselling » (1995) 3 *Health LJ* 153 à la p 155.

¹¹ Walker, *supra* note 6 à la p 2.

patients quant aux options disponibles selon leur état, avant et après un test génétique. Ils sont aujourd'hui sollicités par plusieurs sphères de la médecine, dont la pédiatrie¹², l'obstétrico-gynécologie¹³ et l'oncologie¹⁴. Éventuellement, les conseillers en génétique devront peut-être travailler avec des médecins spécialistes autres que des médecins généticiens ou même travailler au sein de départements n'ayant pas encore employé de spécialistes en génétique médicale¹⁵. Ils pourraient aussi être amenés à travailler en collaboration avec des médecins omnipraticiens dans des régions éloignées dont les hôpitaux ne peuvent compter sur les services de médecins généticiens. Contrairement à certains pays qui ont intégré cette nouvelle profession à leur législation, le Québec et les autres provinces canadiennes n'ont pas encore encadré législativement la pratique du conseiller en génétique¹⁶.

Devant cette absence de législation et dans l'optique de la protection du public, il est utile d'étudier les interactions professionnelles entre le conseiller en génétique, les médecins et les infirmières. En effet, sachant que le conseil génétique est *a priori* le rôle du médecin généticien¹⁷ et qu'il a été prodigué par des infirmières pendant un certain temps, une absence d'encadrement juridique de la pratique de ces conseillers peut s'avérer problématique puisqu'il existe un risque d'empiétement sur la pratique médicale et infirmière. Une clarification des limites que devra respecter le conseiller en génétique lorsqu'il prodigue des services aux patients permettra d'encadrer le chevauchement de compétences entre les différents membres d'une équipe et favorisera une meilleure cohésion dans une équipe multidisciplinaire. Un tel éclaircissement réduira également les risques de poursuites pénales. Enfin, un ordre professionnel chargé de superviser et

¹² MB Mahowald, MS Verp et RR Anderson, « Genetic Counselling: Clinical and Ethical Challenges » (1998) 32 Annual Review of Genetics 547 à la p 549.

¹³ Barbara B Biesecker et Theresa M Marteau, « The Future of Genetic Counselling: An International Perspective » (1999) 22 Nature Genetics 133 à la p 134.

¹⁴ Weil, *supra* note 1 à la p 590.

¹⁵ Biesecker et Marteau, *supra* note 13 à la p 135.

¹⁶ Voir par ex art L1132-1 à L1133-10, art R1132-2 à R1132-20, art R2131-10 à R2131-19 *Code de la santé publique* [C santé publique] ; UNESCO et Comité international de bioéthique, *Rapport de Michel Revel sur le conseil génétique*, CIP/BIO/CONF.002/4, Paris, (1995) à la p 14 [UNESCO et Comité international de bioéthique].

¹⁷ FMSQ, *supra* note 5. Le site de la Fédération des médecins spécialistes du Québec mentionne que le médecin généticien est le spécialiste du conseil génétique.

d'encadrer l'exercice de la profession des conseillers en génétique au Québec pourrait être créé.

Toutefois, notre recherche nous permet de constater qu'il n'existe aucune doctrine ou jurisprudence qui traite précisément de la nature juridique des interactions professionnelles qu'ont les conseillers en génétique avec les autres membres de professions de la santé au Québec. Cette réalité réduit donc grandement la possibilité d'utiliser des sources primaires et nous oblige à adopter une méthode comparative afin d'élucider les différents éléments formant le corps de cette étude.

Notre réflexion est exposée en trois parties. La Partie I examine l'encadrement normatif entourant le rôle du conseiller en génétique en faisant référence aux lois et aux règles d'éthique¹⁸. Ainsi, nous procédons à une analyse comparative des normes internationales, régionales et nationales afin d'identifier les points communs entre les différentes définitions du rôle du conseiller en génétique. Toujours dans cette première partie, nous examinons les tâches du conseiller en génétique au Québec, et ce, grâce à une revue de la littérature scientifique enseignée aux conseillers en génétique au Québec et ailleurs.

La Partie II de cet article tente de repérer les situations où les tâches du conseiller en génétique risquent d'empiéter sur les pratiques médicale et infirmière. Nous y abordons les conséquences juridiques que peut avoir un tel chevauchement pour le conseiller en génétique et les membres de l'équipe avec lesquels il collabore. À cet effet, nous entreprenons une analyse détaillée de la législation et de la jurisprudence traitant de l'exclusivité des pratiques du médecin et de l'infirmière. Le but de cet exercice n'est pas de critiquer les tâches du conseiller en génétique, mais plutôt de lancer un appel au législateur pour qu'il clarifie certains points qui portent à confusion, et ce, en prévoyant un encadrement juridique approprié.

Dans la Partie III, nous proposons des solutions législatives et organisationnelles aux différentes problématiques soulevées dans les deux premières parties de l'article. Pour cela, le cas de la France est étudié en raison de la pertinence des éléments de comparaison qu'il offre. En effet, la

¹⁸ Philippe Pedrot, « Éthique médicale et norme nationale » dans Dominique Folscheid, Brigitte Feuillet-Lemintier et Jean-François Mattei, *Philosophie, éthique et droit de la médecine*, Paris, Presses Universitaires de France, 1997, 261 à la p 262.

France est un pays de tradition civiliste où le législateur a décidé de reconnaître législativement la profession du conseiller en génétique depuis 2004. Celui-ci a délimité le champ de compétence du conseiller en génétique et a mis en place différentes règles professionnelles pour régir sa pratique. À la lumière de l'expérience française, nous proposons des solutions législatives et organisationnelles pour le Québec, tout en commentant leur applicabilité.

En guise de conclusion, nous exposons les principales observations et problématiques apparues au fil des analyses entreprises dans ce texte. Ceci permet de synthétiser les questions sur lesquelles le législateur, les ordres professionnels et les associations nationales et provinciales de conseillers en génétique doivent se pencher afin de présenter une solution au manque d'encadrement juridique actuel.

I. Le rôle et les tâches professionnelles du conseiller en génétique

Avant d'aborder en détail les tâches professionnelles du conseiller en génétique, il est important de considérer les diverses définitions du rôle de ce dernier proposées par les documents normatifs internationaux, régionaux et nationaux afin de mieux comprendre son apport au sein d'une équipe multidisciplinaire. Certains documents tels que les lois, les conventions et les codes professionnels ont une force obligatoire tandis que d'autres ne sont que des vecteurs de normes non contraignantes.

A. Le conseiller en génétique et l'absence d'une définition uniforme

Le conseil génétique est une discipline relativement nouvelle. Sa première définition date de 1975 lorsque l'*American Society of Human Genetics* (ASHG) a proposé d'identifier le conseil génétique comme étant un

processus de communication qui traite des difficultés humaines associées à l'occurrence ou au risque d'occurrence d'un désordre génétique dans une famille. Ce processus implique une tentative par laquelle une ou plusieurs personnes qualifiées aident un individu ou une famille à 1) comprendre les faits médicaux incluant le diagnostic, le pronostic et les choix thérapeutiques possibles, 2) apprécier la façon dont l'hérédité joue un rôle dans la maladie et les risques d'une récurrence dans la famille, 3) comprendre les alternatives pour faire face au risque de récurrence, 4) faire le choix qui leur semble approprié eu égard aux risques, aux buts familiaux, à ses valeurs socioculturelles, éthiques et religieuses, et finalement 5) faire le meilleur ajustement thérapeu-

tique pour le membre affecté devant le risque de récurrence de cette maladie dans la famille [notre traduction]¹⁹.

Nous remarquons dans cette définition la présence de deux éléments à la fois primordiaux et caractéristiques du rôle du conseiller en génétique, soit le fait qu'il s'agisse 1) d'un processus de communication qui vise la bonne compréhension de faits médicaux et 2) qui s'échelonne dans le temps.

Au niveau international, le *Rapport sur le conseil génétique* du Comité international de bioéthique (CIB) de l'UNESCO a été l'un des premiers documents normatifs à discuter du rôle du conseil génétique²⁰. Dans ce document publié en 1995, le CIB définit ce dernier comme étant une « communication d'informations concernant un état génétique diagnostiqué, permettant de prendre une décision, aussi autonome que possible », et ce, « tout en protégeant les particularités psychologiques et éthiques de la personne qui demande la consultation »²¹. Depuis, la *Déclaration internationale sur les données génétiques humaines* de l'UNESCO a défini, en 2003, le conseil génétique comme étant une « procédure consistant à expliquer les conséquences possibles des résultats d'un test ou d'un dépistage génétique, ses avantages et ses risques et, le cas échéant, à aider l'individu concerné à assumer durablement ces conséquences »²². La *Déclaration*, un document non contraignant, précise toutefois que le conseil génétique doit se faire d'une manière non directive, qu'il doit être culturellement adapté et qu'il doit être « conforme à l'intérêt supérieur de la personne concernée »²³.

Du point de vue européen, la *Convention sur les Droits de l'Homme et la*

¹⁹ American Society of Human Genetics, « Report of Ad Hoc Committee on Genetic Counseling » (1975) 27: 2 American Journal of Human Genetics 240 à la p 240. Pour des informations générales sur l'organisme, voir American Society of Human Genetics, en ligne : ASHG <www.ashg.org>.

²⁰ UNESCO et Comité international de bioéthique, *supra* note 16.

²¹ *Ibid* à la p 2. Voir aussi Luba Djurdjinovic, « Psychosocial Counseling » dans Uhlmann, Schuette et Yashar, *supra* note 6 à la p 133.

²² Organisation des Nations Unies pour l'éducation, la science et la culture, *Déclaration internationale sur les données génétiques humaines*, Paris, 2003, art 2 (xiv), en ligne : UNESCO <portal.unesco.org/fr/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html>.

²³ *Ibid*, art 11.

biomédecine du Conseil de l'Europe est avare de définitions²⁴. En effet, cette *Convention*, qui a force exécutoire pour les États qui l'ont ratifiée, prévoit simplement que les tests prédictifs de maladies génétiques ne pourront, entre autres, être prodigués que sous réserve d'un conseil génétique approprié²⁵. Le *Protocole additionnel à la Convention sur les Droits de l'Homme et la biomédecine relative aux tests génétiques à des fins médicales*, quant à lui, n'est pas plus généreux en informations, mais explique tout de même que la forme et l'étendue du conseil génétique « devront être définies en fonction des implications des résultats du test et de leur signification particulière pour la personne concernée ou les membres de sa famille »²⁶. Il veut également que le conseil génétique soit dispensé de façon non directive²⁷.

À la lumière de ces définitions prévues dans les documents internationaux et régionaux, on perçoit un certain manque d'uniformité quant à la portée du rôle du conseiller en génétique, et ce, malgré des similitudes. C'est pourquoi des auteurs se sont résolus à analyser cinquante-six directives internationales et européennes afin de relever neuf composantes qui formeraient « l'idéal » du conseil génétique²⁸. Ceux-ci soulignent dans leur article que le rôle du conseiller en génétique serait axé sur la présentation des faits génétiques et médicaux aux patients²⁹. Ils ajoutent que le conseiller en génétique devrait s'assurer de présenter à son patient les différents choix thérapeutiques possibles³⁰.

²⁴ Conseil de l'Europe, *Convention pour la protection des Droits de l'Homme et de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine: Convention sur les Droits de l'Homme et la biomédecine*, Oviedo, 4.IV (1997).

²⁵ *Ibid*, art 12.

²⁶ Conseil de l'Europe, *Protocole additionnel à la Convention sur les Droits de l'Homme et la biomédecine relatif aux tests génétiques à des fins médicales*, Strasbourg, 27.XI (2008), art 7(2), al 1.

²⁷ *Ibid*, art 8(2), al 4. Voir à cet effet Walker, *supra* note 6 à la p 10 ; Peter S Harper, *Practical Genetic Counselling*, 7^e éd, Londres, Hoddon Arnold, 2010 aux pp 16-18.

²⁸ Elina Rantanen et al, « What is Ideal Genetic Counselling? A Survey of Current International Guidelines » (2008) 16:4 *European Journal of Human Genetics* 445 [Rantanen et al, « What is Ideal Genetic Counselling? »]. Les auteurs ont expressément exclu les documents normatifs nationaux de leur méthodologie de recherche.

²⁹ *Ibid* à la p 446.

³⁰ *Ibid* à la p 447.

En plus de mettre l'accent sur l'importance du fait que le conseil génétique soit prodigué par un professionnel de la santé qui maîtrise la génétique et ses implications éthiques³¹, la majorité des directives de cette même étude recommandent que le conseiller en génétique 1) traite, lors de la consultation avec son patient, d'éléments allant de l'information sur la condition de ce dernier jusqu'aux options de traitement et les risques qui y sont associés, en passant par les informations concernant les groupes pouvant offrir du soutien au patient en question; 2) s'assure que son patient comprend bien l'information fournie; 3) appuie psychologiquement son patient, tout en étant le plus objectif possible; 4) s'assure d'avoir obtenu un consentement libre et éclairé; 5) protège la confidentialité des informations obtenues³²; 6) considère les conséquences potentielles pour les membres de la famille, le cas échéant³³; 7) ne se conduise pas d'une manière discriminatoire pendant la consultation³⁴ et finalement; 8) s'assure de l'autonomie de sa clientèle dans toutes les prises de décisions³⁵.

Au Canada, l'Association canadienne des conseillers en génétique (ACCG) décrit le conseiller en génétique comme un « professionnel » de la santé fournissant aux individus et aux familles de l'information sur la nature, le caractère héréditaire et les implications d'une maladie génétique afin de leur permettre de prendre une décision médicale informée³⁶.

Tel que mentionné plus haut, le législateur québécois n'a toujours pas légiféré sur le conseil génétique dans ses lois et règlements sur les professions. Cette situation ne se limite pas au Québec, mais s'étend

³¹ *Ibid.*

³² *Ibid* à la p 448 ; Walker, *supra* note 6 aux pp 13-14 ; Djurdjinovic, *supra* note 21 à la p 133 ; Susan Schmerler, « Ethical and Legal Issues » dans Uhlmann, Schuette et Yashar, *supra* note 6 aux pp 369-370 ; Mahowald, Verp et Anderson, *supra* note 12 à la p 556.

³³ Rantanen et al, « What is Ideal Genetic Counselling? », *supra* note 28 à la p 448 ; Schmerler, *supra* note 32 à la p 392.

³⁴ Rantanen et al, « What is Ideal Genetic Counselling? », *supra* note 28 à la p 449 ; *Ibid* aux pp 391-92.

³⁵ Rantanen et al, « What is Ideal Genetic Counselling? », *supra* note 28 à la p 448 ; Djurdjinovic, *supra* note 21 aux pp 139-40.

³⁶ Association Canadienne des Conseillers en Génétique, en ligne : Association Canadienne des Conseillers en Génétique <cagc-accg.ca/content/view/12/32/> [ACCG].

également aux autres provinces canadiennes³⁷. La seule définition concrète du rôle du conseiller en génétique au Québec nous vient du Ministère de la Santé et des Services sociaux. En effet, ce dernier définit le conseiller en génétique comme étant « une personne qui, à partir de l'histoire génétique qu'elle établit, coordonne les démarches diagnostiques, analyse la condition génétique du client et formule un plan d'action. »³⁸ Toutefois, cette définition est à la fois vague et problématique. D'une part, elle est vague car elle ne délimite pas clairement le rôle du conseiller en génétique. D'autre part, elle est problématique car elle peut permettre au conseiller génétique d'empiéter sur ceux du médecin et de l'infirmière pratiquant dans le domaine de la génétique³⁹. Nous revenons sur ce point dans la Partie II.

Toujours sur le plan des documents normatifs nationaux, la France présente une situation bien différente du fait de l'encadrement législatif prévu pour la pratique des conseillers en génétique. En effet, le *Code de la santé publique* français stipule d'une part que le conseiller en génétique agisse sur prescription médicale et sous la responsabilité d'un médecin généticien⁴⁰. D'autre part, il indique que le conseiller en génétique s'assure de la « prise en charge médico-sociale, psychologique et [du] suivi des personnes [...] »⁴¹. Afin de réduire toute ambiguïté professionnelle, le législateur français en est donc venu, par cette définition, à délimiter la marge de manœuvre du conseiller en génétique en créant un mécanisme clair d'interopérabilité dans une équipe multidisciplinaire. Nous revenons sur cette approche lorsque nous explorons les solutions possibles pour pallier les conséquences juridiques résultant de l'empiètement du conseiller sur la pratique médicale et infirmière au Québec (Partie III).

Après avoir examiné plusieurs définitions du rôle du conseiller en

³⁷ Voir par ex *Regulated Health Professions Act*, SO 1991, c 18 ; *Health Professions Act*, RSA 2000, c H-7, *Health Disciplines Act*, RSA 2000, c H-2 ; *Health Professions Act*, RSBC 1996, c 183.

³⁸ Québec, Ministère de la santé et des services sociaux, *Nomenclature des titres d'emploi, des libellés, des taux et des échelles de salaire du réseau de la santé et des services sociaux: à partir du 1er avril 2010*, MSSS, Direction des relations de travail du personnel salarié, version du 25 janvier 2012 à la p II.10 [MSSS « Nomenclature des titres d'emploi »].

³⁹ *Loi médicale*, LRQ, c M-9, art 31 ; *Loi sur les infirmières et infirmiers*, LRQ, c I-8, art 36.

⁴⁰ Art L1132-1 al 1, *supra* note 16.

⁴¹ Art L1132-1, al 2, *ibid.*

génétique, il convient maintenant de faire un survol des principales tâches qu'il prodigue au Québec. Pour cela, nous suivons le cheminement d'une demande de consultation. Au cours de ce survol, il importe de garder en tête que les conseillers en génétique sont toujours appelés à s'adapter à la réalité de la génétique médicale qui est en constante évolution.

B. Les tâches professionnelles du conseiller en génétique au Québec

1. L'étape préliminaire : réception des demandes de consultation et triage

Il existe en pratique deux façons de consulter un conseiller en génétique : à la suite d'une demande de consultation du médecin traitant⁴² ou à la suite d'une demande personnelle faite au service de génétique de l'hôpital⁴³.

En ce qui a trait à la demande de consultation par le médecin traitant, elle se présente lorsque ce dernier rencontre une problématique médicale qui dépasse son champ de compétences ou lorsqu'il estime que le cadre de pratique d'une équipe multidisciplinaire permettra de communiquer une information plus complète au patient⁴⁴. Quant aux demandes personnelles, elles se font directement au service de génétique de l'hôpital dans lequel le conseiller en génétique offre ses services.

Dans les deux cas, le rôle du conseiller en génétique consiste dans cette étape préliminaire à recevoir les demandes et à les trier par ordre d'importance⁴⁵. Par exemple, un couple sans grossesse en cours qui demande une consultation pour une évaluation des risques sera convoqué après la femme enceinte âgée de 45 ans référée par son médecin traitant qui doit prendre une décision rapide puisqu'elle présente un risque élevé d'avoir un

⁴² Wendy R Uhlmann, « Thinking It All Through : Case Preparation and Management » dans Uhlmann, Schuette et Yashar, *supra* note 6 à la p 93.

⁴³ *Ibid.*

⁴⁴ *Code de déontologie des médecins*, RRQ c M-9, r 17, art 42 ; Suzanne Philips-Nootens, Pauline Lesage-Jarjoura et Robert Kouri, *Éléments de responsabilité civile médicale : le droit dans le quotidien de la médecine*, 3^e éd, Cowansville, Yvon Blais, 2007 aux pp 283-85.

⁴⁵ Uhlmann, *supra* note 42 aux pp 95 et 125.

enfant souffrant du syndrome de Down⁴⁶. Au besoin, le conseiller en génétique peut demander l'avis d'un médecin généticien à l'étape du triage des demandes de consultation.

Finalement, les consultations sont attribuées soit à un conseiller en génétique, soit à un médecin spécialisé en génétique médicale, selon la complexité de la situation en cause. Il se peut également que les consultations se fassent en étroite collaboration entre le conseiller en génétique et le médecin généticien, surtout lorsqu'un diagnostic n'a pas encore été établi⁴⁷.

2. L'étape de la préconsultation : obtention de l'information médicale pertinente au cas en espèce

Afin de mieux se préparer pour la consultation avec son patient, le conseiller en génétique doit obtenir les dossiers médicaux pertinents afin de procéder à l'interprétation des données médicales qui s'y trouvent⁴⁸.

Les dossiers médicaux du patient peuvent être transmis avec la demande de consultation du médecin. Dans ce cas, le conseiller en génétique ne se limite pas aux dossiers acheminés; il doit s'assurer auprès du patient qu'il n'existe ailleurs aucun autre dossier pertinent. Le cas échéant, l'autorisation du patient est nécessaire pour obtenir toute autre documentation⁴⁹. Ceci s'applique particulièrement lorsque le patient demande une consultation de sa propre initiative.

Non seulement les dossiers médicaux servent à l'interprétation des données médicales, ils permettent également au conseiller en génétique de s'assurer du diagnostic révélé par le patient ou le médecin référent. De plus, ils contribuent à déterminer les évaluations diagnostiques à faire, le cas

⁴⁶ Voir le site de la Société Alzheimer, en ligne : Société Alzheimer <www.alzheimer.ca/french/disease/causes-down.htm>. Le syndrome de Down est une affection génétique due à la présence de trois copies du chromosome 21 au lieu de deux.

⁴⁷ Walker, *supra* note 6 à la p 12.

⁴⁸ Uhlmann, *supra* note 42 à la p 100.

⁴⁹ Loi sur les services de santé et les services sociaux, LRQ c S-4.2, art 19 ; *Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels*, LRQ c A-2.1, art 53.

échéant⁵⁰. Constaté que les évaluations nécessaires ont bel et bien été complétées permet au conseiller en génétique de gagner énormément de temps et d'évaluer de manière plus précise les risques d'occurrence de certaines maladies génétiques⁵¹.

De plus, le domaine de la génétique comporte une caractéristique propre : les diagnostics médicaux de certains membres de la famille d'un patient peuvent avoir une pertinence sur la condition de ce dernier et vice-versa⁵². Il est donc important pour le conseiller en génétique de confirmer certaines informations médicales pertinentes relatives à l'entourage du patient⁵³. Il va de soi que le principe de l'autorisation médicale s'applique également en l'espèce.

Après avoir examiné les dossiers médicaux du patient et de l'entourage de ce dernier, le conseiller en génétique établit une feuille de route pour la consultation à venir. À cet effet, il doit tenter d'avoir en main un historique familial qui lui permette de cerner la problématique et d'évaluer les risques d'occurrence de certaines maladies génétiques chez ce patient⁵⁴. La consultation ne se limite pas nécessairement à la maladie génétique ou à la question pour laquelle le patient est référé; grâce à l'historique familial, le conseiller en génétique peut évaluer d'autres enjeux potentiels⁵⁵.

De plus, le conseiller en génétique est encouragé à utiliser certaines bases de données comme par exemple *Online Mendelian Inheritance in Man* (OMIM), *Gene Reviews* et *PubMed* afin d'obtenir les plus récentes

⁵⁰ Uhlmann, *supra* note 42 aux pp 100-01 ; Association Française contre les Myopathies, *Conseil génétique et maladies neuromusculaires*, Paris, Association Française contre les Myopathies, 2008 à la p 4.

⁵¹ Uhlmann, *supra* note 42 à la p 100.

⁵² Weil, *supra* note 1 à la p 591 ; Au sujet de l'interaction avec les membres de la famille, voir Elina Rantanen et al, « Regulations and Practices of Genetic Counselling in 38 European Countries: The Perspective of National Representatives » (2008) 16:10 *European Journal of Human Genetics* 1208 aux pp 1212-13 [Rantanen et al, « Regulations and Practices »].

⁵³ Uhlmann, *supra* note 42 à la p 124.

⁵⁴ *Ibid* à la p 99.

⁵⁵ *Ibid* à la p 98.

informations concernant les maladies génétiques⁵⁶.

3. L'étape de la consultation

a. L'anamnèse

L'« anamnèse » est la pratique médicale qui réfère à la collecte d'informations. En effet, c'est à ce moment que le conseiller en génétique pose des questions plus détaillées à son patient afin de connaître ses préoccupations⁵⁷. Cette étape s'avère primordiale, d'une part, pour le conseiller en génétique qui peut évaluer les risques d'occurrence d'une condition génétique chez son patient et, d'autre part, pour le patient lui-même qui se sent écouté et compris. Ceci rappelle l'importance de l'aspect psychosocial du conseil génétique⁵⁸.

b. L'évaluation des risques

En ce qui a trait à l'évaluation des risques, on utilise des méthodes scientifiques pour déterminer les risques d'occurrence de certaines maladies génétiques⁵⁹. Cette évaluation est généralement effectuée à l'aide de l'historique familial qui permet au conseiller en génétique de constituer le lignage de la famille⁶⁰. Connaître l'âge du patient ainsi que le moment où la maladie suspectée surviendra est essentiel au conseiller en génétique dans le

⁵⁶ *Ibid* aux pp 102-03 ; « Online Mendelian Inheritance in Man », en ligne : National Center for Biotechnology Information <www.ncbi.nlm.nih.gov/omim> ; « GeneReviews », en ligne : National Center for Biotechnology Information <www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=gene> ; « PubMed », en ligne : National Center for Biotechnology Information <www.ncbi.nlm.nih.gov/pubmed>.

⁵⁷ Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 à la p 274.

⁵⁸ Walker, *supra* note 6 aux pp 4-5 ; Pour connaître certaines formes d'interactions psychosociales, voir par ex Rantanen et al, « Regulations and Practices », *supra* note 52 à la p 1213.

⁵⁹ Uhlmann, *supra* note 42 aux pp 108-109 ; le « Bayesian analysis » en est une parmi d'autres. Elle a pour base l'évaluation initiale des risques et modifie celle-ci en tenant compte notamment de l'âge, du statut clinique et des résultats des tests de la personne concernée. Cette méthode s'applique notamment à l'analyse du risque d'une personne de développer un jour la maladie de Huntington ou d'une patiente d'être porteuse de la myopathie de Duchenne.

⁶⁰ *Ibid* à la p 108 ; Biesecker et Marteau, *supra* note 13 à la p 133.

cadre de la détermination du risque. À titre d'exemple, un patient dont le père est atteint de la maladie de Huntington⁶¹, une maladie à caractère dominant, a un risque de 50% d'avoir cette maladie⁶². Si le patient est un homme asymptomatique âgé de 65 ans, les risques d'avoir la maladie de Huntington diminuent puisque l'âge moyen de survenue de cette maladie est généralement entre 35 et 44 ans⁶³. Il est important d'ajouter qu'aujourd'hui, un test génétique prédictif est disponible pour les patients à risques qui veulent savoir s'ils ont les gènes causant cette maladie, et ce, grâce à la découverte du gène responsable de la maladie de Huntington en 1993⁶⁴. Malgré l'existence de ce test, l'évaluation des risques demeure une étape importante pour déterminer si ce test génétique est indiqué ou non pour le patient en consultation.

Finalement, il est important de noter que l'interprétation des risques d'occurrence d'une maladie génétique peut être influencée par les résultats de tests de laboratoire⁶⁵. Le syndrome de Duchenne en est un bon exemple. En effet, les femmes porteuses de cette maladie – caractérisée par une dystrophie des muscles du corps – ont, parmi d'autres indications cliniques, une quantité élevée de *serum creatine kinase*⁶⁶. L'évaluation des risques d'occurrence d'une maladie génétique consiste donc en une étape importante dans les tâches du conseiller en génétique, car elle peut déterminer les

⁶¹ Voir le site de la Société Huntington du Canada, en ligne : Société Huntington du Canada <www.huntingtonsociety.ca/english/content/?page=91>. La maladie de Huntington est une affection cérébrale héréditaire qui provoque la destruction des cellules de certaines parties spécifiques du cerveau.

⁶² Harper, *supra* note 27 à la p 26.

⁶³ Simon C Warby, Rona K Graham et Michael R Hayden, « Huntington Disease », en ligne: National Center for Biotechnology Information, *GeneReviews* <www.ncbi.nlm.nih.gov/books/NBK1305/>.

⁶⁴ The Huntington's Disease Collaborative Research Group, « A Novel Gene Containing a Trinucleotide Repeat that is Expanded and Unstable on Huntington's Disease Chromosomes » (1993) 72: 6 Cell 971.

⁶⁵ Uhlmann, *supra* note 42 à la p 109.

⁶⁶ A Y Manzur, M Kinali et F Muntoni, « Update on the Management of Duchenne Muscular Dystrophy » (2008) 93 : 11 Archives of Disease in Childhood 986 à la p 987. Voir aussi Victor Dubowitz, « The female carrier of Duchenne muscular dystrophy » (1982) 284: 6327 Br Med J (Clin Res Ed)1423 dans Hugo R Martinez et al, « Childhood Onset of Left Ventricular Dysfunction in a Female Manifesting Carrier of Muscular Dystrophy » (2011) 155: 12 Am J Med Genet Part A 3025 ¶ 3025.

actions ultérieures que devront prendre les patients⁶⁷.

c. La coordination des examens génétiques et diagnostiques

La coordination des examens génétiques et diagnostiques réfère, entre autres, à l'exploration des options de tests génétiques et diagnostiques avec le patient⁶⁸. D'ailleurs, si le patient asymptomatique risque d'être atteint d'une maladie génétique, le « test présymptomatique » peut être envisagé⁶⁹. Par exemple, une femme enceinte âgée de 45 ans qui s'inquiète que son enfant puisse être atteint du syndrome de Down peut voir ses craintes confirmées ou infirmées par le test de diagnostic prénatal.

Le rôle du conseiller en génétique ne se limite pas seulement à l'exploration des options envisageables. Il inclut également l'évaluation de l'applicabilité de ces options à la maladie du patient et l'explication de la teneur de tels tests à ce dernier afin de lui permettre de donner un consentement libre et éclairé⁷⁰.

Il est essentiel de mentionner qu'en droit québécois, la prescription des tests génétiques et diagnostiques est un acte réservé au médecin ayant un permis d'exercice au Québec⁷¹. Donc comme le conseiller en génétique ne peut prescrire, il doit laisser cette tâche au médecin.

4. L'étape de l'après-consultation

Si la consultation préliminaire se termine avec une demande de tests génétiques, l'étape suivante consiste à la réception des résultats de ces tests. À ce stade, le rôle primordial du conseiller en génétique est de s'assurer que

⁶⁷ Uhlmann, *supra* note 42 à la p 109.

⁶⁸ *Ibid* à la p 114.

⁶⁹ Ces tests « sont effectués auprès d'individus asymptomatiques et visent à déterminer s'ils ont une mutation génétique responsable du développement d'une maladie inscrite dans leurs gènes. Malgré le fait que les tests présymptomatiques permettent de savoir si telle personne sera ou non atteinte, le moment du début de la maladie et sa sévérité demeurent incertains. » Voir le site HumGen, en ligne : HumGen <www.humgen.org/int/faq.cfm?Idsuj=1&lang=2>, section FAQ.

⁷⁰ *ST c Dubois*, 2008 QCCS 1431 au para 75, [2008] RRA 481 ; Uhlmann, *supra* note 42 aux pp 112-13.

⁷¹ *Loi médicale*, *supra* note 39, art 31(6).

l'interprétation n'est pas erronée⁷².

Suite à cette vérification, le conseiller en génétique communique avec son patient afin de lui transmettre les résultats⁷³. Cette communication peut se faire par téléphone ou lors d'une rencontre personnelle. Cette dernière méthode est encouragée, car elle peut favoriser les échanges et permettre au patient de partager ses inquiétudes⁷⁴. Le conseiller en génétique a donc la possibilité d'apporter un soutien psychologique plus efficace à son patient. Enfin, il coordonne aussi les soins du patient en transmettant, si nécessaire, son dossier aux autres professionnels de la santé⁷⁵.

Après avoir exploré les différentes tâches du conseiller en génétique, nous examinons à présent son statut juridique au Québec ainsi que les éléments de responsabilité civile en jeu.

II. Les conseillers en génétique et les professions médicales et infirmières: y a-t-il un risque d'empiètement ?

A. Les tâches du conseiller en génétique et le rôle du médecin généticien

Sachant que le conseil génétique fait partie *a priori* des attributions du médecin généticien⁷⁶, il est intéressant de considérer le risque d'empiètement de certaines des tâches du conseiller en génétique au Québec sur la pratique médicale.

Pour ce faire, il faut d'abord s'en remettre à la définition de la pratique médicale prévue dans la *Loi médicale*. En effet, selon l'article 31 de cette *Loi* :

L'exercice de la médecine consiste à évaluer et à diagnostiquer toute déficience de la santé de l'être humain, à prévenir et à traiter les maladies dans le but de maintenir la santé ou de la rétablir.

⁷² Uhlmann, *supra* note 42 à la p 122.

⁷³ *Ibid* à la p 123.

⁷⁴ *Ibid* à la p 124.

⁷⁵ *Ibid* à la p 128.

⁷⁶ Walker, *supra* note 6 à la p 17.

Dans le cadre de l'exercice de la médecine, les activités réservées au médecin sont les suivantes:

- 1° diagnostiquer les maladies ;
- 2° prescrire les examens diagnostiques ;
- 3° utiliser les techniques diagnostiques invasives ou présentant des risques de préjudice ;
- 4° déterminer le traitement médical ;
- 5° prescrire les médicaments et les autres substances ;
- 6° prescrire les traitements [...]⁷⁷.

Entrée en vigueur le 30 janvier 2003, cette version de l'article 31 énonce d'une manière exhaustive, et du coup précise, les actes réservés aux médecins. La version précédente, qui datait de 1973, était « très large, voire illimitée »⁷⁸. En effet, selon cette ancienne version :

Constitue l'exercice de la médecine tout acte qui a pour objet de diagnostiquer ou de traiter toute déficience de la santé d'un être humain.

L'exercice de la médecine comprend, notamment, la consultation médicale, la prescription de médicaments ou de traitements, la radiothérapie, la pratique des accouchements, l'établissement et le contrôle d'un diagnostic, le traitement de maladies ou d'affections⁷⁹.

Tel que l'énonce le juge Tôth de la Cour supérieure du Québec dans l'affaire *Collège des médecins c Galipeau*, le premier alinéa visait « tout acte » tandis que le deuxième alinéa énumérait les activités des médecins d'une manière non limitative. Selon la Cour, ce changement législatif, en 2003, n'a pas modifié la définition de la médecine, mais a offert une meilleure explication de ses champs d'activités professionnelles⁸⁰. Nous revenons sur ce point particulier lors de notre discussion sur les actes partagés et les actes délégués.

Toujours selon la Cour supérieure, puisque la *Loi médicale* établit les

⁷⁷ *Supra* note 39, art 31.

⁷⁸ *Collège des médecins du Québec c Galipeau*, 2008 QCCS 2983 au para 9 (disponible sur WL Can) [*Galipeau*].

⁷⁹ *Loi médicale*, LRQ 1973, c M-9.

⁸⁰ *Supra* note 78 aux para 11 et 12.

activités réservées aux médecins, elle doit recevoir une interprétation stricte⁸¹. Par conséquent, « [...] ce qui est exclusivement réservé aux professionnels ne peut pas être fait par un non-professionnel. Autrement, on perd de vue l'objet de la loi. »⁸² Advenant un recours en responsabilité pénale pour exercice illégal, la Cour doit également prendre en compte l'objet ainsi que la finalité de l'acte afin de décider s'il s'agit d'un empiètement ou non⁸³. Puisqu'une telle décision résulte d'une évaluation purement circonstancielle, nous nous attardons, aux fins de ce texte, à analyser comment certaines tâches du conseiller en génétique risquent d'empiéter sur celles d'autres professions.

Le conseiller en génétique accomplit deux tâches problématiques au regard de l'exercice protégé de la pratique médicale : l'évaluation de risques (point 1) et la contribution aux démarches diagnostiques du médecin par l'anamnèse et la coordination des examens génétiques et diagnostiques (point 2). En d'autres termes, ce n'est pas l'intégralité des tâches du conseiller en génétique qui recoupe l'exercice exclusif de la profession médicale. Aux fins de cette analyse, nous étudions les deux tâches mentionnées ci-dessus au regard du rôle du médecin consistant à « diagnostiquer les maladies »⁸⁴.

1. L'évaluation des risques : une forme de diagnostic médical ?

Tel que mentionné précédemment, nous entendons par « évaluation des risques », l'évaluation des risques d'occurrence d'une maladie génétique. Cette étape est déterminante lorsque le patient confirme qu'il s'agit de la raison unique de sa consultation.

Ceci étant dit, les développements récents dans le domaine de la génétique permettent dorénavant de subir des tests génétiques pouvant

⁸¹ *Ibid* au para 13.

⁸² *Ibid* au para 14.

⁸³ *Corporation professionnelle des médecins du Québec c Larivière*, [1984] CA 365 (disponible sur WL Can) ; *Ordre des podiatres du Québec c Auger*, 2002 CanLII 38960, 2002 CarswellQue 1162 (WL Can) (CQ crim & pén) [*Auger*].

⁸⁴ Cette affirmation a pour contexte une consultation génétique, sachant que le dentiste peut également diagnostiquer certaines maladies. Voir *Loi sur les dentistes*, LRQ c D-3, art 26.

détecter certaines maladies monogéniques⁸⁵, telles que la maladie de Huntington⁸⁶. Ces tests identifient, avec un degré de certitude élevé, l'existence d'une mutation génétique associée à l'avènement de la maladie. Malgré cela, et tel que nous l'avons soulevé plus tôt, les conseillers en génétique continuent d'utiliser l'évaluation traditionnelle des risques afin d'identifier les patients à haut risque pour qui ces tests sont recommandés. Autrement dit, malgré l'existence de tests génétiques d'une grande précision, l'évaluation des risques demeure une étape, au moins préliminaire, permettant de décider si un certain test est indiqué ou non⁸⁷. De plus, il est important de préciser qu'en principe, lesdits tests sont volontaires et ne sont pas obligatoires. Par conséquent, le patient peut décider de ne pas les subir⁸⁸, ce qui rend nécessaire le recours à l'évaluation des risques pour ces cas particuliers.

Plus encore, les évaluations de risques peuvent également être utilisées par les conseillers en génétique pour déterminer les risques d'occurrence des maladies multifactorielles⁸⁹ pour lesquelles aucun test génétique n'a encore été développé⁹⁰.

⁸⁵ Une maladie est dite monogénique quand sa genèse est provoquée par la mutation d'un seul gène. Voir par ex le site de l'Institut national de la santé et de la recherche médicale, en ligne : Institut national de la santé et de la recherche médicale <www.inserm.fr/de-a-a-z/maladie-monogenique>.

⁸⁶ En ce qui a trait aux tests génétiques pour la maladie d'Huntington, voir Warby, Graham et Hayden, *supra* note 63.

⁸⁷ Uhlmann, *supra* note 42 à la p 113.

⁸⁸ Association Médicale Mondiale, « Prise de position de l'Association Médicale Mondiale sur la génétique et la médecine », Santiago, 2005, art 16, en ligne: AMM <www.wma.net/fr/30publications/10policies/g11/>.

⁸⁹ Une maladie est dite multifactorielle quand son apparition renvoie à divers facteurs génétiques et environnementaux. Voir par ex le site de l'Institut national de la santé et de la recherche médicale, en ligne : Institut national de la santé et de la recherche médicale <www.inserm.fr/de-a-a-z/maladie-multifactorielle>.

⁹⁰ Voir William M McMahon, Bonnie Jeanne Baty et Jeffrey Botkin, « Genetic counseling and ethical issues for autism » (2006) 142C : 1 American Journal of Medical Genetics : Seminars of Medical Genetics 52 à la p 53. En effet, les auteurs nous informent qu' « [i]n the absence of genetic testing based on known loci or mutations, empiric risk estimates are the foundation for the genetic counseling. »

En somme, que ce soit pour une maladie monogénique, polygénique⁹¹ ou multifactorielle, l'évaluation des risques chez un patient demeure une étape importante puisqu'elle permet de déterminer les actions ultérieures à entreprendre⁹². Toutefois, il reste à savoir si cette évaluation ne s'apparente pas à un diagnostic médical. Afin de répondre à cette question, un survol de la législation et de la jurisprudence pertinente s'avère nécessaire.

Tout d'abord, la *Loi médicale* prévoit expressément que l'action de diagnostiquer une maladie relève de la compétence exclusive du médecin pratiquant au Québec⁹³. Elle n'offre, par ailleurs, aucune définition du terme « diagnostiquer ». À ce sujet, il faut examiner la jurisprudence et la doctrine pour clarifier la portée de ce terme et déterminer si l'évaluation des risques s'y apparente.

En ce qui concerne le terme « diagnostic », la jurisprudence mentionne la nécessité d'y donner une interprétation large⁹⁴. Donc pour les tribunaux québécois, la simple observation par un non-médecin du blocage de la jugulaire d'un individu⁹⁵, ou le fait d'affirmer à quelqu'un qu'il ne souffre d'aucun cancer⁹⁶, constituent des diagnostics médicaux.

De leur côté, les auteurs Baudouin et Deslauriers proposent de définir le diagnostic comme « l'opinion donnée par le médecin sur l'état de son patient, à la suite des révélations faites par ce dernier, des tests médicaux que celui-ci a pu subir et des propres observations du professionnel »⁹⁷.

⁹¹ Une maladie polygénique est une maladie génétique causée par l'action combinée d'au moins deux gènes. Voir *Medical Terms: Online Medical Dictionary/Glossary*, « Polygenic Disease » en ligne : www.medicaltermsonline.org/index.php?section=pages&item=Polygenic-disease.

⁹² Uhlmann, *supra* note 42 à la p 114.

⁹³ *Supra* note 39, art 31.

⁹⁴ *Collège des médecins du Québec c Provencher*, 2005 CanLII 3754, 2005 CarswellQue 630 (WL Can) (CQ crim & pén) au para 28 [*Provencher*] ; *Collège des médecins du Québec c Demers*, [1999] RJQ 3080 (disponible sur CanLII) (CQ).

⁹⁵ *Collège des médecins du Québec c Labonté*, 2006 QCCQ 6346 (disponible sur WL Can).

⁹⁶ *Provencher*, *supra* note 94.

⁹⁷ Jean-Louis Baudouin et Patrice Deslauriers, *La responsabilité civile*, 7^e éd, Cowansville (Qc), Yvon Blais, 2007 aux para 2-67.

L'évaluation des risques répond bien à cette définition puisque le diagnostic est une opinion (probabilité d'occurrence d'une maladie génétique) exprimée suite à des informations données par un patient (âge, historique familial...). Quant à l'étape de l'examen physique, les patients qui reçoivent une évaluation des risques sont dans la plupart des cas asymptomatiques⁹⁸, ce qui rend cette étape plus ou moins nécessaire lors d'une telle consultation.

De plus, le fait qu'une évaluation des risques soit produite sous la forme d'un pourcentage et qu'elle n'offre pas de réponse tranchée n'empêche pas de la comparer au diagnostic puisque ce dernier n'est pas toujours exact et est susceptible de comporter des erreurs⁹⁹. L'aspect préventif qui caractérise l'évaluation de risques de prédisposition s'accorde bien avec la définition législative de la pratique médicale¹⁰⁰. En effet, l'exercice de la médecine, tel qu'énoncé par l'article 31 de la *Loi médicale*, ne se limite pas seulement au traitement des maladies; il inclut également la prévention de celles-ci. Plus particulièrement, dans le domaine de la génétique, le médecin fournit davantage un pronostic dans la mesure où il cherche à prévoir l'évolution d'une maladie lorsqu'il élabore son diagnostic¹⁰¹. Ces aspects de prévention et de prévisibilité caractérisant le diagnostic ont été reconnus par la Cour du Québec dans l'affaire *Collège des médecins c Provencher* lorsque le juge Bonin a précisé que le « diagnostic s'entend aussi de prévisions de malaises probables suivant l'état d'une personne »¹⁰². Il souligne également que le diagnostic consiste en un examen par méthode scientifique. Cette définition est importante ici, car l'évaluation des risques produite par le conseiller en génétique se veut une prévision des malaises probables, mais fondée sur des méthodes de calcul statistique dont l'une d'entre elles est mieux connue sous le nom de *Bayesian analysis*¹⁰³.

À la lumière de l'analyse qui précède, il est raisonnable de conclure que, par son caractère préventif et scientifique, l'évaluation des risques prodiguée par le conseiller s'apparente à la formulation d'un diagnostic médical. Par conséquent, une telle approche risque d'empiéter sur le champ de pratique exclusif du médecin. Le législateur est donc appelé à clarifier cette situation

⁹⁸ Presseault, *supra* note 7.

⁹⁹ Baudouin et Deslauriers, *supra* note 97 aux para 2-67.

¹⁰⁰ *Loi médicale*, *supra* note 39, art 31.

¹⁰¹ Presseault, *supra* note 7.

¹⁰² *Provencher*, *supra* note 94 au para 28.

¹⁰³ Uhlmann, *supra* note 42 à la p 108. Pour un rappel du *Bayesian analysis*, voir *supra* note 59.

en encadrant le rôle du conseiller en génétique. De plus, l'évaluation des risques n'est pas la seule tâche qui s'apparente au diagnostic médical. L'anamnèse et la coordination des examens génétiques et diagnostiques, prises conjointement, risquent également d'empiéter sur la pratique médicale.

2. La contribution à l'établissement d'un diagnostic : faire indirectement ce que l'on ne peut faire directement

Une seconde façon pour un patient de consulter un conseiller en génétique consiste à être référé par son médecin traitant¹⁰⁴. Cette référence vise essentiellement à confirmer et parfois à découvrir la nature des symptômes dont souffre ce patient. Cependant, le rôle du conseiller en génétique lors de ce processus n'est pas entièrement défini et n'est pas sujet à des directives internes de l'hôpital dans lequel il œuvre. Ceci nous amène à nous interroger sur la marge de manœuvre permise et l'empiètement susceptible de se produire sur la pratique médicale.

Nous avons déjà noté que le conseiller en génétique joue un grand rôle lors de la consultation au département de génétique d'un hôpital, notamment lors de l'anamnèse et de la coordination des examens génétiques et diagnostiques. Il est intéressant de voir si ces tâches s'apparentent aux démarches entreprises par le médecin pour arriver à un diagnostic médical. Dans la section précédente (point 1), nous avons étudié comment l'évaluation des risques s'apparente à un diagnostic médical. Dans cette section, il s'agit plutôt d'analyser certaines des tâches principales du conseiller en génétique et d'évaluer comment, lorsque considérées dans leur ensemble, elles empiètent sur les démarches entreprises par le médecin pour arriver à un diagnostic.

En effet, la notion de « diagnostic » exige d'entreprendre une série de démarches qui aboutissent à un diagnostic médical¹⁰⁵. En d'autres termes, un médecin ne peut établir un diagnostic sans avoir effectué plusieurs étapes lui permettant de se prononcer¹⁰⁶.

¹⁰⁴ *Ibid* aux pp 93, 95.

¹⁰⁵ Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 aux pp 274-83.

¹⁰⁶ Jean-Pierre Ménard, « L'erreur de diagnostic : fautive ou non fautive » dans Barreau du Québec, Service de la Formation permanente, *Développements récents*

Cette notion de démarche diagnostique transparait dans la jurisprudence québécoise¹⁰⁷. Elle se trouve également dans la doctrine traitant de ce sujet. En effet, les auteurs Phillips-Nootens, Lesage-Jarjoura et Kouri expliquent que le diagnostic comprend quatre composantes importantes : 1) l'anamnèse; 2) l'examen physique; 3) les examens de laboratoire et paracliniques; et 4) l'établissement du diagnostic¹⁰⁸. Nul besoin de préciser que ces étapes relèvent toutes de la responsabilité du médecin. En effet, lorsque ce dernier est poursuivi pour une erreur de diagnostic, la Cour ne se limite pas à l'analyse de la validité du diagnostic établi, mais vérifie plutôt la justesse des actions entreprises pour arriver à un tel diagnostic¹⁰⁹.

À ce sujet, les auteurs Baudouin et Deslauriers précisent que pour déterminer s'il y a faute, le tribunal doit, entre autres, considérer 1) si le médecin a utilisé les bonnes méthodes et les techniques appropriées pour arriver à son diagnostic; 2) si le médecin a évalué les risques pour le patient en fonction du recours aux différentes techniques de diagnostic possibles en l'espèce et 3) s'il a « utilisé des méthodes couramment acceptées » pour arriver à son diagnostic¹¹⁰.

Dans le cas qui nous préoccupe, la majorité des démarches sont effectuées par le conseiller en génétique. C'est en effet ce dernier qui rencontre le patient et qui lui pose des questions détaillées, à la fois pour recueillir les informations pertinentes et pour connaître la véritable raison de sa consultation. De plus, il coordonne les examens diagnostiques, ce qui inclut la divulgation de la nature et de l'objectif du traitement ou de l'intervention (tests génétiques) ainsi que les choix thérapeutiques possibles. Ceci nous amène à conclure que ces tâches, considérées dans leur ensemble, risquent d'empiéter sur la pratique médicale¹¹¹, car le conseiller en génétique n'aurait qu'à prodiguer un examen physique - lequel n'est pas toujours nécessaire - et à contresigner le diagnostic établi par le généticien, grâce aux démarches qu'il a lui-même entreprises, pour compléter le processus requis

en responsabilité médicale et hospitalière, Cowansville, Yvon Blais, 2005, 247 aux pp 264-65.

¹⁰⁷ *Collège des médecins du Québec c Galipeau*, 2007 QCCQ 6585 au para 26 (disponible sur CanLII), inf par 2008 QCCS 2983 ; *Provencher*, *supra* note 94 au para 28.

¹⁰⁸ *Supra* note 44 aux pp 273-83.

¹⁰⁹ Ménard, *supra* note 106 aux pp 259-61.

¹¹⁰ *Supra* note 97 aux para 2-68.

¹¹¹ Phillips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 à la p 145.

pour diagnostiquer une maladie génétique.

Ceci étant dit, la question qui se pose devient la suivante : le conseiller en génétique profite-t-il d'actes partagés avec les médecins l'habilitant à faire les tâches mentionnées précédemment ? La section suivante tente d'y répondre.

B. Les conseillers en génétique bénéficient-ils d'actes partagés avec les médecins ?

En 2002, le Ministre de la Justice Paul Bégin fait adopter, par l'Assemblée nationale, un projet de loi visant à modifier le *Code des professions* ainsi que d'autres dispositions législatives dans le domaine de la santé¹¹². Cette loi a notamment pour but « d'effectuer un nouveau partage des éléments de cette exclusivité [dans le champ de la pratique médicale] entre différents professionnels compétents et d'en assouplir les conditions d'exercice »¹¹³. Cette loi élargit donc les champs de compétences de certains professionnels afin de leur permettre d'accomplir certains actes qui, jusque-là, étaient réservés aux médecins.

Aujourd'hui, l'article 43 de la *Loi médicale* incorpore ce principe lorsqu'il édicte que « sous réserve des droits et privilèges expressément accordés par la loi à d'autres professionnels, nul ne peut exercer l'une des activités décrites au deuxième alinéa de l'article 31, s'il n'est pas médecin »¹¹⁴. De ce fait, certains professionnels peuvent partager des actes avec le médecin si le législateur l'a prévu expressément. À titre d'illustration et en ce qui a trait plus précisément à la démarche diagnostique, le législateur a remplacé l'ancien article 36 de la *Loi sur les infirmières et les infirmiers* afin que dorénavant, l'infirmière puisse « initier des mesures diagnostiques et thérapeutiques, selon une ordonnance »¹¹⁵. Afin de protéger le public, le législateur a cru bon, d'une part, de prévoir explicitement ce partage dans la *Loi sur les infirmières et les infirmiers* et, d'autre part, de ne permettre cet

¹¹² PL 90, *Loi modifiant le Code des professions et d'autres dispositions législatives dans le domaine de la santé*, 2^e sess, 36^e lég, Québec, 2002.

¹¹³ Québec, Assemblée nationale, *Journal des débats de l'Assemblée nationale*, 36^e lég, 2^e ses, vol 37 (12 juin 2002) 20h20 (Paul Bégin).

¹¹⁴ *Supra* note 39, art 43.

¹¹⁵ *Supra* note 39, art 36.

acte qu'à la suite d'une ordonnance de la part du médecin selon le *Règlement sur les normes relatives aux ordonnances faites par un médecin*¹¹⁶.

Le conseiller en génétique n'est ni encadré par le *Code des professions* ni par une loi constitutive; le législateur n'a pas prévu d'actes partagés avec les médecins. En d'autres termes, le conseiller en génétique contribue de façon active à l'établissement d'un diagnostic médical sans y être formellement habilité.

C. Le conseil génétique est-il un acte médical délégué ?

Étant donné que le conseiller en génétique ne profite pas d'une autorisation législative pour prodiguer certains actes médicaux propres aux médecins, voyons maintenant si le législateur prévoit un mécanisme de délégation justifiant l'empiétement sur la pratique médicale.

1. Le principe de la délégation de l'acte médical

Dans l'optique d'un manque de ressources, le législateur québécois a créé un deuxième mécanisme juridique permettant l'exécution de certains actes médicaux par des personnes autres que des médecins, soit celui de la délégation¹¹⁷.

Il s'agit, en effet, d'un pouvoir octroyé par le *Code des professions*.

Le Conseil d'administration [d'un ordre] peut, par règlement:

[...]

h) déterminer, parmi les activités professionnelles que peuvent exercer les membres de l'ordre, celles qui peuvent être exercées par les personnes ou les catégories de personnes que le règlement indique [...] ainsi que les conditions et modalités suivant lesquelles elles peuvent les exercer; ce règlement peut déterminer parmi les normes réglementaires applicables aux membres, celles applicables aux personnes qui ne sont pas membres d'un ordre; sauf s'il s'agit d'autoriser l'exercice d'une activité professionnelle aux personnes inscrites à un programme donnant ou-

¹¹⁶ RRQ, c M-9, r 25.

¹¹⁷ Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 à la p 117.

verture au permis de l'ordre ou effectuant un stage de formation professionnelle, le Conseil d'administration doit, avant d'adopter un règlement en vertu du présent paragraphe, consulter tout ordre dont les membres exercent une activité professionnelle qui y est visée¹¹⁸.

À cet effet, l'article 19 de la *Loi médicale* dispose :

En outre des devoirs prévus aux articles 87 à 93 du Code des professions (chapitre C-26), le Conseil d'administration doit, par règlement:

[...]

b) déterminer parmi les activités visées au deuxième alinéa de l'article 31 celles qui, suivant certaines conditions prescrites, peuvent être exercées par des classes de personnes autres que des médecins [...]

Dans la même veine, le paragraphe d) du deuxième alinéa de l'article 43 de la *Loi médicale* prévoit :

Sous réserve des droits et privilèges expressément accordés par la loi à d'autres professionnels, nul ne peut exercer l'une des activités décrites au deuxième alinéa de l'article 31, s'il n'est pas médecin.

Les dispositions du présent article ne s'appliquent pas aux activités exercées:

[...]

d) par une personne faisant partie d'une classe de personnes visée dans un règlement pris en application du paragraphe b) du premier alinéa de l'article 19, pourvu qu'elle les exerce suivant les conditions qui y sont prescrites¹¹⁹.

Le législateur québécois a mis en place plusieurs règlements déléguant à des personnes autres que des médecins la possibilité de pratiquer des actes

¹¹⁸ *Code des professions*, LRQ c C-26, art 94(h) [*Code des professions*].

¹¹⁹ *Supra* note 39, art 43.

médicaux. En effet, le *Règlement sur les activités visées à l'article 31 de la Loi médicale qui peuvent être exercées par des classes de personnes autres que des médecins* vise spécifiquement trois types de personnes, soit les infirmières premières assistantes en chirurgie, les infirmières praticiennes spécialisées et les « autres personnes »¹²⁰. La dernière catégorie est constituée de la candidate infirmière praticienne spécialisée ainsi que de l'infirmière inscrite dans un programme universitaire hors Québec menant à l'obtention d'un diplôme d'infirmière praticienne spécialisée¹²¹. Ce règlement spécifie pour chacune des catégories visées l'expérience nécessaire ainsi que les actes autorisés. Le *Règlement sur les activités professionnelles qui peuvent être exercées par des personnes autres que des médecins* est un autre exemple de règlement permettant la délégation de certains actes médicaux. Ce règlement vise les étudiants en médecine ainsi que les moniteurs, soit toute personne qui effectue un stage de perfectionnement dans le cadre d'un programme universitaire dans le domaine clinique ou de la recherche¹²². D'autres règlements de délégation existent également et visent autant des professionnels que des non-professionnels. Nous pouvons citer, notamment : le *Règlement sur une activité professionnelle pouvant être exercée par un préposé ou mécanicien en orthopédie*, le *Règlement sur les activités professionnelles pouvant être exercées dans le cadre des services et soins préhospitaliers d'urgence*, le *Règlement sur les activités professionnelles pouvant être exercées par un orthoptiste* et le *Règlement sur les activités professionnelles qui peuvent être exercées par des personnes autres que des ergothérapeutes*, tels les étudiants et les stagiaires en ergothérapie¹²³.

¹²⁰ RRQ 1981, c M-9, r 13, art 1 [Règlement sur les activités visées à l'article 31 de la Loi médicale].

¹²¹ *Ibid*, art 9-10.

¹²² RRQ, c M-9, r 12.1, art 1 para 2.

¹²³ *Règlement sur une activité professionnelle pouvant être exercée par un préposé ou mécanicien en orthopédie*, RRQ, c M-9, r 9 ; *Règlement sur les activités professionnelles pouvant être exercées dans le cadre des services et soins préhospitaliers d'urgence*, RRQ, c M-9, r 2 ; *Règlement sur les activités professionnelles pouvant être exercées par un orthoptiste*, RRQ, c M-9, r 8 ; *Règlement sur les activités professionnelles qui peuvent être exercées par des personnes autres que des ergothérapeutes*, RRQ, c C-26, r 107, art 1.

2. L'absence de délégation de l'acte médical dans le cas du conseiller en génétique

Afin d'accomplir légitimement un acte médical en vertu de la délégation, il faut être expressément visé par un des règlements mentionnés dans la section plus haut¹²⁴, ce qui n'est pas le cas du conseiller en génétique. En effet, il n'existe aucun règlement prévoyant, ou même mentionnant, que ce dernier peut exercer des actes médicaux propres aux médecins. Cette réalité, au Québec, diffère grandement de celle connue en Nouvelle-Écosse où une requête par le *Maritime Medical Genetics Service* au Collège des médecins et chirurgiens de la province, en 2003, a permis au médecin de déléguer trois de ses fonctions aux conseillers en génétique, soient 1) la détermination des tests de laboratoires requis par l'état du patient; 2) la référence de ce dernier à d'autres professionnels de la santé et 3) la communication des résultats au patient ainsi qu'au médecin traitant¹²⁵.

Au Québec, l'absence de délégation de l'acte médical peut engendrer, entre autres, la responsabilité civile du conseiller en génétique. La faute civile étant de nature contractuelle selon les principes de l'article 2098 CcQ, elle constitue, par conséquent, la transgression d'un devoir assumé par convention¹²⁶. Ce devoir découle des obligations qu'assume le conseiller envers son patient¹²⁷. À cet égard, le *Code d'éthique des conseillers en génétique canadiens* prévoit que le conseiller en génétique « agira dans le meilleur intérêt de ses patients [...] et référera à d'autres professionnels si

¹²⁴ Jean-Guy Villeneuve, « L'exercice illégal, tenants, aboutissants et troubles de voisinage professionnel » dans *Développement récents en déontologie, droit professionnel et disciplinaire (2009)*, Service de la Formation continue, Barreau du Québec, Cowansville (Qc), Yvon Blais, 2009, 1 à la p 19.

¹²⁵ Halifax, College of Physicians and Surgeons of Nova Scotia, *Décision du 24 octobre 2003* (octobre 2003). Cette décision approuve la demande du Maritime Medical Genetics Service soumise quelques mois plus tôt : Maritime Medical Genetics Service, *Application for Delegated Medical Functions*, soumise au College of Physicians and Surgeons of Nova Scotia (27 août 2003).

¹²⁶ Cet article du CcQ s'applique bien au cas du conseiller en génétique qui fournit des conseils lors de sa consultation avec son patient moyennant une somme généralement versée à titre de soin de santé à l'institution pour laquelle il travaille ; Baudouin et Deslauriers, *supra* note 97 aux para 1-180.

¹²⁷ *Ibid.*

nécessaire. »¹²⁸ De plus et toujours selon le *Code d'éthique*, il doit tenir compte de ses propres limites et y être attentif lorsqu'il accepte de recevoir un patient en consultation¹²⁹. Ainsi, si le conseiller en génétique fournit un service pour lequel il n'a pas la compétence légale requise, telle que la production d'un diagnostic ou la prescription d'un test génétique ou d'un médicament, il doit référer le patient au professionnel compétent, en l'occurrence, le médecin généticien.

Bref, devant l'absence de législation spécifique régissant la pratique des conseillers en génétique, le fait de prodiguer des services empiétant sur la pratique médicale sans avoir la compétence légale requise (actes partagés ou délégués) constitue, selon la probabilité de la preuve, une faute civile pour ledit conseiller.

3. Responsabilité du médecin délégant dans une situation d'absence de délégation de l'acte médical

Après avoir vu qu'une délégation illégale peut entraîner la responsabilité civile du conseiller en génétique (délégué), qu'en est-il de la responsabilité du médecin (délégant)? Pour répondre, il faut tout d'abord évaluer la nature de l'obligation du médecin traitant lors de la délégation d'actes médicaux.

Selon la doctrine, l'obligation du médecin, lors d'une délégation légale, est une obligation de surveillance¹³⁰. Cette dernière en est une de résultat et non de moyens¹³¹. Devant un acte médical délégué illégalement au conseiller en génétique, nous parlons d'une faute de délégation plutôt que d'une surveillance inadéquate¹³².

À titre d'illustration, dans une affaire portée devant la Cour d'appel du Québec, on a reproché à un anesthésiste de s'être absenté de la salle d'opération et d'avoir été assisté par une personne non qualifiée et un

¹²⁸ *Code d'éthique des conseillers en génétique canadiens (2006)*, en ligne : Association Canadienne des Conseillers en Génétique <cagc-accg.ca/images/docs/Professional_Issues/code%20of%20ethics%20f-071107.pdf> [Code d'éthique des conseillers en génétique canadiens].

¹²⁹ *Ibid.*

¹³⁰ Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 à la p 119.

¹³¹ *Ibid.*

¹³² *Ibid* à la p 120.

personnel insuffisant¹³³. Dans ce cas précis, il s'agissait d'une étudiante en inhalothérapie. Il s'agirait donc d'une délégation fautive que de se fier à un personnel qui ne répond pas aux exigences de la loi¹³⁴. Ceci dit, dans l'éventualité où un préjudice survient suite à une telle délégation illégale d'un acte médical par un médecin, les tribunaux peuvent conclure au partage de la responsabilité entre le délégant et le délégué¹³⁵.

4. Responsabilité du médecin traitant dans une situation d'absence de délégation de l'acte médical

Tel que mentionné antérieurement, un des deux moyens permettant de consulter un conseiller en génétique consiste en une demande de consultation par le médecin traitant au service de génétique. La question qui se pose est la suivante : qu'encourt le médecin traitant dans l'éventualité d'une délégation illégale faite par le généticien au conseiller en génétique?

Pour ce faire, il est important de comprendre la dynamique qui existe entre le médecin traitant et le médecin consultant (donc ici le généticien). Tout d'abord, il faut distinguer le transfert pur et simple de la consultation. Un transfert pur et simple exonère le médecin traitant initial de ses responsabilités et de son obligation de suivre son patient, tandis qu'une consultation vise à obtenir l'avis d'un médecin d'une spécialité différente pour faire une investigation¹³⁶. Dans ce dernier cas, le médecin traitant conserve ses responsabilités et son obligation de suivre son patient. Dans le cas qui nous occupe, les demandes au département de génétique par les médecins sont généralement des demandes de consultation. Conséquemment, les réponses doivent être acheminées au médecin traitant. En ce qui a trait à la responsabilité de ce dernier lors d'une consultation, la doctrine prétend qu'elle est limitée. La position traditionnelle veut que le médecin traitant ne suive pas les recommandations du spécialiste aveuglément, mais qu'il

¹³³ *Houde c Côté*, [1987] RJQ 723 (CA) à la p 738, 4 QAC 112.

¹³⁴ Philips-Nootens, Lesage- Jarjoura et Kouri, *supra* note 44 à la p 120, commentant sur *Houde c Côté*, *ibid*.

¹³⁵ Pour des informations sur la responsabilité et la délégation d'un acte médical, voir *ibid* à la p 120 ; Jean-Pierre Ménard et Denise Martin, *La responsabilité médicale pour la faute d'autrui*, Cowansville, Yvon Blais, 1992 aux pp 100-03. Le partage de la responsabilité pour un préjudice causé par plusieurs personnes est traité à l'art 1478 CcQ.

¹³⁶ Philips-Nootens, Lesage-Jarjoura et Kouri, *supra* note 44 aux pp 287-88.

s'assure qu'elles sont appropriées afin de ne pas commettre d'actes fautifs pour lesquels il serait tenu responsable¹³⁷. Cependant, des auteurs nuancent cette position en prévoyant qu'advenant une faute commise par le médecin consultant causant un préjudice, le médecin traitant ne sera tenu responsable que des faits qu'il aurait pu, ou aurait dû, contrôler¹³⁸. Nous sommes d'avis que les mêmes principes s'appliquent à une délégation de tâche non prévue par la loi dans le cadre de laquelle le médecin généticien délègue l'exercice d'actes qui lui sont réservés à un conseiller en génétique.

Si le médecin traitant délègue des tâches directement au conseiller en génétique, les mêmes principes que ceux énoncés au point 3 s'appliquent. En d'autres mots, le médecin traitant peut être reconnu fautif d'une délégation illégale et advenant la survenue d'un préjudice causé par la faute du conseiller en génétique, la responsabilité peut être partagée entre le médecin traitant et le conseiller en question.

D. Le conseil génétique et la pratique infirmière

Après avoir analysé l'empiètement susceptible des tâches du conseiller en génétique sur la pratique médicale et les conséquences juridiques qui y sont associées, il est opportun de voir brièvement si les tâches du conseiller en génétique empiètent également sur celles des infirmières au Québec. Une fois de plus, il est important de mentionner que ce ne sont pas toutes les tâches du conseiller en génétique qui sont susceptibles de chevauchement. L'analyse qui suit se penche sur l'évaluation de l'état de santé d'une personne, un acte caractéristique de la pratique infirmière au Québec.

1. Les tâches du conseiller en génétique : une forme d'évaluation de l'état de santé d'une personne conformément à l'article 36 de la *Loi sur les infirmières et infirmiers* du Québec ?

Afin d'assurer l'exclusivité de la pratique infirmière, le législateur québécois protège le titre et les actes de l'infirmière dans le *Code des professions* depuis 1973. Le *Code* prévoit :

¹³⁷ *Ibid* aux pp 288-89.

¹³⁸ *Ibid* aux pp 289-90.

Nul ne peut de quelque façon prétendre être [...] infirmière ou infirmier, [...] ni utiliser l'un de ces titres ou un titre ou une abréviation pouvant laisser croire qu'il l'est [...] ni exercer une activité professionnelle réservée aux membres d'un ordre professionnel, prétendre avoir le droit de le faire ou agir de manière à donner lieu de croire qu'il est autorisé à le faire, s'il n'est titulaire d'un permis valide et approprié et s'il n'est inscrit au tableau de l'ordre habilité à délivrer ce permis, sauf si la loi le permet¹³⁹.

Afin de concrétiser cette protection, le législateur définit, dans la *Loi sur les infirmières et infirmiers* du Québec, l'exercice infirmier et les actes réservés aux infirmières et infirmiers. Selon cette loi, l'exercice infirmier consiste notamment à « évaluer l'état de santé d'une personne. »¹⁴⁰ Selon l'Ordre des infirmières et infirmiers du Québec, la santé et son maintien sont les concepts centraux de la pratique infirmière¹⁴¹. Ces principes ont été largement corroborés par les tribunaux québécois qui ont, à plusieurs reprises, énoncé le devoir qu'ont les infirmières d'évaluer l'état de santé des patients¹⁴².

Toujours selon l'Ordre des infirmières et infirmiers du Québec, l'évaluation de l'état de santé est un acte d'appréciation pratiqué par l'infirmière qui consiste à recueillir, à différencier, à vérifier et à organiser les données relatives au patient¹⁴³. Cette évaluation suppose que les infirmières soient en mesure de différencier la condition de santé normale d'une condition anormale et qu'elles puissent déceler les facteurs de risque

¹³⁹ *Supra* note 118, art 32 al 1.

¹⁴⁰ *Supra* note 39, art 36.

¹⁴¹ Ordre des infirmières et infirmiers du Québec, « La vision contemporaine de l'exercice infirmier au Québec » (2001), p 18, en ligne : Ordre des infirmières et infirmiers du Québec <www.oiiq.org/sites/default/files/166P_doc.pdf> [*Ordre des infirmières et infirmiers*].

¹⁴² *Hôtel-Dieu d'Amos c Gravel* (1988), [1989] RJQ 64, [1989] RRA 10 (CA Qc) [*Gravel*] ; *Bérubé c Cloutier*, [2000] RRA 484 (disponible sur WL Can) (CS Qc), conf par [2003] RRA 374 (disponible sur WL Can) (CA Qc) [*Bérubé*]. Dans cette dernière affaire, les infirmières ont été reconnues fautives lorsqu'elles n'ont pas pu déceler une dégradation de l'état de santé d'une patiente souffrant de complications postopératoires suite à une réduction mammaire. La Cour rappelle l'importance de l'évaluation de l'état de santé par les infirmières qui est une tâche caractéristique de leur pratique professionnelle.

¹⁴³ *Supra* note 141.

présents chez les patients pour intervenir adéquatement¹⁴⁴.

À la lumière de ces précisions, nous percevons une certaine ressemblance entre la définition de ce qui caractérise l'évaluation de l'état de santé d'une personne et certaines tâches du conseiller en génétique. En effet, le conseiller en génétique s'assure d'obtenir les informations pertinentes avant et lors de la séance de consultation au département de génétique, ce qui coïncide nettement avec le rôle de l'infirmière de recueillir, de différencier, de vérifier et d'organiser les données relatives au patient. Effectivement, c'est le conseiller en génétique qui recueille le diagnostic¹⁴⁵, la cause de la consultation¹⁴⁶, les antécédents familiaux¹⁴⁷, les dossiers médicaux pertinents¹⁴⁸, les tests déjà subis, et ce, afin de vérifier ces données et de les organiser pour préparer un plan d'action¹⁴⁹.

Il est vrai que le conseiller en génétique ne procède pas à la vérification et à la surveillance des soins vitaux, des actes généralement associés à l'évaluation de l'état de santé des patients¹⁵⁰. Cependant, la nature des actes caractérisant l'évaluation de l'état de santé est nécessairement changeante et dépend du contexte dans lequel l'infirmière prodigue ses soins. En effet, dans le cas de la génétique, l'Association des infirmières et infirmiers du Canada (une fédération de onze associations provinciales et territoriales d'infirmières) maintient que le rôle de l'infirmière consiste à consigner les antécédents familiaux et à identifier les patients qui ont besoin de services génétiques¹⁵¹. De plus, selon cette Association :

L'infirmière est souvent la première personne qu'un client voit après qu'il a reçu un diagnostic, et si celle-ci comprend la génétique, elle est mieux placée pour conseiller, consoler et guider le client¹⁵².

¹⁴⁴ *Ibid* aux pp 18-19.

¹⁴⁵ Debra Lochner Doyle, « Medical Documentation » dans Uhlmann, Schuette et Yashar, *supra* note 6 aux pp 313-14 ; Uhlmann, *supra* note 42 à la p 100.

¹⁴⁶ Djurdjinovic, *supra* note 21 à la p 136.

¹⁴⁷ Harper, *supra* note 27 à la p 5.

¹⁴⁸ Doyle, *supra* note 145 à la p 314.

¹⁴⁹ Uhlmann, *supra* note 42 à la p 109.

¹⁵⁰ Voir par ex Bérubé, *supra* note 142 au para 68 ; Gravel, *supra* note 142 au para 42.

¹⁵¹ *Supra* note 9.

¹⁵² *Ibid*.

Il n'est pas nécessaire de rappeler combien l'aspect psychologique de la consultation s'avère important dans la relation du conseiller en génétique avec ses patients. En effet, les patients qui viennent consulter un conseiller en génétique reçoivent parfois des informations qui les mènent à vivre des réactions émotionnelles intenses¹⁵³. C'est pourquoi le conseiller en génétique explore avec ses patients leurs expériences, leurs émotions, leurs buts, leurs croyances culturelles et religieuses, leurs relations et dynamiques interpersonnelles, pour ne nommer que ces quelques dimensions¹⁵⁴. Il semble toutefois que ce rôle d'évaluation et de soutien psychologique soit également caractéristique de celui des infirmières. Ceci illustre qu'une clarification législative permettant de différencier les tâches du conseiller en génétique de celles des infirmières et infirmiers est souhaitable.

2. Actes infirmiers partagés et délégués : le conseiller en génétique est-il habilité ?

Il va de soi qu'en l'absence d'une loi constituante pour les conseillers en génétique, ces derniers ne peuvent pratiquer des actes reconnus comme étant ceux des infirmières. Reste à voir s'il existe un mécanisme de délégation qui pourrait permettre au conseiller en génétique d'exercer des actes propres à l'exercice infirmier.

Tout comme pour les médecins, le législateur autorise, dans la *Loi sur les infirmières et infirmiers*, la délégation de certains actes¹⁵⁵. Plusieurs règlements habilite certaines personnes à exercer des activités professionnelles propres aux infirmières et infirmiers. Par exemple, comptons le *Règlement sur une activité professionnelle pouvant être exercée par une personne agissant pour le compte d'Héma-Québec* et le *Règlement sur les activités professionnelles pouvant être exercées par des personnes autres que des infirmières et infirmiers*¹⁵⁶. Ce dernier vise l'étudiante et l'étudiant en soins infirmiers, l'externe en soins infirmiers, la personne

¹⁵³ Djurdjinovic, *supra* note 21 à la p 148.

¹⁵⁴ Voir généralement Gottfried Oosterwal, « Multicultural Counseling » dans Uhlmann, Schuette et Yashar, *supra* note 6 aux pp 331-32.

¹⁵⁵ *Supra* note 39, art 41(b).

¹⁵⁶ *Règlement sur une activité professionnelle pouvant être exercée par une personne agissant pour le compte d'Héma-Québec*, RRQ, c I-8, r 1 ; *Règlement sur les activités professionnelles pouvant être exercées par des personnes autres que des infirmières et infirmiers*, RRQ, c I-8, r 2.

admissible par équivalence et le candidat à l'exercice de la profession d'infirmière¹⁵⁷. Aucun de ces règlements ne mentionne le conseiller en génétique.

Ici encore, nous sommes en présence d'une possibilité d'empiétement de la part du conseiller en génétique sur les tâches d'un autre professionnel, et ce, sans fondement juridique. À présent, explorons brièvement la responsabilité pénale à laquelle s'expose le conseiller en génétique à la suite d'un empiétement sur la pratique médicale ou infirmière.

E. Les conséquences juridiques pour le conseiller en génétique suite à de tels empiétements : la responsabilité pénale

Les ordres professionnels ont un devoir de protection du public et c'est pourquoi ils sont habilités à déposer une plainte pénale contre ceux qui s'approprient un titre réservé ou exercent illégalement une activité réservée à un ordre professionnel¹⁵⁸. Ce droit tire sa source dans l'article 32 du *Code des professions* qui prévoit que :

Nul ne peut de quelque façon prétendre être [...] médecin, [...] infirmière ou infirmier [...] ni utiliser l'un de ces titres ou un titre ou une abréviation pouvant laisser croire qu'il l'est, ou s'attribuer des initiales pouvant laisser croire qu'il l'est, ni exercer une activité professionnelle réservée aux membres d'un ordre professionnel, prétendre avoir le droit de le faire ou agir de manière à donner lieu de croire qu'il est autorisé à le faire, s'il n'est titulaire d'un permis valide et approprié et s'il n'est inscrit au tableau de l'ordre habilité à délivrer ce permis, sauf si la loi le permet¹⁵⁹.

Généralement, le dépôt d'une telle plainte à la Chambre criminelle et pénale de la Cour du Québec est précédé d'une enquête¹⁶⁰. Au cours de cette étape, l'ordre professionnel retient les services d'enquêteurs qui se présentent chez la personne soupçonnée d'exercice illégal pour y recevoir des services et ainsi, donner l'occasion de commettre l'infraction. Dans le cas qui nous occupe, le Collège des médecins et l'Ordre des infirmières et infirmiers du

¹⁵⁷ *Ibid*, art 2.

¹⁵⁸ Voir par ex Jean-Guy Villeneuve et al, *Précis de droit professionnel*, Cowansville (Qc), Yvon Blais, 2007 à la p 339.

¹⁵⁹ *Supra* note 118, art 32 al 1.

¹⁶⁰ Villeneuve, *supra* note 124 à la p 27.

Québec se chargent de ces procédures. Suite à cette enquête et si les soupçons s'avèrent fondés, la procédure pénale qui est intentée par l'Ordre en question prend la forme d'un constat d'infraction qui doit respecter les exigences du *Code de procédure pénale*¹⁶¹.

Quant au fardeau de la preuve nécessaire pour condamner un individu, la jurisprudence affirme que les infractions pénales relatives à l'exercice illégal ou à l'usurpation de titre sont des infractions de responsabilité stricte¹⁶². Autrement dit, la preuve de la *mens rea* n'est pas nécessaire; seule la démonstration de l'*actus reus* conduit à une condamnation.

Pour ce qui est du contrôle de l'exercice de la profession médicale, la *Loi médicale* prévoit que « sous réserve des droits et privilèges expressément accordés par la loi à d'autres professionnels » nul ne peut exercer l'une des activités réservées au médecin à l'article 31 s'il n'est pas lui-même un médecin¹⁶³. Quant aux peines prévues pour un exercice illégal ou pour l'usurpation d'un titre, l'article 49 de ladite loi réfère à l'article 188 du *Code des professions* :

Toute personne qui contrevient à l'une des dispositions du présent code, de la loi, des lettres patentes constituant un ordre ou d'un décret de fusion ou d'intégration commet une infraction et est passible d'une amende d'au moins 1 500 \$ et d'au plus 20 000 \$ ou, dans le cas d'une personne morale, d'au moins 3 000 \$ et d'au plus 40 000 \$.

Généralement, on impose l'amende minimale pour la première infraction, mais, selon les articles 148 et 149 du *Code de procédure pénale*,

¹⁶¹ LRQ c C-25.1, art 144-155 [*Code de procédure pénale*].

¹⁶² Voir *Comeau c Québec (Tribunal des professions)*, [1996] RJQ 2656 (disponible sur WL Can) (CS Qc), conf par 1999 CarswellQue 4250, REJB 1999-16915 (CA Qc) ; *Dubord-Bois c Corporation professionnelle des médecins du Québec*, 1997 CarswellQue 2476, REJB 1997-04994 (CS Qc) ; *Duguay c Ordre des ingénieurs du Québec*, 2000 CanLII 8209, 2000 CarswellQue 1253 (CA Qc) ; *Grenon c Ordre des optométristes du Québec*, [1986] RJQ 1016, EYB 1986-57731 (REJB), 1986 CarswellQue 547 (CA Qc) ; *Ordre des optométristes du Québec c Collège Édouard-Montpetit*, EYB 1986-78970 (REJB), 1986 CarswellQue 1113, (CS Qc) ; *Auger, supra* note 83 ; *Parizeau c Barreau du Québec*, [1997] RJQ 1701 (CS Qc) ; *Ordre des chiropraticiens du Québec c Thomas*, [2000] RJQ 625 (disponible sur CanLII) (CA Qc).

¹⁶³ *Supra* note 39, art 43.

une demande d'une peine plus élevée est possible à condition d'exposer les motifs qui justifient cette sanction¹⁶⁴.

En ce qui a trait au contrôle de l'exercice de la profession infirmière, la situation est très similaire. La *Loi sur les infirmières et infirmiers* du Québec veut que : « sous réserve des droits et privilèges expressément accordés par la loi à d'autres professionnels, nul ne peut exercer l'une des activités décrites au deuxième alinéa de l'article 36, s'il n'est pas infirmière ou infirmier. »¹⁶⁵ L'alinéa deux de l'article 36 réfère aux activités réservées aux infirmières et infirmiers. Quant aux peines prévues pour chaque infraction, l'article 42 de la même loi réfère aussi à l'article 188 du *Code des professions*.

Dans le cas des conseillers en génétique, il pourrait être difficile d'obtenir un verdict d'acquiescement face à une infraction à moins de présenter une défense d'erreur ou de diligence raisonnable¹⁶⁶. De plus, ils ne pourraient invoquer le fait que le Collège des médecins ou l'Ordre des infirmières et infirmiers du Québec n'ont pas agi contre eux au cours des dernières années. En effet, dans l'affaire *Aearo Corporation c Ordre des opticiens d'ordonnances du Québec*, la Cour supérieure a rejeté l'argument d'un défendeur qui a tenté de démontrer qu'il possédait des droits acquis vu l'inaction de l'ordre professionnel qui le poursuivait dans cette cause¹⁶⁷. Finalement, il est important de souligner que la plainte pénale ne peut être déposée que dans un délai d'un an à compter du jour où l'infraction a été commise¹⁶⁸.

Bref, les conseillers en génétique ne sont pas à l'abri de poursuites pénales. De plus, un acquiescement ne constituerait pas nécessairement une fin de non-recevoir à une poursuite au civil puisque les deux régimes, bien qu'indépendants l'un de l'autre, ne sont pas mutuellement exclusifs¹⁶⁹.

¹⁶⁴ Villeneuve et al, *supra* note 158 à la p 358 ; *Supra* note 161.

¹⁶⁵ *Loi sur les infirmières et infirmiers*, *supra* note 39, art 41.

¹⁶⁶ Villeneuve et al, *supra* note 158 à la p 349.

¹⁶⁷ [1998] RJQ 2792, REJB 1998-07776, 1998 CarswellQue 2814 (WL Can), désistement d'appel le 1999-03-08. Voir aussi *Québec (Procureur général) c Tremblay*, 1988 CanLII 1153 (CA Qc) au para 7.

¹⁶⁸ *Code de procédure pénale*, *supra* note 161, art 14.

¹⁶⁹ Voir par ex Patrick De Niverville, « Pertinence et valeur probante d'une décision ou d'un jugement ayant un lien avec l'exercice de la profession », Barreau du

Ceci étant dit, il est important de proposer des solutions législatives et organisationnelles pouvant pallier l'absence actuelle d'encadrement juridique précis causée par la non-reconnaissance légale de la profession de conseiller génétique au Québec. À cet effet, nous nous inspirons de la France.

III. Piste de solutions : le cas de la France

Considérant les conséquences juridiques créées par le *statu quo* législatif entourant les conseillers en génétique, il est souhaitable que le législateur québécois propose des solutions. Afin d'y voir plus clair, explorons les pistes de solutions apportées en France où la profession de conseiller en génétique est reconnue depuis 2004.

A. L'encadrement juridique des conseillers en génétique en France

L'encadrement juridique des conseillers en génétique en France s'est développé en plusieurs étapes depuis 2004¹⁷⁰. Les deux étapes qui nous intéressent sont celles (1) de la reconnaissance législative et (2) de l'établissement des règles professionnelles régissant les tâches du conseiller en génétique.

1. Le *Code de la santé publique* et la reconnaissance de la profession de conseiller en génétique

Tel que souligné dans la première partie du texte, le législateur français a décidé de reconnaître le conseiller en génétique en lui accordant le statut de professionnel¹⁷¹. Depuis l'adoption de la *Loi n°2004-806 du 9 août 2004 relative à la politique de santé publique* - loi qui a modifié le *Code de la santé publique* - le rôle du conseiller en génétique français est désormais

Québec, Service de la formation continue, *Développements récents en déontologie, droit professionnel et disciplinaire (2010)*, Cowansville, Yvon Blais, 2010 à la p 4.

¹⁷⁰ La reconnaissance législative du conseiller en génétique comme professionnel s'est produite avec l'adoption de la *Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique (1)*, JO, 11 août 2004, 14277, art 111 [*Loi n° 2004-806 du 9 août 2004*].

¹⁷¹ Voir Jean Penneau, « Droit médical », [2008] 1:8 D à la p 506.

défini et délimité¹⁷². En effet, le législateur discerne son rôle en indiquant que : « le conseiller en génétique, sur prescription médicale et sous la responsabilité d'un médecin qualifié en génétique, participe au sein d'une équipe pluridisciplinaire [...] »¹⁷³. Cette hiérarchie professionnelle semble être un moyen pour éviter tout empiètement de compétence entre les différents professionnels œuvrant dans l'équipe pluridisciplinaire prévue dans cette définition.

Quant aux tâches spécifiques du conseiller en génétique, le *Code de la santé publique* établit que le conseiller en génétique participe :

- 1° À la délivrance des informations et conseils aux personnes et à leurs familles susceptibles de faire l'objet ou ayant fait l'objet d'un examen des caractéristiques génétiques à des fins médicales [...] ou d'une analyse aux fins du diagnostic prénatal [...]
- 2° À la prise en charge médico-sociale, psychologique et au suivi des personnes pour lesquelles cet examen ou cette analyse est préconisé ou réalisé¹⁷⁴.

Nous remarquons dans cette définition la présence de deux éléments caractérisant le conseil génétique, soit le fait qu'il s'agisse 1) d'un processus ayant plusieurs étapes et 2) que ce processus est avant tout un processus visant à fournir des informations et conseils ayant des aspects social et psychologique et visant la bonne compréhension des faits médicaux. Il est important de mentionner qu'en France, l'information sur les caractéristiques génétiques fait l'objet d'une protection particulière. Les résultats d'un examen des caractéristiques génétiques, accompagnés des informations complémentaires pertinentes, ne peuvent être transmis que par le médecin prescripteur, qu'il s'agisse du médecin traitant ou du médecin spécialiste en génétique médicale¹⁷⁵. Sur prescription médicale, le conseiller en génétique peut intervenir pour transmettre le complément d'information.

Afin de protéger la nouvelle profession, le législateur français a adopté le corollaire juridique du « titre réservé » prévu dans les lois professionnelles québécoises en disposant, dans le *Code de la santé publique*, que : « l'usage

¹⁷² *Supra* note 170. Voir aussi Jean-Christophe Galloux et Hélène Gaumont-Prat, « Droits et libertés corporels » [janvier 2007 - février 2008] 21 DS/D 1435 à la p 1436.

¹⁷³ Art L1132-1 C santé publique, *supra* note 16.

¹⁷⁴ *Ibid.*

¹⁷⁵ Art R1131-14 C santé publique, *supra* note 16.

sans droit de la qualité de conseiller en génétique médicale ou d'un diplôme, certificat ou autre titre légalement requis pour l'exercice de cette profession est puni comme le délit d'usurpation de titre [...]. »¹⁷⁶ La peine rattachée à ce délit est prévue à l'article 433-17 du *Code pénal*¹⁷⁷.

De plus, le législateur français assure la protection de l'exclusivité de l'exercice de la profession du conseiller en génétique en prévoyant une peine d'un an d'emprisonnement et une amende de 15 000 euros pour tout individu qui exerce illégalement le conseil génétique¹⁷⁸.

Bref, en reconnaissant la profession de conseiller en génétique dans sa législation, la France réduit toute ambiguïté quant au rôle que peut jouer ce professionnel au sein d'une équipe multidisciplinaire et protège son titre professionnel ainsi que les tâches qu'il peut exercer.

2. Les règles professionnelles régissant la profession du conseiller en génétique

Suite à la reconnaissance législative du conseiller en génétique, le *Décret n° 2007-1429 du 3 octobre 2007* a modifié le *Code de santé publique* afin d'établir les règles professionnelles qui guident le conseiller en génétique dans la prestation de ses services¹⁷⁹. Ces règles reflètent les devoirs du conseiller en génétique envers les patients qui le consultent et ses collègues professionnels de la santé, quel que soit le cadre de ses activités professionnelles.

En ce qui concerne les patients, le conseiller en génétique est tenu d'agir

¹⁷⁶ Art L1133-10, *ibid.*

¹⁷⁷ Cet article prévoit : « L'usage, sans droit, d'un titre attaché à une profession réglementée par l'autorité publique ou d'un diplôme officiel ou d'une qualité dont les conditions d'attribution sont fixées par l'autorité publique est puni d'un an d'emprisonnement et de 15000 euros d'amende ». Voir Caroline Lacroix, « Usurpation de titres ou de fonctions » (2009) Rép pén & proc pén ¶ 27.

¹⁷⁸ Art L1133-8 C santé publique, *supra* note 16.

¹⁷⁹ *Décret n° 2007-1429 du 3 octobre 2007 relatif à la profession de conseiller en génétique et modifiant le code de la santé publique (dispositions réglementaires)*, JO, 5 octobre 2007, 16350 [*Décret n° 2007-1429 du 3 octobre 2007*]. Voir aussi Galloux et Gaumont-Prat, *supra* note 172 à la p 1435.

dans leur intérêt et de respecter leur dignité et leur intimité¹⁸⁰. De plus, il doit assurer leur suivi¹⁸¹ en n'accomplissant que les actes professionnels qui relèvent de sa compétence en vertu du *Code de la santé publique*¹⁸². Le conseiller en génétique est soumis au secret professionnel qui couvre « non seulement ce qui a été confié, mais aussi ce qui a été vu, entendu, constaté ou compris »¹⁸³. De plus, il « instruit les personnes qui l'assistent de leurs obligations en matière de secret professionnel et veille à ce qu'elles s'y conforment »¹⁸⁴. La raison derrière cette obligation qu'a le conseiller en génétique d'informer les personnes qui l'assistent puise sa source dans le *Code pénal* français qui prévoit que:

La révélation d'une information à caractère secret par une personne qui en est dépositaire soit par état ou par profession, soit en raison d'une fonction ou d'une mission temporaire, est punie d'un an d'emprisonnement et de 15000 euros d'amende¹⁸⁵.

Il s'agit d'une pratique différente de celle suivie au Québec où, dans un contexte de soins, seuls les professionnels de la santé reconnus par le *Code des professions* sont soumis au secret professionnel¹⁸⁶. En effet, cette obligation ne peut être transmise aux assistants de ces professionnels québécois.

Toujours en France et selon les règles professionnelles prévues au *Code de la santé publique*, le conseiller en génétique doit fournir sans discrimination aux patients qui le consultent toutes les informations nécessaires qui leur permettront de faire un choix éclairé¹⁸⁷.

À l'égard des professionnels qui travaillent avec lui, le conseiller en génétique doit entretenir des rapports de confraternité et doit chercher, advenant un conflit, la conciliation¹⁸⁸. À l'égard du médecin prescripteur

¹⁸⁰ Art R1132-7 C santé publique, *supra* note 16.

¹⁸¹ Art R1132-8, *ibid.*

¹⁸² Art R1132-9, *ibid.*

¹⁸³ Art R1132-10, *ibid.*

¹⁸⁴ *Ibid.*

¹⁸⁵ Art 226-13 C pén.

¹⁸⁶ Le droit au secret professionnel est protégé, notamment, par la *Charte des droits et libertés de la personne*, LRQ c C-12, art 9.

¹⁸⁷ Art R1132-12, R1132-13, *supra* note 16.

¹⁸⁸ Art R1132-17, *ibid.*

généraliste ou généticien plus précisément, le conseiller en génétique doit appliquer et respecter la prescription médicale ainsi que le protocole de prise en charge qu'il a définis¹⁸⁹. De plus, il doit solliciter au médecin prescripteur toute information à chaque fois qu'il le juge utile. Le conseiller en génétique doit également communiquer au médecin prescripteur toute « information en sa possession susceptible de concourir à l'établissement du diagnostic ou de permettre une meilleure adaptation du traitement »¹⁹⁰.

Après s'être attardé à l'expérience législative française en ce qui concerne les conseillers en génétique, explorons la possibilité d'une telle expérience dans le cadre juridique et organisationnel québécois.

B. La transposition de l'expérience française au Québec : est-ce possible ?

1. Solutions législatives

Afin d'explorer les solutions législatives québécoises à l'impasse entourant la reconnaissance des conseillers en génétique, récapitulons les points saillants de l'expérience législative française. Ces points peuvent être résumés comme suit: 1) le conseiller en génétique est reconnu officiellement en tant que professionnel et est assujéti à des règles professionnelles¹⁹¹; 2) le conseiller en génétique agit sous la responsabilité d'un médecin généticien et par délégation d'un médecin traitant ou généticien¹⁹² et 3) le conseiller en génétique prodigue ses services suite à une prescription médicale¹⁹³.

La reconnaissance du conseiller en génétique au Québec pourrait s'effectuer par l'incorporation législative de cette profession dans le *Code des professions* québécois. Il est important de mentionner qu'une telle reconnaissance se fait toujours simultanément à la création d'un ordre spécifique aux professionnels en question. Nous traiterons de ce point lorsque nous aborderons les solutions organisationnelles. Une fois le

¹⁸⁹ Art R1132-11, *ibid.*

¹⁹⁰ Art R1132-11, *ibid.*

¹⁹¹ *Loi n°2004-806 du 9 août 2004, supra note 192* ; Décret n° 2007-1429 du 3 octobre 2007, *supra note 179.*

¹⁹² Art L1132-1 C santé publique, *supra note 16.*

¹⁹³ *Ibid.*

conseiller en génétique incorporé dans la liste des professionnels prévue au *Code*, le législateur doit déterminer s'il crée cette profession « à titre réservé » ou « à exercice exclusif ». Le législateur français a décidé de rendre la profession du conseiller en génétique « à exercice exclusif ». Il est difficile d'avancer une raison pour laquelle le législateur québécois devrait faire autrement puisque les actes pratiqués par les conseillers en génétique sont susceptibles d'entraîner de lourdes conséquences pour les patients consultants si ces derniers sont amenés à prendre des décisions s'éloignant de leur intérêt réel. Le fait de limiter cette profession aux seules personnes détentrices d'un permis exclusif réduirait les abus¹⁹⁴.

Afin d'encadrer le chevauchement de compétences entre les conseillers en génétique et les autres professionnels, tels les médecins et les infirmières, deux solutions sont possibles. La première est de prévoir un tel chevauchement dans la loi constitutive d'un Ordre des conseillers en génétique. À cet effet, le *Code des professions* autorise un empiètement entre professions reconnues si cela est prévu par la loi¹⁹⁵. La deuxième solution consiste en la création d'un système de délégation des actes exclusifs aux médecins et aux infirmières. En effet, le législateur peut autoriser une délégation des actes exclusifs aux médecins au conseiller en génétique en vertu du *Règlement sur les activités visées à l'article 31 de la Loi médicale qui peuvent être exercées par des classes de personnes autres que des médecins*¹⁹⁶. En ce qui concerne les infirmières, cela est également possible en vertu du *Règlement sur les activités professionnelles pouvant être exercées par des personnes autres que des infirmières et infirmiers*¹⁹⁷. Le législateur peut également opter pour la création d'un règlement à part, spécifique aux conseillers en génétique, qui désignerait les actes qui lui sont délégués. Un tel règlement pourrait s'intituler « Règlement sur les activités professionnelles pouvant être exercées par des conseillers en génétique ».

Bien qu'il s'agisse d'une solution incomplète pour les conseillers en génétique, le législateur peut choisir de ne pas le reconnaître en tant que professionnel et créer une exception claire dans le *Code des professions* pour lui permettre d'empiéter sur certaines compétences réservées aux autres professionnels. En effet, le législateur prévoit une telle exception dans le cas d'un parent, d'une personne qui assume la garde d'un enfant ou d'un aidant

¹⁹⁴ *Code des professions*, supra note 118, art 26.

¹⁹⁵ *Ibid*, art 31.

¹⁹⁶ *Supra* note 120.

¹⁹⁷ *Supra* note 156.

naturel¹⁹⁸. Toutefois, il ne s'agit pas de la solution idéale puisque ni titre ni compétences spécifiques ne seraient octroyés.

Si le législateur québécois décide de suivre l'exemple de la France et de ne permettre le conseil génétique que suite à une prescription médicale, il doit alors le prévoir dans la loi constitutive de la pratique des conseillers en génétique. Ceci étant dit, le principe voulant que le conseiller en génétique agisse sous la responsabilité d'un médecin généticien peut entraîner d'importantes contraintes dans le contexte québécois et freiner l'accès aux services de génétique en raison du nombre restreint de médecins généticiens.

Finalement, quant aux règles professionnelles que devraient suivre les conseillers en génétique, celles-ci feraient partie intégrante du *Code de déontologie* du nouvel ordre professionnel constitué¹⁹⁹. L'adoption d'un code de déontologie « imposant au professionnel des devoirs d'ordre général et particulier envers le public, ses clients et sa profession, notamment celui de s'acquitter de ses obligations professionnelles avec intégrité » est une obligation prévue dans le *Code des professions*, lequel prévoit les différents sujets que le *Code de déontologie* doit aborder²⁰⁰.

Le *Code de déontologie* doit contenir, entre autres :

1° des dispositions visant à prévenir les situations de conflits d'intérêts;

2° des dispositions définissant, s'il y en a, les professions, métiers, industries, commerces, charges ou fonctions incompatibles avec la dignité ou l'exercice de la profession;

3° des dispositions visant à préserver le secret quant aux renseignements de nature confidentielle qui viennent à la connaissance des membres de l'ordre dans l'exercice de leur profession ainsi que des dispositions énonçant les conditions et les modalités suivant lesquelles un professionnel peut, en application du troi-

¹⁹⁸ *Code des professions*, *supra* note 118, art 39.6.

¹⁹⁹ *Ibid*, art 87.

²⁰⁰ *Ibid*.

sième alinéa de l'article 60.4, communiquer les renseignements qui y sont visés²⁰¹.

Le présent *Code d'éthique* de l'Association canadienne des conseillers en génétique²⁰² ne contient pas tous ces sujets et sections puisqu'il s'agit d'une association canadienne et non d'un ordre professionnel provincial. Un tel document est condamné à la généralité parce qu'une pareille association n'a pas les outils pour imposer des normes à ses membres²⁰³. Il est vrai que ces normes peuvent être la source d'obligations professionnelles, mais elles demeurent non contraignantes tant qu'elles ne sont pas adoptées par le législateur.

Bref, le législateur québécois possède les compétences législatives nécessaires pour mieux réglementer la pratique du conseil génétique. De plus, l'expérience française peut guider l'encadrement de la pratique de ce professionnel au Québec, allant des modalités d'exécution de sa profession jusqu'aux règles déontologiques qu'il doit suivre dans sa pratique.

2. Solutions organisationnelles

Afin de pouvoir déterminer si une solution organisationnelle s'impose, il faut comprendre pourquoi le *statu quo* n'est pas viable. En ce moment, le seul organisme national qui représente les conseillers en génétique est l'Association canadienne des conseillers en génétique. Cette association est accréditrice, mais n'a aucun pouvoir de réglementation, ni d'investigation²⁰⁴. Donc un manquement aux exigences prévues par le *Code d'éthique des conseillers en génétique canadiens* ne peut entraîner la radiation d'un membre. Le processus d'accréditation prend place suite à un examen offert par l'Association. Ce dernier est purement volontaire et les employeurs ne le requièrent pas nécessairement. Une plainte contre un conseiller en génétique est généralement acheminée à son employeur, mais ne peut aboutir à une radiation²⁰⁵. Ceci dit, en tant qu'organisme à portée nationale et dû au fait

²⁰¹ *Ibid.*

²⁰² *Supra* note 128.

²⁰³ Aucune disposition du Code d'éthique canadien ne prévoit les conséquences d'une infraction à ses dispositions.

²⁰⁴ *ACCG*, *supra* note 36.

²⁰⁵ Information reçue suite à une communication personnelle avec Raechel Ferrier, coprésidente du groupe de travail responsable du développement professionnel dans l'Association Canadienne des Conseillers en Génétique, 27 avril 2010.

que le conseiller en génétique n'est pas reconnu en tant que professionnel, l'Association canadienne ne possède aucun outil lui permettant de protéger le titre ou les actes de ses membres. En effet, il n'est pas nécessaire d'être accrédité par l'Association afin de travailler en tant que conseiller en génétique²⁰⁶. Ceci nous mène à conclure que le statut actuel de l'Association canadienne ne lui confère pas les outils lui permettant de faire face aux nombreux défis mentionnés dans les parties précédentes de ce texte.

Quant à la nécessité de créer un ordre professionnel, il n'y a aucun doute que le conseiller en génétique répond aux exigences prévues au *Code des professions* pour une telle reconnaissance. De plus, la création d'un tel ordre professionnel ou l'intégration des conseillers à un ordre professionnel existant est une condition *sine qua non* d'une reconnaissance législative dans le *Code des professions*²⁰⁷. Il est vrai que les conseillers en génétique ne sont pas nombreux au Québec, mais cela ne devrait pas être un obstacle à la création de leur ordre professionnel²⁰⁸. À titre d'exemple, les sages-femmes ont leur propre ordre professionnel au Québec et elles n'étaient qu'au nombre de cent trente-neuf en 2010²⁰⁹.

Devant l'absence d'une reconnaissance législative du conseiller en génétique au Québec, la deuxième solution organisationnelle se caractérise par une entente que pourrait conclure le Collège des médecins ou l'Ordre des infirmières et infirmiers du Québec avec les associations des conseillers en génétique du Québec et du Canada. Une telle entente pourrait définir le rôle

²⁰⁶ Dans une annonce pour un emploi de conseiller en génétique visionnée en 2010 sur leur site Internet, le CSSS-Chicoutimi n'exigeait qu'un diplôme universitaire de deuxième cycle (M.Sc.) en conseil génétique. La fiche d'emploi ne mentionnait point une accréditation de l'Association Canadienne des Conseillers en Génétique. Voir Centre de santé et de services sociaux de Chicoutimi, « Fiche emplois », en ligne : CSSS <www.csss-chicoutimi.qc.ca/Ficheemplois/tabid/4751/language/fr-FR/Default.aspx?numero=1539>.

²⁰⁷ *Supra* note 118, art 24.

²⁰⁸ En 2007, il y avait vingt-trois conseillers en génétique au Québec. En 2008, ce nombre a augmenté à trente-trois. Information reçue suite à une communication personnelle avec l'Association canadienne des conseillers en génétique. Il faut cependant rappeler que les conseillers en génétique du Québec ne sont pas tous membres de l'ACCG.

²⁰⁹ Voir Service Canada, « Sages-femmes et praticiens des médecines douces » en ligne : Service Canada <www.servicecanada.gc.ca/fra/qc/emploi_avenir/statistiques/3232.shtml>.

du conseiller en génétique et limiter les actes qu'il peut accomplir dans une équipe multidisciplinaire. Cependant, cette entente n'aurait pas force de loi et elle ne lierait que les parties concernées. Elle demeure toutefois la seule autre solution envisageable dans les circonstances.

Conclusion

À la lumière de l'analyse qui précède, il est clair que les tâches diversifiées du conseiller en génétique, allant de l'étape préliminaire à l'étape de l'après-consultation, peuvent avoir une incidence importante sur la vie des patients qui viennent le consulter.

Malgré cela, l'encadrement juridique de la pratique demeure incomplet tant que le conseiller en génétique ne figure pas dans la liste des professionnels reconnus par le *Code des professions du Québec*. Une telle reconnaissance permettrait à la fois la protection du public et la protection de la profession en limitant les abus et les fraudes²¹⁰.

Dans la deuxième partie, nous avons vu que certaines tâches du conseiller risquent d'empiéter sur la pratique médicale. En effet, l'évaluation de risques s'apparente à l'établissement d'un diagnostic médical. De plus, une contribution active à la démarche diagnostique du médecin généticien présage une délégation non habilitée des actes propres à la pratique médicale. Ceci n'est pas sans possible conséquence juridique pour le médecin déléguant ni pour le conseiller à qui l'acte est délégué.

Toujours dans la deuxième partie, nous avons constaté que la formulation d'un plan d'action par le conseiller en génétique, suite à la collecte des informations pertinentes au patient, ainsi que son rôle de réconfort envers le patient ressemblait beaucoup à celui de l'infirmière évaluant l'état de santé d'une personne. Ainsi, de tels empiètements risquent d'engendrer la responsabilité pénale du conseiller sous les régimes des articles 43 de la *Loi médicale* et 41 de la *Loi sur les infirmières et infirmiers*.

Dans la troisième partie, nous avons vu que le législateur français reconnaît la profession émergente du conseiller en génétique et lui impose des règles professionnelles. Une transposition de cette initiative au Québec est possible, mais doit se faire conjointement aux niveaux législatif et

²¹⁰ Trudo Lemmens, Mireille Lacroix et Roxanne Mykitiuk, *Reading the Future?: Legal and Ethical Challenges of Predictive Genetic Testing*, Montréal, Thémis, 2007 à la p 158.

organisationnel.

Finalement, il est important de signaler que ce texte ne représente guère une évaluation négative du rôle des conseillers en génétique au Québec, loin de là. Leur apport dans le système de santé d'aujourd'hui est incontestable. Le but ultime de cette analyse est d'exposer les conséquences juridiques susceptibles de se présenter tant et aussi longtemps qu'une reconnaissance législative du conseiller demeure inexistante. Nul besoin de continuer à attendre avant d'entreprendre les étapes nécessaires à une telle reconnaissance, surtout en prévoyant que les tests génétiques offerts directement aux consommateurs changeront la nature des consultations au département de génétique des hôpitaux québécois. Donc la fréquence des consultations des conseillers en génétique devrait augmenter²¹¹. Un encadrement juridique prospectif s'impose et doit être à la mesure d'un tel changement éventuel, surtout face à l'accroissement continu des technologies novatrices en santé.

²¹¹ RB Altman, « Direct-to-Consumer Genetic Testing : Failure Is Not an Option » (2009) 86 : 1 *Clinical Pharmacology & Therapeutics* 15 à la p 17 ; Angus Clarke et Katie Thirlaway, « Genetic counseling for personalized medicine » (2011) 130 : 1 *Human Genetics* 27 à la p 27.

SUBSTITUTE DECISION MAKING ABOUT RESEARCH: IDENTIFYING THE LEGALLY AUTHORIZED REPRESENTATIVE IN FOUR CANADIAN PROVINCES

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Canada's aging population presents new incentives for research on Alzheimer's and other forms of dementia. But the public interest in advancing knowledge about these diseases must be partnered with a concern for exploitation, in particular where a potential research subject is deemed legally incapable of making a decision about research participation.

The Tri-Council Policy Statement requires that the

Le vieillissement de la population canadienne crée de nouveaux incitatifs pour la recherche sur la maladie d'Alzheimer et sur d'autres formes de démence. Toutefois, le souci de faire avancer la recherche sur ces maladies doit aller de pair avec la prévention de l'exploitation, en particulier pour les sujets de recherche potentiels qui sont dans l'incapacité de décider de leur participation à une étude.

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Citation: Sheila Wildeman et al, "Substitute Decision Making About Research: Identifying the Legally Authorized Representative in Four Canadian Provinces" (2012) 6:1 MJLH 189.

Référence : Sheila Wildeman et al, « Substitute Decision Making About Research: Identifying the Legally Authorized Representative in Four Canadian Provinces » (2012) 6 : 1 RDSM 189.

research participation of subjects deemed incapable of consent be contingent upon authorization obtained from their legally authorized representative (“LAR”). However, where the prospective research subject is an adult, the question of who, if anyone, may act as an LAR is often uncertain. While some provinces and territories provide a clear statutory basis for identifying LARs, others do not.

We identified four provincial regimes that differ in their legislative approach to LAR identification. Of the four, British Columbia’s health care consent legislation explicitly addresses the question of who, if anyone, may act as LAR for the purpose of authorizing an adult’s participation in research, even in the absence of an advance directive or guardian. At the time of our study, Alberta’s laws only addressed this question clearly where an advance directive was in place. Legislative reforms in that province have since expanded the circumstances in which an LAR for research may be identified. In contrast, both Nova Scotia and Ontario lacked (and continue to lack) any legislation explicitly addressing who, if anyone, may act as LAR for research. Indeed, Ontario’s health care consent and substitute decision making laws explicitly state that they do not apply to procedures undertaken for the primary purpose of research.

A postal survey of five sub-populations (older adults, informal caregivers, physicians, researchers in aging, and REB members) was conducted in each of the four provinces. Respondents were presented with hypothetical scenarios and asked who, if anyone, had legal authority to make decisions about research participation. The most common response across provinces, scenarios, and population groups was that a close family member could act as an LAR, regardless of whether provincial laws clearly supported, clearly contradicted, or were uncertain with regard to that result. We conclude that the combined lack of clarity in, and lack of knowledge about, provincial laws relating to LAR identification that our study exposes indicates a fundamental gap in the system of research regulation. There is a need for increased legal clarity and public education on this important aspect of research governance.

L’Énoncé de politique des trois Conseils requiert que les recherches, sur la santé ou sur un autre domaine, auxquelles participent des personnes incapables de donner un consentement éclairé, soient soumises à une autorisation de la part du représentant légal du participant (RLP). Toutefois, lorsque le sujet de recherche est un adulte, la question de savoir qui peut agir en tant que RLP est souvent floue.

Nous avons identifié quatre régimes provinciaux qui diffèrent dans leur approche législative pour identifier le RLP. La législation sur le consentement dans le cadre des soins de santé mise en place par la Colombie-Britannique aborde explicitement la question de qui, s’il y a lieu, peut agir comme RLP pour autoriser un adulte à participer à une recherche, même lorsqu’il n’y a pas de directive préalable ou de tuteur. Au moment de notre recherche, les lois albertaines traitaient cette question uniquement lorsqu’une directive préalable était en place. Les réformes législatives de cette province ont depuis élargi les situations dans lesquelles un RLP peut être identifié pour une étude. En revanche, la Nouvelle-Écosse et l’Ontario n’avaient pas (et n’ont toujours pas) de mesures législatives abordant explicitement la question de savoir qui, s’il y a lieu, peut agir comme RLP pour une étude. En effet, les lois ontariennes sur le consentement aux soins de santé et sur la prise de décisions au nom d’autrui affirment explicitement qu’elles ne s’appliquent pas aux procédures entreprises lorsque le but principal est de mener des recherches.

Une enquête postale auprès de cinq sous-populations (personnes âgées, aidants naturels, médecins, chercheurs travaillant sur le vieillissement et membres des comités d’éthique de la recherche) a été menée dans chacune des quatre provinces. On a présenté des situations hypothétiques aux participants qui devaient identifier qui, prendre une décision quant à la participation à une étude. La réponse la plus fréquente pour s’il y avait lieu, avait l’autorité légale pour l’ensemble des provinces, des scénarios et des sous-populations était qu’un membre de la famille immédiate pouvait agir comme RLP, indépendamment du fait que cela ait été abordé, appuyé ou contredit par les lois provinciales. Nous concluons qu’il y a un besoin de clarté juridique et de sensibilisation du public en ce qui concerne cet aspect important de la gouvernance de la recherche.

Introduction	193
I. Background	194
II. Definitions	197
A. <i>Consent versus Authorization</i>	197
B. <i>Research versus Treatment</i>	200
C. <i>Therapeutic Misconception</i>	203
III. Legal Background: The Challenge of Identifying an LAR for Substitute Decision Making about Research	204
A. <i>International Sources</i>	204
B. <i>Domestic Sources</i>	210
1. <i>Liability Attaching to Health Research in the Absence of Valid Authorization</i>	211
a. <i>Federal Sources of Research Norms Mandating an LAR</i>	213
2. <i>Identifying an LAR: Legal Foundations</i>	216
a. <i>Constitutionality</i>	216
b. <i>No Common Law Basis for Identification of an LAR</i>	217
c. <i>Advance Directives</i>	221
d. <i>Provincial Laws and Legally Authorized Representatives</i>	222
i. <i>Category I: Clear Authorization</i>	223
ii. <i>Category II: Unclear Authorization</i>	227
iii. <i>Category III: Clear Lack of Authorization</i>	231
iv. <i>Application to the Four Scenarios in our Survey Questionnaire</i>	233
<i>Table 1. The State of Provincial Laws on LARs at the Time of the Survey</i>	234
IV. The SCORES Survey	237
A. <i>Study Design, Populations and Sampling</i>	237
B. <i>The Questionnaire</i>	238
C. <i>The Postal Survey</i>	243
<i>Table 2. Response Rates and Sample Size per Group and Province</i>	244
<i>Table 3. Respondents' Characteristics</i>	244

V. Responses to the Questionnaire	245
<i>Figure 1. % of Respondents with Correct or Best/Alternative Answers in British Columbia</i>	246
<i>Figure 2. % of Respondents with Correct or Best/Alternative Answers in Alberta</i>	247
<i>Figure 3. % of Respondents with Correct or Best/Alternative Answers in Nova Scotia</i>	248
<i>Figure 4. % of Respondents with Correct or Best/Alternative Answers in Ontario</i>	249
<i>Figure 5. Selection of B – “Family Member” – in Response to the “No-Individual-Benefit” Scenario</i>	252
VI. Discussion	253
A. <i>Other Studies</i>	254
1. The Quebec Study	255
2. Laws Relevant to Research Involving Persons Incapable of Consent	257
3. Understanding of Substitute Decision Making Laws (Not Specific to Research)	258
B. <i>Limitations</i>	261
1. Surveying Knowledge in the Face of Uncertainty	261
2. Surveying Knowledge in the Absence of Legal Consultation	264
3. Surveying Knowledge in the Face of Legal Reforms	265
Conclusions and Policy Recommendations	267
Appendix	271
I. SCORES Vignettes – Research Participation	271
II. Correct, Best and Alternative Responses	274
<i>Table 4. The Correct, Best and Alternative Responses to Each Scenario</i>	274

Introduction¹

When an adult² is legally incapable of deciding whether to participate in health research, who (if anyone) has the legal authority to make that decision? Furthermore, how well do Canadians with a stake in health research, such as older adults, informal caregivers of older persons with cognitive impairments, researchers in aging, and members of research ethics boards (“REBs”), understand the state of the law on this question? These two interrelated matters are addressed by our study.

We find that the laws of the four provinces we target are frequently unclear as to whether, or in what circumstances, a guardian, proxy appointed under an advance directive, or non-appointed family member may make a substitute decision about another adult’s participation in health research. Moreover, we find that stakeholders in all five subgroups surveyed are frequently mistaken about the state of the law and tend to believe that a non-appointed family member can

¹ This research was supported by a grant from the Canadian Institutes of Health Research. We thank Caregivers Nova Scotia, Ontario Alzheimer Societies, and the REBs that assisted us in facilitating this study. We also thank the Canadian Association of Retired Persons, the Alzheimer Society of Canada, and the Royal College of Physicians and Surgeons of Canada for their letters of endorsement. Additionally, we thank our advisory committee members on the state of the relevant provincial laws: Gerrit Clements, Dr Lori Weeks, Jill Steinman, Pat Henderson, Sara Gorelick, and Justice David Marshall. Finally, we thank Brad Abernethy for editorial assistance, Michael Hadskis, Jocelyn Downie, Elaine Gibson, and Vaughan Black for comments on a draft, and Joanna Weiss for research assistance.

² Our study is rooted in the question of whether the statute laws of selected provinces enable identification of a legal representative empowered to authorize another adult’s participation in health research. We set aside questions relating to authorization of a minor’s participation in research. This is primarily because where substitute decision making about health care is at issue, the common law recognizes parents as the guardians of their minor children. No such common law authority is forthcoming where adults are deemed to lack decision making capacity at law. Hence, while the case of substitute decision making for children is clear, there is a legal vacuum in the common law in the case of adults on the matter of third party authorization of any form of bodily or other intervention. That said, there remain important areas of controversy as to the scope of parental authority over a child’s participation in research which overlap with some of the issues discussed here, e.g. must the research serve the prospective subject’s best interests? How are best interests to be defined? See Michael Hadskis, “The Regulation of Human Biomedical Research in Canada” in Jocelyn Downie, Timothy Caulfield & Coleen Flood, eds, *Canadian Health Law and Policy*, 4th ed (Markham: Lexis/Nexis, 2011) 437 at 480-85.

make such decisions, even when this is not supported by legislation. Our findings indicate a disturbing gap between assumptions and reality regarding the legality of health research in Canada, and give rise to specific concerns about liability on the part of researchers, REB members, and research institutions.

I. Background

Historical precedents—from the Jewish Chronic Disease Hospital experiments in the early 1960s,³ to more recent studies involving persons with chronic schizophrenia⁴—indicate the profound legal and ethical concerns that may arise when research is conducted upon adults with conditions that impair their ability to give valid consent.⁵ At the same time, the advance of therapeutic options for such conditions as neurodegenerative disorders, serious mental illness, strokes, and coma-inducing disease or trauma may not be possible without research involving such persons. Thus there is increasing recognition of the need for clarity about the legal and ethical strictures on research into conditions af-

³ See *Hyman v Jewish Chronic Disease Hospital*, 206 NE 2d 338 (1965). The study at the centre of this case involved injection of live cancer cells into 22 elderly patients, in the absence of informed consent either from the subjects themselves (many of whom had dementia or impaired communicative capacities) or from family members. “The research went forward without review by the hospital’s research committee and over the objections of three physicians consulted, who argued that the proposed subjects were incapable of giving adequate consent to participate” (Advisory Committee on Human Radiation Experiments, *The Human Radiation Experiments: Final Report of the President’s Advisory Committee* (New York: Oxford University Press, 1996) ch 3).

⁴ See Carl H Coleman, “Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment” (2008) 83 Ind LJ 743; Rebecca Dresser, “Mentally Disabled Research Subjects: The Enduring Policy Issues” (1996) 276:1 JAMA 67; Rebecca Dresser, “Research Oversight and Adults with Cognitive Impairment” (2003) 33:6 Hastings Cent Rep 9; Alexander M Capron, “Ethical and Human-Rights Issues in Research on Mental Disorders that May Affect Decision-Making Capacity” (1999) 340:18 New Eng J Med 1430.

⁵ Jessica W Berg, “Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines” (1996) 24:1 JL Med & Ethics 18; Richard J Bonnie, “Research with Cognitively Impaired Subjects: Unfinished Business in the Regulation of Human Research” (1997) 54:2 Arch Gen Psychiatry 105; Paul S Appelbaum, “Involving Decisionally Impaired Subjects in Research: The Need for Legislation” (2002) 10:2 Am J Geriatr Psychiatry 120; Dresser, 1996, *supra* note 4; Dresser, 2003, *supra* note 4.

fecting decisional capacity.⁶ These questions become increasingly urgent as population demographics motivate governments and corporate actors alike to sponsor research into health conditions associated with aging, such as Alzheimer's and other forms of dementia.

Commentators on the state of research governance in Canada have remarked upon the "patchwork" nature of applicable laws and policies.⁷ It is difficult for a specialist in health law, let alone a non-legal professional or layperson, to assemble the relevant sources into a coherent framework for guiding action, complete with the possible implications of non-compliance. Where an adult is deemed legally incapable of providing consent to participate in research, the primary sources of legal and ethical guidance require, *inter alia*, that authorization be sought from the legally authorized representative ("LAR"). But the question of who, if anyone, may act as LAR with respect to an adult's research participation opens onto significant provincial variation, and, in certain provinces, deep uncertainty. With this variability and uncertainty come a host of concerns about the protection of research subjects from harm; about the protection of researchers, members of REBs, and affiliated institutions from liability; and about the possibility that liability worries may have a chilling effect on valuable research.

Against this complex background, we conducted a survey involving LAR identification in four provinces (British Columbia ("BC"), Alberta, Nova Sco-

⁶ DN Weisstub, S Verdun-Jones & J Walker, "Biomedical Experimentation Involving Elderly Subjects: The Need to Balance Limited, Benevolent Protection with Recognition of a Long History of Autonomous Decision-Making" in DN Weisstub, ed, *Research on Human Subjects: Ethics, Law and Social Policy* (Oxford: Pergamon, 1998) 405; National Bioethics Advisory Commission, *Research Involving Persons with Mental Disorders that May Affect Decision-Making Capacity*, Volumes 1 & 2 (Bethesda: National Bioethics Advisory Commission, 1998); Scott Kim et al, "Proxy and Surrogate Consent in Geriatric Neuropsychiatric Research: Update and Recommendations" (2004) 161:5 *Am J Psychiatry* 797; Elyn R Saks et al, "Proxy Consent to Research: The Legal Landscape" (2008) 8:1 *Yale J Health Pol'y L & Ethics* 37; Coleman, *supra* note 4.

⁷ On the "patchwork" nature of the regulatory sources, see Hadskis, *supra* note 2 at 441, 450-51; Marie Hirtle, "The Governance of Research Involving Human Participants in Canada" (2003) 11 *Health LJ* 137 at 139-40; Gina Bravo et al, "Comparison of Provincial and Territorial Legislation Governing Substitute Consent for Research" (2005) 24:3 *Canadian Journal on Aging* 237 [Bravo et al, "Comparison Substitute Consent"]; George N Tomossy & David N Weisstub, "The Reform of Adult Guardianship Laws: The Case of Non-Therapeutic Experimentation" (1997) 20:1 *Int'l J L & Psychiatry* 113 at 123.

tia, and Ontario) from September 2007 to April 2009. The provinces selected took a range of legislative approaches to third party authorization of an adult's participation in health research. Some had statutes enabling certain determination of the identity and scope of authority of the LAR (in BC, and where an advance directive was in place, arguably also in Alberta). Others had ambiguous statutes giving rise to uncertainty about whether anyone could function as LAR. Finally, in certain circumstances, in the three provinces other than BC, there was simply no statutory foundation upon which to base the identification of an LAR.

Our objective was to learn how representatives of five groups with distinct relationships to the research enterprise (older adults, informal caregivers of older adults with cognitive impairments, physicians, researchers on aging, and REB members) would respond to the challenge of determining who, if anyone, could act as LAR for the purpose of authorizing another adult's research involvement in a variety of circumstances. The survey we used included four scenarios, each of which briefly described a research study in which an adult who lacked legal capacity to consent was invited to participate (See Appendix I). Each concluded by asking who, if anyone, had the legal authority to make a decision about the individual's participation. In each case, one of the listed options was "No one has clear legal authority." None of the four scenarios included prior authorization of substitute decision making about research participation, whether by advance directive or as a term of court-ordered guardianship. The key variables among the scenarios were: (a) whether a guardianship order not specific to research (scenario 2), an advance directive for health care (scenarios 3 and 4), or neither legal mechanism (scenario 1) was in place; and (b) whether there was a prospect that benefits would flow to the individual research subject (scenarios 1–3), or no such prospect (scenario 4).

The survey results featured a high level of consensus among respondents that an LAR could be identified in each scenario and, moreover, that the properly-identified LAR was the close family member featured in the scenario. This was the case regardless of whether that answer was clearly supported by, clearly contradicted by, or a matter of uncertainty under provincial law.

The structure of the paper is as follows. Part II defines some basic terms. Part III introduces the main sources of legal and ethical guidance, both international and domestic, on third party authorization of an adult's participation in health research. Importantly, given that the common law provides no foundation for third party authorization of an adult's research participation (except perhaps where there is an advance directive), Part III also introduces the stat-

utes of arguable relevance to identifying an LAR in the four provinces featured in our survey, classifying these provincial laws as they interact with our four hypothetical scenarios as follows:

- I. clear authorization (i.e. there is a clear statutory basis for identifying an LAR),
- II. unclear authorization (i.e. there is an ambiguous or uncertain statutory basis for identifying an LAR), or
- III. clear lack of authorization (i.e. there is no statutory basis for identifying an LAR).

Part IV describes our survey methodology. Part V describes the results of the survey. Part VI discusses our research findings in light of the preceding legal analysis and other studies. Our conclusion offers recommendations aimed at redressing the legal uncertainty and public confusion about third party authorization of research identified herein.

II. Definitions

A. Consent versus Authorization

With limited exceptions,⁸ legal authorization is a necessary condition to enrol an individual in health research. As Baylis, Downie, and Kenny observe:

For persons with decision-making capacity, this authorization is their informed consent to research participation. For persons with-

⁸ See Hadskis, *supra* note 2 at 474; Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, arts 2.2-2.6 & 3.6-3.8 (December 2010), online: Government of Canada Panel on Research Ethics <www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf> [TCPS2]. The TCPS2 was approved after our study was completed. The exceptions to the requirement of consent stated in the previous version of the TCPS are similar. See Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, arts 2.1(c) & (d), 2.3 & 3.1-3.3 (1998 with 2000, 2002 and 2005 amendments), online: Government of Canada Panel on Research Ethics <[www.pre.ethics.gc.ca/archives/tcps-epc/docs/TCPS%20October%202005_E .pdf](http://www.pre.ethics.gc.ca/archives/tcps-epc/docs/TCPS%20October%202005_E.pdf)> [TCPS1].

out decisional capacity ... this authorization is the permission to proceed granted by a legally recognized surrogate decisionmaker.⁹

This statement makes a distinction between informed consent obtained from the prospective participant, and third party authorization obtained from a representative of one who is incapable of giving informed consent.

Informed consent is premised upon voluntariness, capacity, and certain informational requisites, such as communication of the risks and possible benefits of the proposed intervention.¹⁰ While the elements of decision making capacity are articulated differently across provinces, as well as across different statutory contexts in a single province, the core elements typically include the ability to understand the information relevant to the decision and to appreciate the consequences of a decision or failure to decide.¹¹ While most provinces lack a statutory definition of decision making capacity specific to participation in health research, the requirement of decision making capacity is implicit in the requirement of consent.¹² If a person lacks capacity to consent to research participation, then his or her participation is invalid unless authorization is obtained from a legally-authorized representative.

To be valid, third party authorization must also be voluntary, capable, and informed. Furthermore, there must be a legal foundation (and where substitute decision making for an adult is at issue, a statutory foundation) that empowers the individual to give the authorization. Specific terms may condition the validity of the authorization. For instance, in some jurisdictions advance directives legislation requires that a proxy appointed under a directive may authorize an adult's research participation only where the directive expressly permits this.¹³

⁹ F Baylis, J Downie & N Kenny, "Children and Decision-Making in Health Research" (1999) 21:4 IRB: A Review of Human Subjects Research 5.

¹⁰ Patricia Peppin, "Informed Consent" in Downie, Caulfield & Flood, *supra* note 2 at 156, 162-75; Hadskis, *supra* note 2 at 469-85 (on the application of the law on informed consent to research settings).

¹¹ See Kathleen Glass, "Refining Definitions and Creating Instruments: Two Decades of Assessing Mental Competence" (1997) 20:1 Int'l JL & Psychiatry 5; *TCPS2*, *supra* note 8 at 40-44; Hadskis, *supra* note 2 at 480.

¹² Hadskis, *supra* note 2 at 478-81.

¹³ This is the case with Manitoba's *Advance Health Care Directives Act*, CCSM c H27, s 14, and Newfoundland and Labrador's *Advance Health Care Directives Act*, SNL 1995, c A-4.1, s 5(3). See Hadskis, *supra* note 2 at 481-85, on the strictures beyond

Legislation and other regulatory instruments may further condition the validity of third party authorization upon the level of risk or prospective benefit ascribed to the research,¹⁴ and may require decision makers to canvass certain considerations—such as the prior capable wishes, current wishes, best interests, or values of the individual. It is also important to note that in the research context, statutes and ethical guidelines may require that researchers obtain the contemporaneous assent, or at least refrain from acting against the contemporaneous dissent, of the prospective research subject.¹⁵

A final point on the distinction between consent to and third party authorization of an adult's participation in research arises in connection with the recent United Nations ("UN") *Convention on the Rights of Persons with Disabilities*.¹⁶ Canada ratified this convention in March 2010. Article 12 states in part that

1. States Parties shall recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life.
2. States Parties shall take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity.¹⁷

It is essential to recognize that in the context of health research, as in other areas of legal and social practice, the government of Canada has made a formal commitment to support the legal capacity of persons acting under a disability.

third-party authorization that may apply where a prospective research subject is incapable of consent to research participation.

¹⁴ See Part III(B), below.

¹⁵ See *TCPS2*, *supra* note 8 art 3.10; art 21 CCQ; Part IIIB, below.

¹⁶ *Convention on the Rights of Persons with Disabilities*, GA Res 61/106, UNGA, 76th Mtg, UN Doc A/Res/61/106, (2006), in force May 3, 2008 (ratification by Canada 11 March 2010) [*CRPD*].

¹⁷ For a searching analysis of the implications of Article 12 for Canadian law, see Michael Bach & Lana Kerzner, "A New Paradigm for Protecting Autonomy and the Right to Legal Capacity" (October 2010), online: Law Commission of Ontario <www.lco-cdo.org/disabilities/bach-kerzner.pdf> [Bach & Kerzner, "New Paradigm"]. On the rise of the supported decision making paradigm in some Canadian provinces, see Robert M Gordon, "The Emergence of Assisted (Supported) Decision-Making in the Canadian Law of Adult Guardianship and Substitute Decision-Making" (2000) 23:1 Int'l JL & Psychiatry 61.

Canadian laws must be interpreted to reflect this commitment.¹⁸ This arguably includes providing supports aimed at fostering the capacity of prospective subjects to make their own decisions whenever possible.¹⁹

B. Research versus Treatment

A second distinction relevant to our study is between research and therapy or medical treatment. Questions of whether and how to distinguish research from treatment for the purposes of ethical and legal norm-setting have attracted controversy in the bioethical and legal literature.²⁰ Nonetheless, a consistent approach is taken in several of the major ethical and legal documents promulgating research norms. On this approach, “treatment” describes therapeutic interventions undertaken in order to ameliorate a specific pathology affecting an individual subject, while “research” describes interventions aimed primarily at testing a hypothesis in order to generate universalizable knowledge. This accords with the definition of research in Canada’s *Tri-Council Policy Statement (“TCPS2”)*,²¹ as well as the preamble to the Council of International Organizations of Medical Sciences’ (“CIOMS”) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.²² This matter takes on particular relevance in the interpretation of substitute decision making laws that speak to health care or treatment, but not, or not explicitly, to health research.²³

¹⁸ See *Baker v Canada (Minister of Citizenship and Immigration)*, [1999] 2 SCR 817 at paras 69-71, 142 DLR (4th) 554.

¹⁹ See Bach & Kerzner, “New Paradigm”, *supra* note 17.

²⁰ Robert J Levine, “Clarifying the Concepts of Research Ethics” (1979) 9:3 *Hastings Cent Rep* 21 [Levine, “Clarifying Concepts”]; Trudo Lemmens & Paul B Miller, “Avoiding a Jekyll-And-Hyde Approach to the Ethics of Clinical Research and Practice” (2002) 2:2 *Am J Bioethics* 14.

²¹ *TCPS2*, *supra* note 8 at 15 (defines research as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation”). Compare *TCPS1*, *supra* note 8, commentary under art 1.1.

²² Council for International Organizations of Medical Sciences, in collaboration with the World Health Organization, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 1982, 1993, 2002) [*CIOMS Guidelines*].

²³ We recognize that the legal definition of research and treatment may differ depending on the purposes of the regulatory instruments employing these terms. But, as recounted in what follows in connection with the thesis of therapeutic misconception, we argue that there are good reasons to ensure that a distinction between research and

A further distinction is sometimes made between “therapeutic” and “non-therapeutic” research. Yet there is controversy about the nature of this distinction and the consequences it may entail. “Therapeutic research” typically describes research protocols or particular interventions within a single protocol that hold out a prospect of therapeutic benefit to the individual participant, while “non-therapeutic research” describes research that offers no benefit to participants.²⁴ Those who draw this distinction tend to claim that therapeutic research should attract less stringent regulatory requirements than non-therapeutic research. Such arguments, and the category of therapeutic research on which they rely, have been criticized for creating confusion about the different aims and risks of treatment and research.²⁵

treatment is maintained across the field of regulatory instruments concerned with third-party authorization of health care or research.

²⁴ See Levine, “Clarifying Concepts”, *supra* note 20.

²⁵ See e.g. George J Annas, “Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research” (1996) 12 J Contemp Health L & Pol’y 297 (Annas argues that the term “therapeutic research” is “used to disguise the true nature of experimental protocols and to obscure the ideology of science (which follows a protocol to test a hypothesis) with the ideology of medicine (which uses treatments in the best interests of individual patients)” at 314). Commenting on the distinction between therapeutic and non-therapeutic research, Robert J Levine states:

The class of activities covered by the term “therapeutic research” is also problematic because all clinical trials of therapeutic agents include some components that may be therapeutic (or at least are so intended) and others that are clearly nontherapeutic. Those who rely on the distinction between therapeutic and nontherapeutic research usually categorize research protocols with one or more components that are intended to be therapeutic as therapeutic research. Thus, all components of such protocols, both therapeutic and nontherapeutic, are justified according to the relatively permissive standards for therapeutic research. Among the nontherapeutic interventions that have been justified on this basis are placebos, some of which have been administered by catheterization of the coronary artery, and repeated coronary angiography and endoscopy in patients who would not have undergone such procedures if they had been treated outside a research protocol. I refer to this phenomenon as the “fallacy of the package deal.” (“The Need to Revise the Declaration of Helsinki” (1999) 341:7 N Eng J Med 531 at 531)

Levine also notes that in the US, “federal regulations were revised in the early 1980s to classify interventions and procedures—not entire protocols—as either beneficial or not” (“Some Recent Developments in the International Guidelines on the Ethics of Research Involving Human Subjects” (2000) 918:1 Ann N Y Acad Sci 170 at 173).

Tomossy & Weisstub (*supra* note 7), in canvassing the gaps in Canadian guardianship laws with respect to decision making about participation in research, appear to accept

For this study, the primary question arising out of these controversies is whether some research might, because of its potential to deliver an individualized therapeutic benefit, be classed as “treatment” or “health care” under certain provincial substitute decision making laws. As related below, we do not deny that some research studies may be more likely to yield health benefits to individual research subjects than others. Indeed, we acknowledge that a research protocol offering a prospect of individual health benefits *might* be deemed treatment or health care as a matter of statutory interpretation, while it is impossible that a protocol offering no prospect of individual health benefits would be so classed. At the same time, we reject the stronger claim that research offering a prospect of health benefits may be unambiguously equated with health care for the purpose of interpreting substitute decision making laws. Rather, we acknowledge the possibility of competing legal arguments on this question.

To this definitional and descriptive point, we add a normative argument that bears on our ultimate policy recommendations. That is, there are persuasive reasons for a court to decide that so-called therapeutic research *should not* be equated with health care in the interpretation of substitute decision making laws. The inclusive interpretation diverts attention from the risks generated by elements of research protocols aimed primarily at producing knowledge, as opposed to therapeutic benefit,²⁶ and from important research-specific imperatives

the critique that the concept of therapeutic research may inadequately distinguish treatment and research. They further note that “[t]he Law Reform Commission of Canada recommended that this term [“therapeutic research”] be dropped from the medical lexicon” (*ibid* at 114 n 4, citing Law Reform Commission of Canada, “Working Paper No 61: Biomedical Experimentation Involving Human Subjects”, (Ottawa: LRCC, 1989) at 5). However, they argue that it is possible to salvage from these critiques a distinction whereby non-therapeutic research includes research protocols that are “primarily non-therapeutic, based on an objective appraisal of the experiment as a whole rather than the stated intent of the researcher” (*ibid* at 115). They class as therapeutic research that which offers a reasonably foreseeable likelihood of direct benefit (*ibid* at 114 n 2). In light of the critiques already noted, the problems attached to this approach include that of defining what it means for a protocol to be “primarily” therapeutic without, again, insupportably blurring the aims and attendant risks of treatment and research.

²⁶ Franklin G Miller & Howard Brody, “A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials” (2003) 33:3 *Hastings Cent Rep* 19 at 22. Miller and Brody argue that the contrast between therapeutic and non-therapeutic research is “misleading” because it blurs the distinction between patient-oriented

such as identifying and articulating any conflicts of interest and alerting research subjects where an individualized therapeutic program would present more favourable risk-benefit prospects.²⁷

C. *Therapeutic Misconception*

The normative argument just made is reinforced by the observation that blurring the legal status of research and individualized therapy may create conditions conducive to the therapeutic misconception:²⁸ the psychological or insti-

treatment and research interventions aimed at generalizable knowledge. Moreover, they find that the contrast

diverts attention from key ethical issues. Consider a nontherapeutic trial in which one interviews subjects and takes saliva samples, and a therapeutic trial in which one is testing a new cancer drug that has some promise for creating remission, but also has potentially life-threatening toxicity. Is the latter trial less in need of stringent regulatory oversight because it is “therapeutic”? Or does the therapeutic-nontherapeutic distinction distract the observer from those aspects of the trials that assume far greater moral weight, such as the level of risks and the potential vulnerability of subjects? (*ibid*).

But see Lemmens & Miller, *supra* note 20. These authors argue that Miller and Brody are wrong to assert a fundamental difference between the aims and obligations attendant to research versus treatment. Rather, they believe it is essential to “continue to recognize the primacy of therapeutic obligations in clinical care and research” (*ibid* at 17).

²⁷ Coleman states the key arguments against aligning therapeutic research with regulatory regimes devoted to medical decision making (including best-interests-based surrogate decision making) as follows:

Even studies that offer a prospect of direct medical benefit involve additional risks not present when patients undergo individualized medical treatment. There are also risks associated with the fact that the experimental intervention has never been proven to work. Moreover, even when the experimental intervention offered in a study looks especially promising as compared to existing therapeutic options, it will often be possible to obtain that intervention outside of research, either by finding a doctor willing to prescribe an approved drug off-label or seeking a compassionate use exemption to permit the non-research use of an unapproved drug. If the potential direct benefits of a study can be obtained without assuming the added risks of research, it is difficult to see how exposing an incapacitated person to those risks can be justified under a best interests analysis (*supra* note 4 at 768).

²⁸ See Paul S Appelbaum, Loren H Roth & Charles W Lidz, “The Therapeutic Misconception: Informed Consent in Psychiatric Research” (1982) 5 Int’l J L & Psychiatry 319; Paul S Appelbaum et al, “False Hopes and Best Data: Consent to Research and the Therapeutic Misconception” (1987) 17:2 Hastings Cent Rep 20;

tutional predisposition of persons with an opportunity to participate in research—and potentially others, such as family members or researchers themselves—to exaggerate the possibility of individual benefits and underestimate the risks of research involvement.²⁹

The validity of consent to or third party authorization of participation in research is dependent upon researchers clearly communicating to prospective subjects or third party decision makers that research and treatment are distinct. In other words, researchers must make it clear that the purpose of the research enterprise is advancement of knowledge about matters that are in some significant respect uncertain.³⁰ Again, this may require particular attention to disclosure of the risks and benefits of participation in a research protocol as compared with the risks and benefits of strictly therapeutic options, and identification of the interests and objectives beyond patient well-being that have informed the design or conduct of the research.³¹

Arguably, the therapeutic misconception may be minimized by ensuring that health care consent laws and policies clearly distinguish between treatment and research and address the terms for valid authorization of each.³² Where prospective research subjects are deemed legally incapable of consent, their vulnerability to exploitation makes it particularly important that the researcher, the prospective research subject (as much as possible), and any substitute decision maker entrusted with advancing the subject's wishes or best interests are alerted to this fundamental distinction. Moreover, to avoid exacerbating the tendency to conflate treatment with research, laws that do contemplate substitute decision making about treatment without explicit contemplation of research arguably should not be interpreted to authorize substitute decision making about research.

Jay Katz, "Human Experimentation and Human Rights" (1993) 38 Saint Louis ULJ 7; Rebecca Dresser, "The Ubiquity and Utility of the Therapeutic Misconception" (2002) 19 Social Philosophy & Policy 271.

²⁹ See Appelbaum, Roth & Lidz, *supra* note 28; Appelbaum et al, *supra* note 28; Dresser, *supra* note 28.

³⁰ See Katz, *supra* note 28; Michael Hadskis et al, "The Therapeutic Misconception: A Threat to Valid Parental Consent for Paediatric Neuroimaging Research" (2008) 15:13 Accountability in Research 133; Coleman, *supra* note 4.

³¹ See Coleman, *ibid* at 788; Saks et al, *supra* note 6 at 77.

³² See Katz, *supra* note 28; Jesse A Goldner, "An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously" (1993) 38 Saint Louis ULJ 63.

III. Legal Background: The Challenge of Identifying an LAR for Substitute Decision Making about Research

A. *International Sources*

In this section, we review international health research norms addressing third party authorization of research participation. Some clearly have the status of international law and others, if not clearly expressive of customary international law, are nonetheless highly influential statements of research ethics norms.³³ We found no source of international legal or ethical guidance that speaks directly to the question of who may act as LAR for third party authorization of an adult's participation in health research. Indeed, some of the international sources canvassed here may be interpreted to indicate that health research (or "experimentation") should not be conducted at all in the absence of the individual's direct consent. We may perhaps read these sources as simply failing to contemplate the possibility of third party authorization, with safeguards. The remaining documents (which contemplate either direct or third party authorization) ultimately defer to domestic law on the matter of identifying an LAR.

One of the foundational sources of research ethics norms is the 1947 *Nuremberg Code*,³⁴ fashioned by US judges as part of the Military Tribunal process following the Allied victory in World War II. While the status of the *Code* as a source of norms at customary international law is contested,³⁵ it has nonetheless been recognized as a primary source of ethical guidance (and, on occa-

³³ George F Tomossy & Jolyon Ford note: "Arguments have been advanced both for ... and against ... whether the basic principles enunciated in the most oft-cited international instruments, the *Nuremberg Code* and *Declaration of Helsinki*, provide a source of norms under customary international law." ("Globalization and Clinical Trials: Compensating Subjects in Developing Countries" in Belinda Bennett & George F Tomossy, *Globalization and Health: Challenges for Health Law and Bioethics* (Dordrecht, The Netherlands: Springer, 2006) 27 at 35). On the complexities of appealing to international law in Canadian courts, see Gibran Van Ert, *Using International Law in Canadian Courts*, 2d ed (Toronto: Irwin Law, 2008).

³⁴ *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No 10*, vol 2 (Washington, DC: US Government Printing Office, 1948) at 181-82.

³⁵ Tomossy & Ford, *supra* note 33. See also George J Annas, "Globalized Clinical Trials and Informed Consent" (2009) 360:20 N Eng J Med 2050; Erin Talati, "An Open Door to Ending Exploitation: Accountability for Violations of Informed Consent Under the Alien Tort Statute" (2006) 155:1 U Pa L Rev 231 at 259 n 139.

sion, as a touchstone for legal standard setting) by administrative and adjudicative bodies, both national and international.³⁶

A plain reading of the *Code* yields the conclusion that no one may act as LAR. The *Code*'s first principle is that "the voluntary consent of the human subject is absolutely essential." There is no provision recognizing the possibility of third party authorization where legal capacity is lacking. It may be argued, however, that the silence of this early statement of research norms on the matter of third party authorization reflects a failure to contemplate the possibility of such authorization, with appropriate safeguards, rather than a clear intention to proscribe it.

Article 7 of the UN *International Covenant on Civil and Political Rights* follows in the same vein. It states that "[n]o one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."³⁷ Once again, the statement appears unequivocal. However, here too it may be argued that this statement of international norms (acceded to by numerous states, including Canada) fails to contemplate, but does not necessarily prohibit, third party authorization of research participation where other safeguards are in place.³⁸

³⁶ See Annas, *supra* note 35; Hadskis, *supra* note 2 at 449 ("[t]he Nuremberg Code and the Declaration of Helsinki continue to influence the regulation of research in Canada"). While these instruments do not have direct legal force, they inform the reasoning of policy-makers as well as judges in setting Canadian standards. See also Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2001) 46 McGill LJ 473 at 484-85, 487 (Campbell and Glass discuss the general concerns that may be raised around employment of professional norms such as the Declaration of Helsinki as guides to legal standards).

³⁷ *International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 171, Can TS 1976 No 47, 6 ILM 368 (entered into force 23 March 1976, accession by Canada 19 May 1976). [ICCPR]

³⁸ The Office of the High Commissioner for Human Rights, General Comment No. 20 (Forty-fourth session, 1992), states of Article 7 of the ICCPR that "special protection in regard to such experiments is necessary in the case of persons not capable of giving valid consent, and in particular those under any form of detention or imprisonment. Such persons should not be subjected to any medical or scientific experimentation that may be detrimental to their health." Canada is a party to the First Optional Protocol to the Covenant, which establishes a complaint mechanism

This argument is more difficult to make with respect to the recent UN *Convention on the Rights of Persons with Disabilities*.³⁹ Article 15 of the *Convention* prohibits “medical or scientific experimentation,” again without the “free consent” of the individual.⁴⁰ Given that this historic statement of the rights of persons with disabilities explicitly addresses questions of legal capacity, including the duty of states to support legal capacity,⁴¹ a persuasive case may be made that it registers a strict prohibition of research (or “experimentation,” which may or may not include research offering a therapeutic benefit), except where there is personal consent. This may be taken as an unequivocal response to the historical record of egregious harms done to persons with disabilities (including psychosocial and intellectual disabilities) in the name of research. Yet we might ask whether the prohibition may be qualified in light of the general commitment of parties to the *Convention* to ensure that persons with disabilities enjoy “full and effective participation and inclusion in society,”⁴² a commitment that must guide the interpretation of the *Convention*. This principle may be read to support the inclusion of persons living with profound cognitive disabilities in the social good of health research, at least where stringent protections (including support for decision making capacity) are provided, and where participation will enable a more equitable distribution of the benefits of research.⁴³

whereby individuals may bring complaints against states parties to the Human Rights Committee for breach of covenant rights, following the exhaustion of all domestic remedies. See *Optional Protocol to the International Covenant on Civil and Political Rights*, 16 December 1966, 999 UNTS 302 (entered into force 23 March 1976, accession by Canada 19 May 1976).

³⁹ *Supra* note 16.

⁴⁰ *Ibid.* Article 15(1) states that

1. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation.

⁴¹ *Ibid.* Canada is not a party to the Optional Protocol to the Convention. Under the Optional Protocol, persons alleging violations of their rights under the Convention may bring complaints to the Committee on the Rights of Persons with Disabilities. See *Optional Protocol to the Convention on the Rights of Persons with Disabilities*, 13 December 2006, GA Res 61/106, Annex II, UN GAOR, 61st Sess, Supp No 49 at 80, UN Doc A/61/49 (2006) (entered into force 3 May 2008).

⁴² *CRPD*, *supra* note 16 art 3(c).

⁴³ *TCPS2*, *supra* note 8 art 1.1 lays out three general principles intended to inform the interpretation and application of research ethics norms: respect for persons, welfare, and justice. The principle of justice is articulated so as to include the distributive

Other international statements of research norms recognize the legitimacy of third party authorization, while reflecting a concern for the unjustified exclusion of persons with cognitive disabilities from the fruits of research.⁴⁴ The World Medical Association's *Declaration of Helsinki*⁴⁵ falls into this category, though—like the *Nuremberg Code*—its status as a source of customary international law remains contested.⁴⁶ Article 5 states that “[p]opulations that are underrepresented in medical research should be provided appropriate access to participation in research.” Article 9 states that among those research populations requiring special protections are persons who “cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.” More directly, article 27 states *inter alia* that “[f]or a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative.”⁴⁷ Three additional requirements are stated, as follows:

justice concern of allocating the benefits of research fairly (at 11). The *TCPS2* also underlines the importance of providing meaningful inclusion of vulnerable groups (including those deemed incapable of consent) in research, provided that appropriate protections from exploitation or other forms of oppression are in place (at 10). For arguments that there is no justification—based in justice, welfare, utility, or autonomy—for involving persons who lack legal capacity in non-therapeutic research (research producing no individual health benefit), see Penney Lewis, “Procedures That are Against the Medical Interests of Incompetent Adults” (2002) 22:4 *Oxford JLS* 575.

⁴⁴ See Tomossy & Weisstub, *supra* note 7 at 118-19.

⁴⁵ World Medical Association, *Declaration of Helsinki: Ethical Principles For Medical Research Involving Human Subjects*, (June 1964), online: WMA <www.wma.net/en/30publications/10policies/b3/index.html> [*Declaration of Helsinki*]. The Declaration has undergone six revisions since its original formulation in 1964, the latest of these having been made in 2008.

⁴⁶ Erin Talati observes that “[t]he Declaration of Helsinki is widely accepted as the most influential guidance document in the creation of statutory protections for human subjects” (*supra* note 35 at 260). See Talati’s discussion, *ibid* at 260 n 142, of the recognition of a distinction between therapeutic and non-therapeutic research in earlier versions of the Declaration of Helsinki, with different ethical requirements imposed for each (even allowing physicians to proceed without consent where research was therapeutic). As Talati notes, later versions of the Declaration (from 2000 on) do not preserve this distinction, a change that “may represent recognition of the possibility for exploitation under the therapeutic misconception” (*ibid*).

⁴⁷ *Declaration of Helsinki*, *supra* note 45 art 27. The *CIOMS Guidelines* take this same approach, stating that research can proceed if consent is obtained from the legally authorized representative in accordance with applicable law (*supra* note 22 art 4).

These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.⁴⁸

As we will see, the terms of the *Declaration* find support in Canada's regulatory regime for oversight of clinical drug trials and Canada's *TCPS2*.⁴⁹

One final international document has particular relevance to Canadian law, specifically as it relates to the legal regulation of clinical drug trials. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use has promulgated the 1996 *Good Clinical Practice: Consolidated Guideline* ("GCP Guideline")⁵⁰ as a statement of research ethics norms common to the US, the European Union, and Japan. This guideline has been endorsed by Health Canada as an interpretive aid for the *Clinical Trial Regulations* under the *Food and Drugs Act*.⁵¹ Section 4.8.12 of the *GCP Guideline* indicates that both therapeutic and non-therapeutic research

The *Guidelines*, prepared by the CIOMS in consultation with the World Health Organization, seek "to indicate how the ethical principles that should guide the conduct of biomedical research involving human subjects, as set forth in the Declaration of Helsinki, could be effectively applied, particularly in developing countries, given their socioeconomic circumstances, laws and regulations, and executive and administrative arrangements" (at "Background"). For a description of other international codes or guidelines on the conduct of research, see Kevin M King, "A Proposal for the Effective International Regulation of Biomedical Research Involving Human Subjects" (1998) 34 *Stanford J Int'l Law* 163. It is important to additionally note among the international legal instruments of significance the Council of Europe's *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*, (Council of Europe Treaty Series No 164), and *Additional Protocol Concerning Biomedical Research* (Council of Europe Treaty Series No 195). Tomossy & Ford canvass the controversies among nations regarding the latter instrument's endorsement of surrogate consent for non-therapeutic research, *supra* note 33 at 36.

⁴⁸ *Declaration of Helsinki*, *supra* note 45 art 27.

⁴⁹ *Supra* note 8 arts 3.9, 4.6.

⁵⁰ International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline on Good Clinical Practice: Consolidated Guideline E6(R1)* (1996) [*GCP Guideline*].

⁵¹ *Food and Drug Regulations*, CRC, c 870, Part C Division 5 (*Drugs for Clinical Trials Involving Human Subjects*) [*Food and Drugs Regulations*].

require authorization from a legally acceptable representative.⁵² Section 1.37 defines “legally acceptable representative” as “[a]n individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.” The *GCP Guideline*, like the *Declaration of Helsinki*, also stipulates further requirements, including obtaining assent from the subject who is deemed incapable of consent, when possible.⁵³

In summary, there is some divergence among key statements of international health research norms with respect to the permissibility, or the conditions of permissibility, of research involving persons deemed incapable of consent. It may be argued that the conventions prohibiting experimentation without the individual's free consent are simply silent on the matter of third-party authorization and the circumstances in which such authorization would be valid. Those sources of research ethics norms that explicitly contemplate the possibility of such research may be understood to seek to bring into harmony the potentially conflicting imperatives of respect for persons and justice in distributing the fruits of research. One condition they impose is that third party authorization must be obtained. The problem, however, of identifying the lawful source of third party authorization remains.

B. Domestic Sources

There is a lack of clear and comprehensive guidance in Canada on the legality (or the conditions of legality) of health research involving adults who are legally incapable of providing consent. In particular, it is often not clear whether substitute decision makers recognized for other purposes are also authorized to make decisions about research.⁵⁴ Similar criticism has been made of US laws.⁵⁵

⁵² *GCP Guideline*, *supra* note 50 s 4.8.12.

⁵³ *Ibid* at ss 4.8.12, 4.8.13. Article 28 of the *Declaration of Helsinki*, *supra* note 45 sets out a requirement to seek assent (where the research subject is deemed capable of assent) and to respect dissent.

⁵⁴ Bravo et al, “Comparison Substitute Consent”, *supra* note 7; Paddi O’Hara & Ineke Neutel, “A Shadow of Doubt: Ethical Issues in the Use of Proxy Consent in Research, Part II: Competence and Proxy Consent in Terms of Guidelines and Regulations” (2004) 9:1 *Can Bioethics Soc Newsletter* 7; Tomossy & Weisstub, *supra* note 7 at 134.

⁵⁵ Kim et al, *supra* note 6; Saks et al, *supra* note 6.

This section first identifies the sources of liability that may apply where research is conducted in the absence either of consent or third party authorization. Next, it examines key statements of federal law and policy imposing an imperative of third party authorization where prospective research subjects lack capacity to consent, noting the lack of any basis for identifying an LAR in either federal law or policy, or at common law. Finally, this section outlines a set of legal sources that do present a basis for identifying an LAR to authorize research participation. Here we focus on the substitute decision making laws—guardianship, advance directive, and health care consent laws—of the four provinces targeted in our study.⁵⁶ Throughout, we supplement our central concern with the legal bases for identifying an LAR with attention to any conditions (e.g. risk-benefit thresholds) placed upon the validity of third party authorization of research.

We do not address federal and provincial laws relating to the protection of privacy and lawful disclosure of health information. In presenting the results of our study, however, we do note that these laws may have affected responses to the last of our four research scenarios.

1. Liability Attaching to Health Research in the Absence of Valid Authorization

In the absence of valid consent or third party authorization, interventions affecting the bodily integrity or property interests of an individual, whether in the name of treatment or research, may give rise to liability. The *Criminal Code*⁵⁷ may ground liability where research involving bodily interventions proceeds in the absence of valid consent or third party authorization. Specifically, unauthorized bodily touching may give rise to charges of assault or criminal negligence.⁵⁸ In addition, property-based offences may be engaged where bodily materials are seized without authorization.⁵⁹

At common law, an unauthorized touching may ground a tort claim of battery, while a threat of unauthorized touching may ground a claim of assault. In the civil law, such activities may amount to a breach of article 1457 of the *Civil*

⁵⁶ For a more comprehensive analysis of all provincial and territorial laws as they stood in 2005, see Bravo et al, “Comparison Substitute Consent”, *supra* note 7.

⁵⁷ RSC 1985, c C-46.

⁵⁸ Bernard M Dickens, “The Legal Challenge of Health Research Involving Children” (1998) 6 Health LJ 131 at 135.

⁵⁹ *Ibid* at 136-37.

Code of Quebec, which outlines the province's general regime of civil responsibility. Where research is conducted in the absence of valid third party authorization, liability in battery or assault may attach to the actions of the researcher, with a potential for vicarious liability on the part of the research institution if the researcher is an employee. In addition, liability in negligence may attach to researchers, research sponsors, research institutions, or REB members if the conduct, approval, or support of research is found to breach the applicable legal standard of care—for example, by failing to ensure sufficient disclosure of risks or otherwise failing to ensure the validity of authorization.⁶⁰

REBs may, in addition, be susceptible to administrative law review, either because they carry out specific statutory mandates⁶¹ or because their position within the decision making apparatus of a university or other institution falls within the reach of administrative law.⁶² On this basis, an REB's approval of a research protocol without ensuring valid third party authorization might be quashed as a substantive illegality (e.g. for failing to consider a factor of mandatory relevance). Furthermore, if an REB or research institution were deemed either to be part of the apparatus of government or, alternatively, a private body acting in furtherance of a specific government program or policy,⁶³ its decision to permit research in the absence of valid third party authorization may be susceptible to challenge under the *Canadian Charter of Rights and Freedoms*.⁶⁴

⁶⁰ Hadskis, *supra* note 2 at 495-99; Mary M Thomson, "Bringing Research into Therapy: Liability Anyone?" in Trudo Lemmens & Waring Duff, eds, *Law and Ethics in Biomedical Research: Regulation, Conflict of Interest and Liability* (Toronto: University of Toronto Press, 2006) 183; Jennifer L Gold, "Watching the Watchdogs: Negligence, Liability, and Research Ethics Boards" (2003) 11 Health LJ 153.

⁶¹ See Michael Hadskis & Peter Carver, "The Long Arm of Administrative Law: Applying Administrative Law Principles to Research Ethics Boards" (2005) 13:2 & 3 Health L Rev 19 (on the "recent proliferation of statutory REB mandates" at 22-23, and at 24-28 on a set of possible bases of administrative law regulation of REB decision making).

⁶² *Ibid* at 20-22.

⁶³ See Patricia Kosseim & Megan Brady, "Policy By Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes" (2008) 2 McGill JL & Health 5 at 13 n 34; *Eldridge v British Columbia (AG)*, [1997] 3 SCR 624, 151 DLR (4th) 577; *Douglas/Kwantlen Faculty Assn v Douglas College*, [1990] 3 SCR 570, 77 DLR (4th) 94; *Slaight Communications Inc v Davidson*, [1989] 1 SCR 1038, 59 DLR (4th) 416; *Blencoe v British Columbia (Human Rights Commission)*, 2000 SCC 44, [2000] 2 SCR 307.

⁶⁴ Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982 (UK)*, 1982, c 11 [*Charter*] (e.g. as interfering with the section 7 right to liberty and bodily

Whether traced to government or private actors, research norms and practices must also conform to the requirement of non-discrimination imposed by federal and provincial human rights codes. Research that imposes a disproportionate burden on persons with disabilities (including cognitive disabilities) may attract penalties, financial or otherwise.

Failure of a researcher to obtain valid third party authorization may also breach medical ethics codes promulgated by provincial colleges of medicine. Breach of these codes may result in professional disciplinary processes.⁶⁵ Additionally, legal action may be grounded in breach of privacy interests when personal information is appropriated or used for research purposes without consent or third party authorization.⁶⁶

a. Federal Sources of Research Norms Mandating an LAR

In addition to the foregoing sources of liability, penalties may apply where non-compliance with research-specific codes or guidelines is established. Two sources of research norms at the federal level are of particular relevance.

As noted, the *TCPS2*⁶⁷ sets out guidelines for research on humans that are applicable to institutions and researchers receiving funding from one of Canada's three federal research funding agencies.⁶⁸ While the *TCPS2* is not a statutory instrument, a requirement of adherence to its terms is incorporated into these agencies' funding agreements with research institutions.⁶⁹ Failure to comply may result in termination of funding and an obligation to repay funds

integrity). Note that a recent judgment of the Supreme Court of Canada indicates that administrative decisions involving adjudicative discretion should be reviewed under common law administrative law principles, even where the decision engages *Charter* values (*Doré v Barreau du Québec*, 2012 SCC 12 (available on CanLII)).

⁶⁵ Hadskis & Carver, *supra* note 61. Compliance with *TCPS2* guidelines is specifically required by some provincial medical associations. See Hadskis, *supra* note 2 at 443, 449.

⁶⁶ See Elaine Gibson, "Health Information: Confidentiality and Access" in Downie, Caulfield & Flood, *supra* note 2 at 286-88; Hadskis, *supra* note 2 at 485-90.

⁶⁷ *Supra* note 8.

⁶⁸ These are: the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

⁶⁹ See Hadskis, *supra* note 2 at 442-43.

conferred.⁷⁰ Among the *TCPS2* guidelines relevant to research involving persons deemed legally incapable of giving consent is article 3.9(b), which states that researchers must obtain “consent from authorized third parties in accordance with the best interests of the persons concerned.”⁷¹

The *TCPS2* also includes commentary on the assessment of decisional capacity,⁷² and a requirement that research involving persons who lack capacity to consent not “expose the participants to more than minimal risk without the prospect of direct benefits for them.”⁷³ It further requires that the wishes of

⁷⁰ See Natural Sciences and Engineering Research Council of Canada, *Tri-Agency Process for Addressing Allegations of Non-Compliance with Tri-Agency Policies*, online: NSERC <www.nserc-crsng.gc.ca/NSERC-CRSNG/governance-gouvernance/process-processus_eng.asp>.

⁷¹ *TCPS2*, *supra* note 8 at 41. The *TCPS2* at 27 defines “authorized third party decision maker” as “any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project.” The *TCPS1* also stated a requirement of third party authorization where the research subject is incapable of consent, and indicated that the identity of the LAR must be determined in light of provincial law. See *TCPS1*, *supra* note 8 s 2E (“Competence”), especially arts 2.5, 2.6.

⁷² The *TCPS2*, *supra* note 8 at 41 acknowledges that the standard of legal capacity applicable to decisions about research participation may shift depending on the jurisdiction. Yet this section nonetheless advises that capacity to decide about research participation demands an ability to understand the information relevant to the decision and to appreciate that information or evaluate the decision’s likely consequences for oneself, reflecting the standards in place in certain Canadian jurisdictions, most notably Ontario’s, which were subject to judicial interpretation in the case *Starson v Swayze*, 2003 SCC 32, [2003] 1 SCR 722. The *TCPS2* further provides at 40 that “[t]his ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought.”

⁷³ *TCPS2*, *ibid* art 4.6(b). This article stipulates two additional conditions:

(a) the research question can be addressed only with participants within the identified group; and ...

(c) where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

Also see article 3.9(a-e). “Minimal risk” is defined in the *TCPS2* as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” The passage adds:

prospective subjects with “some ability to understand the significance of the research” be ascertained by researchers and that those who dissent not be involved in the research.⁷⁴

The other federal source of relevant research-specific norms is the *Clinical Trials Regulations*.⁷⁵ These regulations under the *Food and Drugs Act*⁷⁶ apply to clinical trials of drugs for human use.⁷⁷ Consequences of non-compliance may include “warning letters, suspension or cancellation of an authorization to sell or import a drug for the purposes of a clinical trial, injunctions, and criminal prosecutions.”⁷⁸

Under the regulations, sponsors of research must obtain REB approval “at each clinical trial site,”⁷⁹ and approving REBs must attest to upholding the standards of “good clinical practices.”⁸⁰ Some guidance on the substance of those standards is given through Health Canada’s endorsement of the *GCP*

In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (at 23).

The minimal risk standard has been subject to critical commentary (see e.g. Loretta M Kopelman, “Moral Problems in Assessing Research Risk” (2000) 22:5 IRB: A Review of Human Subjects Research 3), while attracting in some quarters at least a partial defence (see e.g. Paul B Miller & Charles Weijer, “Moral Solutions in Assessing Research Risk” (2000) 22:5 IRB: A Review of Human Subjects Research 6).

⁷⁴ *TCPS2*, *supra* note 8 art 3.10. For commentary on the requirements of respect for assent and dissent, see Betty S Black et al, “Seeking Assent and Respecting Dissent in Dementia Research” (2010) 18:1 Am J Geriatr Psychiatry 77.

⁷⁵ Food and Drugs Regulations, *supra* note 51.

⁷⁶ *Ibid.*

⁷⁷ A description of the terms of the regulations is provided in Hadskis, *supra* note 2 at 444-46.

⁷⁸ *Ibid* at 445; see Health Products and Food Branch Inspectorate, “Policy-0001: Compliance and Enforcement Policy, Version 2” (date of implementation: 31 May 2005) at 8-10, online: HC <www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/pol_1_e.pdf>.

⁷⁹ *Food and Drug Regulations*, *supra* note 51 s C.05.006(1)(c).

⁸⁰ *Ibid* ss C.05.010, C.05.012(h).

Guideline.⁸¹ As noted earlier, the *GCP Guideline* states that research involving persons who lack capacity to consent requires permission from their “legally authorized representative.”⁸² The *GCP Guideline* adds that a researcher should inform and seek assent from the subject in accordance with his or her understanding.⁸³ Article 4.8.14 states further conditions that apply specifically to “non-therapeutic”⁸⁴ clinical trials:

- (a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.
- (b) The foreseeable risks to the subjects are low.
- (c) The negative impact on the subject’s well-being is minimized and low.
- (d) The trial is not prohibited by law.
- (e) The approval/favourable opinion of the [REB] is expressly sought on the inclusion of such subjects, and the written approval/favourable opinion covers this aspect.

Moreover, subjects are to be withdrawn “if they appear unduly distressed.”⁸⁵

2. Identifying an LAR: Legal Foundations

We have seen that health research conducted without valid authorization may attract various forms of liability. Moreover, we have seen that both the *TCPS2* and the *Clinical Drug Trial Regulations* indicate that research involving persons who are incapable of consent is permissible only if the researcher obtains valid third party authorization, among other conditions. We must turn to

⁸¹ *GCP Guideline*, *supra* note 50. See the statement of Health Canada adopting the Guideline, “Clinical Trials Regulations” (17 October 2007) online: HC <www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/pol/clini-reg-eng.php>.

⁸² *GCP Guideline*, *supra* note 50 ss 3.1.6, 4.8.12, 4.8.14.

⁸³ *Ibid* s 4.8.12.

⁸⁴ *Ibid* s 4.8.13 defines a non-therapeutic trial as “a trial in which there is no anticipated direct clinical benefit to the subject.”

⁸⁵ *Ibid* s 4.8.14.

provincial law to determine who, if anyone, possesses the legal power to give third party authorization of research.

a. Constitutionality

The legal sources that may enable identification of an LAR must be constitutionally valid. In Canada, legislative authority over matters relating to health is shared between provincial and federal governments,⁸⁶ with general legislative authority falling to the provinces.⁸⁷ On the matter of jurisdiction over health research, whether that jurisdiction is exclusively federal, exclusively provincial, or shared is a matter of some controversy.⁸⁸ As we have seen, both federal laws, such as the clinical drug trials regulations under the *Food and Drugs Act*,⁸⁹ and provincial laws (like those canvassed below) speak to the regulation of health research.

Furthermore, all legislation and government action must conform to the *Charter*.⁹⁰ Laws contemplating third party authorization of research offering no prospect of individual benefit are susceptible to *Charter* challenge, al-though

⁸⁶ The federal government's claim to legislative powers with respect to health arises in virtue of the federal spending power, along with, *inter alia*, its jurisdiction over criminal law, trade and commerce, quarantine and the establishment of marine hospitals, and the promotion of peace, order and good government under s 91 of the *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3, reprinted in RSC, 1985, App II, No 5 [*Constitution Act, 1867*].

⁸⁷ The provinces' legislative powers with respect to health arise in virtue of, *inter alia*, their authority over property and civil rights (s 92(13)), hospitals (s 92(7)), and matters of a local or private nature (s 92(16)) under the *Constitution Act, 1867*, *supra* note 86. See *Schneider v British Columbia*, [1982] 2 SCR 112, 139 DLR (3d) 417.

⁸⁸ See *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 SCR 457; Erin Nelson, "Regulating Reproduction" in Downie, Caulfield & Flood, *supra* note 2 at 326-34 (discussing the *Assisted Human Reproduction Act* reference). And see Jennifer Llewellyn, Jocelyn Downie & Robert Holmes, "Protecting Human Research Subjects: A Jurisdictional Analysis" (2003) Health LJ Special Edition: Health Law in the 21st Century 207 (the authors argue for substantial if not exclusive federal jurisdiction over research involving humans).

⁸⁹ *Food and Drugs Regulations*, *supra* note 51.

⁹⁰ Kosseim & Brady, *supra* note 63.

some argue that such laws (or the constitutionally-sensitive interpretation and application thereof) could be justified under section 1.⁹¹

b. No Common Law Basis for Identification of an LAR

There is no common law basis for identifying an LAR. While the common law recognizes parental authority to make health care or other decisions in the best interests of their minor children,⁹² there is no comparable common law foundation for establishing third party decision making for a legally-incapable adult. Though this is clearly recognized in the academic literature,⁹³ it does not

⁹¹ See Dickens, *supra* note 58 at 145-46 (citing sections 7 (life, liberty and security of the person), 8 (right to be free from unreasonable search and seizure), 12 (right to be free from cruel and unusual punishment) and 15(1) (non-discrimination)). Dickens indicates that such laws might be justified under s 1 of the *Charter* if the government were to demonstrate that the contribution of the laws to advancing the interests of the individuals or groups concerned, or the public interest, outweighs the harm done to the protected interests.

⁹² See *B(R) v Children's Aid Society of Metropolitan Toronto*, [1995] 1 SCR 315 at 372, 122 DLR (4th) 1, per La Forest J: "[T]he common law has always, in the absence of demonstrated neglect or unsuitability, presumed that parents should make all significant choices affecting their children, and has afforded them a general liberty to do as they choose." Where it is alleged that parental decision making about the health care of minor children comes into conflict with the best interests of the child, a legal challenge may be raised under provincial child welfare legislation or by way of an application to a court to exercise its *parens patriae* jurisdiction to protect the best interests of the child (see Joan Gilmour, "Children, Adolescents, and Health Care" in Jocelyn Downie, Tim Caulfield & Colleen Flood, eds, *Canadian Health Law and Policy*, 3rd ed (Markham: LexisNexis, 2007) 205 at 206-07).

⁹³ See Gerald B Robertson, *Mental Disability and the Law in Canada*, 2d ed (Scarborough: Carswell, 1994) at 473; Gilbert Sharpe, *The Law & Medicine in Canada*, 2d ed (Toronto: Butterworths, 1987) at 78-79; Bernard M Dickens, "The Role of the Family in Surrogate Medical Consent" (1980) 1:3 Health L Can 49; Marc E Schiffer, *Psychiatry Behind Bars: A Legal Perspective* (Toronto: Butterworths, 1982) at 187; Lorne Elkin Rozovsky, "Consent to Treatment" (1973) 11 Osgoode Hall LJ 103 at 110. As Robertson points out, in the domain of health care, "an application may be brought to have the court exercise its *parens patriae* jurisdiction and authorize the treatment" (Robertson, *ibid* at 473). As we discuss below, it is not clear that such authorization would extend to research.

See also Manitoba Law Reform Commission, *Substitute Consent to Health Care* (Winnipeg: Manitoba Queen's Printer, 2004). Unlike most Canadian provinces and territories, Manitoba has no statutory basis for vesting medical decision making authority in a family member or other in case of an adult individual's incapacity: "[a]t

appear to be widely understood beyond the domain of academics or specialized legal professionals. It is worth noting that the common law in England has developed differently than the common law in Canada, by allowing medical treatment without third party authorization where the patient is incapable of consent, and when the care is necessary (but not urgently necessary) to the patient's health.⁹⁴ English legislation was recently passed codifying this principle (which has the effect of protecting treating physicians from liability); the legislation also fills historical gaps in the common law of England on the legality of research involving persons deemed incapable of consent.⁹⁵

common law, only a court-appointed guardian (such as a committee) or the court itself, under its *parens patriae* jurisdiction, can consent to or refuse treatment on behalf of an incapable patient" (at 9). At the time of the Commission's research, substitute consent to treatment was authorized in the province only in the narrow circumstances covered by the *Mental Health Act*, SM 1998, c 36, CCSM c M110, the *Vulnerable Persons Living With a Mental Disability Act*, SM 1993, c 29, CCSM c V90, or, where an advance directive for health care was in place, the *Health Care Directives Act*, SM 1992, c 33, CCSM c H27 (at 10-12). The Commission observed, however, that despite the lack of legal justification outside these limited contexts, "[i]n most cases, the health care provider will turn to the person's family for consent because, even though there is no legal justification for doing so, it is the most reasonable course of action in the circumstances" (at 19). In view of the consequent risks of liability, along with the possibility that patient self-determination may be compromised, the Commission recommended that substitute decision making legislation be adopted (at 19-21).

⁹⁴ *In re F* (1989), [1990] 2 AC 1 HL (Eng). This represents an extension of the defence of necessity (not limited to emergency situations) that has never been recognized in Canada.

⁹⁵ With the *Mental Capacity Act 2005* (UK), c 9, English law has codified the authority of health professionals to give treatment according to their understanding of the individual's best interests and without third-party authorization, unless an advance directive applicable to the circumstances is in place (s 5). In the case of research (or "intrusive" research—defined as research interventions that would require consent as a matter of law if the subject was capable of consent (*ibid* s 30(2)))—the requirements under the *Mental Capacity Act 2005* differ. Apart from stating certain threshold conditions (including a requirement of minimal risk and of prospective benefits likely to outweigh the risks), the Act requires third-party authorization (s 32). The researcher must identify a family member, unpaid caregiver, or other person who fits the statutory criteria for acting as a "consultant." Where that person indicates that the prospective research subject would not wish to be involved in the research, that person must not be involved, unless the research is already underway and withdrawal would compromise his or her health (ss 32(2-3), (5-6)). Respect for the subject's contemporaneous dissent is also required (s 33). The conditions placed upon clinical

In the absence of a common law foundation, third party authorization of medical interventions or research for an adult must be based in one of three sources: (1) guardianship legislation, which typically requires a court order indicating the guardian's identity and scope of authority; (2) legislation vesting a narrower form of decision making authority in a family member or another in the event of an individual's incapacity (e.g. health care consent legislation); or (3) an advance directive, the authority of which may be recognized under legislation or at common law. We return briefly to advance directives below.

There remains the possibility of an application to a superior court to exercise its *parens patriae* jurisdiction to authorize a particular intervention. However, this is at best an uncertain route to authorization of research involvement.⁹⁶ The Supreme Court of Canada's decision in *E (Mrs) v Eve* confirms that the *parens patriae* jurisdiction of superior courts may be exercised only to advance the interests of the individual acting under a legal incapacity.⁹⁷ Specifically, the Court relied upon this principle to refuse an application by Mrs. E for authorization to consent to the surgical sterilization of her intellectually disabled daughter. In his judgment on behalf of the Court, Justice La Forest characterized the requested procedure as "non-therapeutic." In other words, the proposed surgical sterilization was intended to alleviate concerns that were not clearly or directly related to Eve's health. Rather, the Court understood the application to be primarily motivated by Eve's mother's concerns about the supervisory and child-rearing responsibilities potentially falling to her as a result of Eve's reproductive potential.⁹⁸

drug trials in England are separately addressed under the *Medicines for Human Use (Clinical Trials) Regulations 2004* (SI 2004/1031, as amended by SIs 2006/1928, 2006/2984, and 2008/941). These regulations also include a requirement of third-party authorization (*ibid*, Schedule 1, Part 1 s 1(4), Part 5).

⁹⁶ Tomossy & Weisstub, *supra* note 7 at 127 (their emphasis is on the uncertainty of a court actually authorizing non-therapeutic research).

⁹⁷ [1986] 2 SCR 388 at 400-01, 31 DLR (4th) 1 [*Re Eve*].

⁹⁸ *Ibid* at 401. It should be noted that the identification of Eve's interests with strictly-defined medical or therapeutic interests has attracted critical commentary in the years since this decision. See Sheila Wildeman, "The Supreme Court of Canada at the Limits of Decisional Capacity" in Jocelyn Downie & Elaine Gibson, eds, *Health Law at the Supreme Court of Canada* (Toronto: Irwin Law, 2007) 239 at 261-65; M Anne Bolton, "Whatever Happened to Eve? A Comment" (1987-88) 17:2 Man LJ 219; Colleen M Olesen, "Eve and the Forbidden Fruit: Reflections on a Feminist Methodology" (1994) 3 Dal J Leg Stud 231; Kristin Savell, "Sex and the Sacred:

Just as the *parens patriae* jurisdiction does not admit authorization of non-therapeutic sterilization, so this jurisdiction may also be incompatible with authorization of health research, which describes interventions intended to produce societal benefits, not (or not primarily) to advance the interests of the individual subject. On this argument, then, even a court may not be able to authorize “non-therapeutic” research.

Controversy persists as to whether the *parens patriae* jurisdiction might ever be compatible with the authorization of research and if so, under what conditions. This controversy is echoed in debates about the scope of parental guardianship at common law and the scope of broadly-stated statutory guardianship (including adult guardianship) powers.⁹⁹ Bernard Dickens has opined that the most defensible, or least risky, interpretation of *Re Eve*'s relevance to research is that the court's *parens patriae* jurisdiction (and we may argue, by analogy, the authority of parental and perhaps other guardians) is limited to authorizing interventions that offer a reasonably foreseeable therapeutic benefit to the subject. Those prospective benefits may arguably include psychological and social benefits.¹⁰⁰ Dickens further suggests, however, that parents may be able to enrol children in research that lacks a therapeutic benefit as long as the risks are “minimal” (i.e. no greater than the background risks routinely faced in the child's daily life).¹⁰¹ Might guardians of adults be argued to be similarly empowered; i.e., might such authority be recognized by way of interpretation of the broad or vague powers conferred by some guardianship laws?¹⁰² These controversies concern the scope of authority of one already vested with legal pow-

Sterilization and Bodily Integrity in English and Canadian Law” (2004) 49:4 McGill LJ 1093.

⁹⁹ Dickens, *supra* note 58 (in *Re Eve* “[t]he court was concerned with the scope of its own power rather than that of Eve's mother, but it approached its rights when acting *in loco parentis* in close analogy to the rights of natural parents” at 132-33).

¹⁰⁰ See Dickens, *ibid* (noting that both the understanding of “health” expressed in *Re Eve* and the definition of the World Health Organization comprehend “physical, mental and social well-being” at 134); Françoise E Baylis & Jocelyn Downie, “An Ethical and Criminal Law Framework for Research Involving Children in Canada” (1993) 1 Health LJ 39 at 49; Norman L Cantor, *Making Medical Decisions for the Profoundly Mentally Disabled* (Cambridge, Mass: MIT Press, 2005).

¹⁰¹ Dickens, *supra* note 58 at 135-36. See also Tomossy & Weisstub, *supra* note 7 at 126-27.

¹⁰² Of course, controversy would likely arise around whether this authority is implicit in generally worded provisions conferring guardianship powers, i.e. whether the interpretation would amount to a legitimate realization of statutory purposes or an illegitimate instantiation of judicial “legislation”.

er to make decisions on behalf of another individual. They do not contradict the earlier point that there is no common law foundation for identification of an LAR, except to the extent that a court might itself possess this power, were authorization of research to be found to fall within the *parens patriae* jurisdiction.

In sum, there is no common law basis in Canada on which third party authorization of an adult's participation in research (or, for that matter, health care) may be said to vest in a family member or other individual. Moreover, the Canadian jurisprudence on the limits of the court's *parens patriae* jurisdiction offers no clear basis for asserting that a court could directly authorize research if faced with an application to do so. However, some argue that research presenting a prospect of therapeutic benefit, and potentially even research offering no prospect of direct benefit but no more than minimal risk, might fall under the court's *parens patriae* jurisdiction or the powers of parental or statutory guardians.

c. Advance Directives

The validity of advance directives at common law is a separate matter. In *Malette v Shulman*,¹⁰³ the Ontario Court of Appeal upheld the validity of an instructional directive about health care in the absence of a legislative basis for the validity of the document. Ontario currently has a legislative regime for advance directives that provides for appointment of a proxy for substitute decision making about health care.¹⁰⁴ Moreover, Ontario's health care consent law requires substitute decision makers to follow the instructions (or prior express wishes) of those they represent.¹⁰⁵ *Malette v Shulman* continues to be of importance in grounding the authority of instructional directives which do not appoint a proxy, and serves as persuasive authority on the legal status of this sort of document in other jurisdictions lacking applicable legislation. The validity of advance directives for research participation, however, remains uncertain as a matter of common law.¹⁰⁶ As we will see, certain provinces have adopted legislation that clarifies the conditions of validity of research-specific directives.

¹⁰³ *Malette v Shulman* (1990), 72 OR (2d) 417, 67 DLR (4th) 321 (Ont CA).

¹⁰⁴ *Substitute Decisions Act*, SO 1992, c 30, s 46.

¹⁰⁵ *Ibid* s 46(7). See also *Health Care Consent Act, 1996*, SO 1996, c 2, Schedule A, ss 5 & 21.

¹⁰⁶ See *TCPS2*, *supra* note 8 at 42-44 (acknowledging that "[t]he efficacy of research directives is unknown and their legal status has not yet been recognized or tested,"

d. Provincial Laws and Legally Authorized Representatives

As discussed earlier, neither international statements of research norms nor federal law and policy can be relied on to identify an LAR where an adult lacks capacity to decide about his or her participation in research. In what follows, we address whether the laws of the four provinces targeted in this study enable identification of an LAR for authorizing an adult's participation in research. These laws may be divided into three categories:

- I. clear authorization (i.e. there is a clear source of law allowing identification of an LAR),
- II. unclear authorization (i.e. the law is ambiguous; whether there is a source of law allowing identification of an LAR is legally contestable), and
- III. clear lack of authorization (i.e. there is clearly no legal basis for identification of an LAR).¹⁰⁷

Category III encompasses situations in which statutes clearly state that there shall not be an LAR in an identified circumstance and situations in which no statute applies, even in an ambiguous or legally-contestable manner. This assumes the point made in the last section: that there is no common law foundation for third party authorization of health research (at least in the absence of an advance directive, in which case the common law offers an uncertain foundation for recognition of an LAR per category II).

Categories II and III are both described by the phrase supplied within our study: "no one has clear legal authority." Category II, however, also admits of alternative responses, adopting a stance of certainty about identification of an LAR in the face of uncertainty or ambiguity. Such responses, while defensible, ignore the unsettled status of the law on point. In contrast, the third category admits of no such alternative response, as we see it, even on a generous construction of the law.

In what follows, we describe these different categories further with reference to the four provinces targeted in our study and the primary mechanisms

but advising that such directives be consulted by researchers and LARs for guidance about the advisability of involving the individual in research). See also Hadskis, *supra* note 2 at 484-85.

¹⁰⁷ Bravo et al, "Comparison Substitute Consent", *supra* note 7.

through which an LAR for research may be empowered: general health care consent legislation applicable in the absence of an advance directive or court-appointed guardian, court-ordered guardianship, or an advance directive.

i. Category I: Clear Authorization

1. *British Columbia*

Of the four provinces targeted in this study, BC most clearly addresses the question of who may make substitute decisions about research and on what conditions. The power of a third party to authorize health research involving another adult in BC flows from the *Health Care (Consent) and Care Facility (Admission) Act* (“HCCFA”).¹⁰⁸ This statute allows substitute decision making about “health care,” which is defined in section 1 to include “participation in a medical research program approved by an ethics committee designated by regulation.” The individual authorized to make decisions about health care (and, by implication, REB-approved research) may be a court-appointed guardian authorized under the *Patients Property Act*,¹⁰⁹ a proxy appointed by the individual through an advance directive in accordance with the *Representation Agreement Act*,¹¹⁰ or a “temporary substitute decision maker”: a family member or close friend, designated in descending order of priority under the *HCCFA*.¹¹¹ By regulation, family members recognized as default or “temporary” decision makers cannot authorize “removal of tissue from a living human body ... for medical education or research,”¹¹² or participation in “health care or medical research” not approved by a prescribed REB.¹¹³ Such decisions are also excluded from the authority of proxies (or “representatives”) appointed under the *Representation Agreement Act*, except where an advance directive expressly permits the activity.¹¹⁴

¹⁰⁸ RSBC 1996, c 181 [HCCFA].

¹⁰⁹ RSBC 1996, c 349, s 6. While new guardianship legislation has long been anticipated in BC, this remains the relevant Act.

¹¹⁰ RSBC 1996, c 405.

¹¹¹ HCCFA, *supra* note 108 s 16(1).

¹¹² *Ibid* s 34(2)(f); *Health Care Consent Regulation*, BC Reg 20/2000, s 5(1)(d) [BC Consent Regulation].

¹¹³ BC Consent Regulation, *ibid*, s 5(1)(f).

¹¹⁴ *Representation Agreement Act*, *supra* note 110 s 9(2)(a). Note that reforms to this Act (in force as of September 1, 2011) remove the former requirement under section 9

One complexity arising under the *HCCFA* is that the provision giving proxies appointed under a representation agreement, or court-appointed guardians, authority to make substitute decisions about health care (major or minor, as defined in the *HCCFA*) is premised on a health provider's determination that the individual "needs the health care."¹¹⁵ This arguably disables the appointed proxy or guardian from making decisions about research, especially research holding out no prospect of therapeutic benefit. In contrast, a "temporary decision maker" may make decisions about "minor health care" without a parallel restriction to interventions that the subject needs.¹¹⁶ In other words, where REB-approved research lacks a therapeutic benefit satisfying the section 11 criterion of "need" and falls into the class of "minor health care" (interventions not involving "major surgery"; "a general anaesthetic"; "major diagnostic or investigative procedures"; or "any health care designated by regulation as major health care," such as radiation treatment or electroconvulsive therapy),¹¹⁷ the decision making authority of the designated proxy or court-appointed guardian apparently gives way to that of the "temporary decision-maker." No one appears to be empowered to authorize research involving interventions classed as "major health care," absent a prospect of therapeutic benefit.

It is worth adding that in making decisions about either health care or research, the temporary decision maker must consult with the person represented and must decide in accordance with that person's instructions, expressed while capable, or in the absence of such instructions, in accordance with the person's best interests.¹¹⁸ The criteria for decision making by proxies appointed in ac-

that a person consult with a lawyer or other prescribed person in order to include such terms in a representation agreement. It is important to note, as well, that recent reforms to the *HCCFA*, *supra* note 108 ss 19.1-19.91 (also in force 1 September 2011), recognize instructional directives (termed "advance directives" under the Act), whereby an individual may indicate consent to or refusal of specified health care without appointing a representative. Such directives displace recognition of a default statutory decision maker under section 16 of the *HCCFA*. Moreover (as per section 19.3(1)(b) of the *HCCFA*), they have the effect of indicating the prior capable wishes of the adult to a representative (if any) appointed under the *Representative Agreement Act*, *supra* note 110.

¹¹⁵ *HCCFA*, *supra* note 108 s 11.

¹¹⁶ *Ibid* s 15.

¹¹⁷ *Ibid* s 1; *BC Consent Regulation*, *supra* note 112 s 4.

¹¹⁸ *HCCFA*, *supra* note 108 s 19. The Act was reformed in June, 2011. Prior to that, a temporary decision maker who lacked information about the individual's prior capable wishes was to decide in light of the person's "known beliefs or values," and only in the absence of such knowledge, in accordance with best interests. Now "known be-

cordance with the *Representation Agreement Act*¹¹⁹ and guardians appointed under the *Patients Property Act*¹²⁰ are stated in different terms, which could lead to different outcomes in certain circumstances.

2. Alberta – Personal Directives

Alberta's *Personal Directives Act* also falls into the first category.¹²¹ Like BC's legislation, this statute expressly contemplates research. However, the argument for identification of an LAR is less direct. Section 15 of the *Personal Directives Act* states: "an agent has no authority to make personal decisions relating to the following matters unless the maker's personal directive contains clear instructions that enable the agent to do so." Included in the ensuing list is "participation by the maker in research or experimental activities, if the participation offers little or no potential benefit to the maker."¹²²

liefs and values" are among the considerations informing a best interests-based decision. Section 19(3) elaborates on "best interests" as requiring consideration of

- (a) the adult's current wishes, and known beliefs and values
- (b) whether the adult's condition or well-being is likely to be improved by the proposed health care,
- (c) whether the adult's condition or well-being is likely to improve without the proposed health care,
- (d) whether the benefit the adult is expected to obtain from the proposed health care is greater than the risk of harm, and
- (e) whether a less restrictive or less intrusive form of health care would be as beneficial as the proposed health care.

¹¹⁹ *Supra* note 110. A proxy appointed under a representation agreement must take account of the subject's current wishes or, if those cannot be ascertained or are "not reasonable to comply with," his or her wishes expressed while capable, or, in the absence of knowledge of these, his or her known beliefs or values. In the absence of any of the foregoing information, the decision is to be made in light of the individual's best interests (s 16).

¹²⁰ *Supra* note 109. Less clarity about the considerations required for valid decision making is conveyed under this Act. Guardians appointed under this Act have all the powers of a guardian of the person (s 17) and are to exercise authority for the benefit of "the patient and the patient's family" (s 18).

¹²¹ RSA 2000, c P-6.

¹²² *Ibid* s 15(d).

This limitation gives force to directives that expressly authorize an LAR to make decisions about research that offers little or no potential benefit to the individual who made the directive. Furthermore, it implicitly authorizes an LAR to make decisions about research participation in the absence of a specific instruction, in instances where the research offers *more* than little or no benefit. Some may dispute the second part of this claim, arguing that the statutory language does not amount to “clear authorization” of substitute decisions about research meeting the stated benefit threshold. Moreover, important arguments may arise about how to interpret this threshold. However, we conclude that the statute is more clearly permissive of substitute decisions about research, even where the advance directive fails to contemplate research offering little or no potential benefit, than the ambiguous statutes that we have included in Category II. We have identified no case law on this question. In sum, we understand the *Personal Directives Act* to authorize an appointed proxy to make substitute decisions about the above-noted circumscribed category of research, even in the absence of terms specific to research in the directive.

ii. Category II: Unclear Authorization

The second type of legal situation encountered among the four provinces is one where there is no clear basis in law for third party authorization of research. This category includes situations that allow some scope for arguing, in the face of statutory ambiguity, that legislation *might* ground third party authorization, at least in some circumstances. While such arguments would be novel—we have not found any case law directly on this point—they are not unreasonable, at least where research holds out a prospect of therapeutic benefit.

We include the following in this category: first, the statutes of the four provinces that refer to third party authorization of health care or medical treatment without specifically addressing research; second, the statutes that provide for court-appointed guardianship, again, without specifically addressing research; and third, the special case of Ontario’s health care consent, advance directive, and guardianship laws, which explicitly exclude from their ambit interventions undertaken “for the primary purpose of research.” We have already noted that, as a matter of common law, uncertainty also attaches to the legal effectiveness of advance directives as they apply to research participation.

I. *Nova Scotia – Consent to “Health Care” or
“Medical Treatment”*

Nova Scotia’s health care consent laws authorize substitute decisions about “health care” or “medical treatment” without mentioning research. More specifically, both the *Hospitals Act*¹²³ and the *Involuntary Psychiatric Treatment Act*¹²⁴ contemplate substitute decisions about “treatment” and “health care,”¹²⁵ but neither term is defined to include health (or other) research.

Additionally, Nova Scotia’s advance directives legislation in force at the time of our study, the *Medical Consent Act*, allowed appointment of a proxy decision maker for the purpose of substitute decisions about “medical treatment,” but did not specifically address research. This Act was repealed and replaced after our study was completed.¹²⁶ Potential confusion around this legislative reform, and the implications of such confusion for our study, are discussed in Part V.

Again, the best interpretation of laws that authorize substitute consent to health care or treatment without specifically contemplating research is that they give rise to ambiguity, thereby grounding competing legal arguments regarding identification of an LAR for research involvement purposes. “No one has clear legal authority” is the characterization that best recognizes this ambiguity. However, because there are reasonable arguments for identification of an LAR based on an analogy between research that offers a prospect of therapeutic benefit and treatment, we recognize this as an alternative interpretation that is defensible where the research does hold out such a prospect.

2. *Nova Scotia and Alberta – Guardianship*

Legal uncertainty or ambiguity is also encountered in connection with the provincial guardianship regimes in Nova Scotia and Alberta.¹²⁷ The situation

¹²³ RSNS 1989, c 208.

¹²⁴ SNS 2005, c 42 [*IPTA*].

¹²⁵ *Ibid* ss 17-18, 39-40; *Hospitals Act*, *supra* note 123 ss 52-53.

¹²⁶ RSNS 1989, c 279 as repealed by *Personal Directives Act*, SNS 2008, c 8, s 40 (in force April 1, 2010).

¹²⁷ Our assessment of the provincial guardianship laws of the four provinces we targeted corresponds with the broad conclusions of Tomossy & Weisstub on the state of Canadian guardianship laws in respect to authorization of research participation:

with regard to the substitute decision making powers of guardians in BC was discussed above, and the situation in Ontario is discussed below.

Nova Scotia's *Incompetent Persons Act*¹²⁸ confers upon court-appointed guardians broad authority over the person and finances of persons deemed incompetent. Yet, read in light of common law restrictions on guardianship, the power conferred by this statute is limited to decisions that promote the interests of the ward. Here we may recall the limitations on the *parens patriae* jurisdiction stated in *Re Eve*, where the Supreme Court drew upon cases decided under superior courts' wardship jurisdiction as a "solid guide to the exercise of the *parens patriae* power even in the case of adults."¹²⁹

The best interests limitation on guardianship powers may be explicitly stated in guardianship statutes, or implied by operation of the common law.¹³⁰ This limitation (in Nova Scotia, an implicit one) renders a guardian's power to authorize research unclear, given that the primary aim of research is to advance knowledge as opposed to delivering an individualized therapeutic benefit.¹³¹ However, where a prospect of therapeutic benefit to the participant is present-

"The issue of participation in research is either specifically excluded, not mentioned at all, or if referred to, dealt with in an ambiguous manner" (*supra* note 7 at 123).

¹²⁸ RSNS 1989, c 218, ss 9-12.

¹²⁹ *Supra* note 97 at paras 36, 73 ("The *parens patriae* jurisdiction is, as I have said, founded on necessity, namely the need to act for the protection of those who cannot care for themselves. The courts have frequently stated that it is to be exercised in the 'best interest' of the protected person, or again, for his or her 'benefit' or 'welfare'"). The argument that a statutory guardian is limited by the best interests principle is derived in part from this limitation upon the court's *parens patriae* jurisdiction, which informs interpretation of vaguely-stated statutory guardianship powers.

¹³⁰ Robertson, *supra* note 93 at 171.

¹³¹ See Tomossy & Weisstub, *supra* note 7. "[E]xisting guardianship laws are generally poorly suited to resolving questions that cannot be answered easily through the application of a 'best-interests' calculation. Non-therapeutic experimentation, and indeed any other activity that does not lead to a concrete benefit for the subject, throws the proverbial wrench into the machinery of substitute decision making. It is difficult enough for guardians, and also for the judiciary, to rationalize exposing an incompetent adult to risks, however minute, for a hypothetical treatment or cure, let alone in those cases where the benefits will never accrue to the subject, but rather to others with the same affliction or disability. This effort is frustrated further because it entails placing the interests of society ahead of those of the subject, which may constitute a breach of the guardian's cardinal duty to protect his ward" (at 123-24). On this basis, the authors recommend legislative reforms specifically contemplating and setting conditions upon a guardian's ability to authorize research (at 124-25).

ed, it may be argued that the guardian's authority extends to decision making about research participation.¹³² That said, the fact that even research offering some prospect of benefit necessarily also involves interventions directed solely at producing knowledge—and, moreover, these research-related interventions may be less likely to benefit the individual than would a non-research-related therapy—renders the authority of the guardian to consent, even to so-called therapeutic research, uncertain. In short, even in situations involving a prospect of therapeutic benefit (as in our scenario 2),¹³³ the ability of a court-appointed guardian to authorize research participation in the absence of a specific legislative provision or court order is unclear.¹³⁴

Alberta's *Dependent Adults Act*¹³⁵ (in force at the time of our survey) contemplated a range of decision making powers that might be conferred by a court upon a guardian. Research participation was not addressed in the non-exhaustive list of forms of decision making authority potentially conferred. However, among the decision making powers listed was authority "to consent to any health care that is in the best interests of the dependent adult."¹³⁶ For the reasons previously discussed, the *Dependent Adults Act*, like Nova Scotia's guardianship statute, is properly classed as offering an unclear foundation for third party authorization of research participation. There is scope to contest the consistency of such authority with the purposes of this guardianship regime. And this uncertainty extends even to research offering a prospect of benefit.

¹³² Our study did not include a scenario in which a guardian is in place and authorization of no-benefit research is in issue.

¹³³ Scenario 2 involves a guardian. See Tables 1 and 4 (Table 4 is located in the Appendix).

¹³⁴ See Coleman, *supra* note 4. Coleman notes that in the US, some guardianship statutes require specific court approval before a guardian may authorize research (at 760-61). Where guardianship statutes are silent on this question, Coleman suggests, it is unclear whether the decision making authority extends to research, or specifically those elements of a research intervention that are directed at generating universalizable knowledge rather than individualized therapy (at 761).

¹³⁵ *Dependent Adults Act*, RSA 2000, c D-11, repealed by *Adult Guardianship and Trusteeship Act*, SA 2008, c A-4.2, s 153 (the latter statute came into force on 30 October 2009). We address the implications of repeal of the *Dependent Adults Act*, along with the implications for our study of the repeal of Nova Scotia's *Medical Consent Act*, *supra* note 126, in Part V, below.

¹³⁶ *Dependent Adults Act*, *supra* note 135 s 10(3)(h).

However, there may be occasions where there are compelling arguments for deeming a given research intervention to be in the best interests of a particular patient (e.g. where there are no comparable therapeutic options and the subject's condition is dire enough to arguably warrant the risks of an unproven intervention). Given this possibility, and the related possibility that a court may be persuaded that the decision making powers of a guardian encompass decisions about research (at least, where a prospect of therapeutic benefit is offered), we acknowledge this as a reasonable alternative interpretation. This interpretation, however, captures the state of the law less accurately than the response "no one has clear legal authority."

3. Ontario – Explicit Exclusion of Substitute Consent to Research

Ontario's laws demand separate analysis. In that province, the laws that address general health care consent, advance directives, and guardianship explicitly exclude third party authorization of research from their ambit. Ontario's *Health Care Consent Act*¹³⁷ confers the power to make substitute decisions about "health care" on guardians of the person, proxies acting under a power of attorney for personal care, or, in the absence of these, a decision maker prescribed by statute. It further states: "This Act does not affect the law relating to giving or refusing consent on another person's behalf to any of the following procedures: ... A procedure whose primary purpose is research."¹³⁸

Similarly, the *Substitute Decisions Act*,¹³⁹ which confers substitute decision making authority on proxies acting under a power of attorney for personal care and court-appointed guardians, states: "Nothing in this Act affects the law relating to giving or refusing consent on another person's behalf to a procedure whose primary purpose is research."¹⁴⁰ Because no other statute addresses third party authorization of research in Ontario, apart from provincial legislation on the collection, use, and disclosure of personal health information,¹⁴¹ the best interpretation of Ontario's law is that it offers no legal basis for third party authorization of another adult's participation in health research beyond the confines of the laws concerning personal information.

¹³⁷ *Supra* note 105.

¹³⁸ *Ibid* s 6.

¹³⁹ *Supra* note 104.

¹⁴⁰ *Ibid* s 66(13).

¹⁴¹ See e.g. *Personal Health Information Protection Act*, SO 2004, c 3, Schedule A, ss 26(4), 44 [PHIPA (Ont)].

It may be argued, however, that in some circumstances, where research offers a prospect of individualized therapeutic benefit, the intervention can be understood as initiated not for the “primary purpose” of research, but for pursuing the possibility of therapeutic benefit for the individual. This would require an assessment of the prospective benefits held out by the research, along with an assessment of the individual’s condition and any therapeutic alternatives. Were it determined that research was not the primary purpose of the intervention, the intervention might possibly be deemed a form of health care (or personal care), such that the substitute decision maker under the *Health Care Consent Act* or, alternatively, a power of attorney for personal care or guardian under the *Substitute Decisions Act*, could act as LAR. While this constitutes a possible alternative argument to “no clear authorization” where there is a prospect of health benefit, it is both uncertain in law and intensely fact-dependent.

iii. Category III: Clear Lack of Authorization

A third type of legal situation arises where there is no statutory foundation on which basis anyone may be recognized as empowered to authorize an adult’s participation in research.

1. *No Prospect of Benefit to the Individual’s Health – No Guardian, Not BC*

It is uncertain whether, on an expansive approach to guardianship powers, a guardian could authorize health research even where no individual health benefit is offered. This has been argued with reference to the implicit authority of parents to involve their minor children in activities that offer no benefit so long as they do not “unreasonably risk harm.”¹⁴²

There is no comparable uncertainty, however, in the case of statutory decision makers accorded discrete powers to authorize “health care” or “treatment,” rather than the broad or open-ended decision making authority granted some statutory guardians. On a purposive (indeed, even on a plain meaning) reading the authority conferred by such terms necessarily involves a therapeutic dimension, whereby some benefit to the individual’s health (even broadly construed, to include social or emotional well-being) is engaged.¹⁴³ This leads to the ob-

¹⁴² Dickens, *supra* note 58 at 134-35.

¹⁴³ See Baylis & Downie, *supra* note 100 at 49; Dickens, *supra* note 58 at 134; Cantor, *supra* note 100.

ervation that, where research offers no prospect of an individual health benefit, there is no basis in law for grounding identification of an LAR in a health care consent or advance directive statute that authorizes substitute decisions about health care or treatment, but not research. As noted, in BC, statutorily designated substitute decision makers have express authority to make decisions about REB-approved research, without limitations based in likely health benefits to the prospective research subject.

2. *Further Special Circumstances*

At the time of our survey, the “clear lack of authorization” category applied in Alberta, where no guardian or advance directive was in place, and in Nova Scotia, where no guardian or advance directive was in place and where the proposed research was to occur outside the context of a hospital or community treatment order. Prior to recent law reforms, these provinces lacked legislation (in Nova Scotia, legislation that extended beyond the hospital or community treatment order setting) that conferred the authority to make substitute decisions about treatment or health care upon a family member or other party. Therefore, in the absence of a court-appointed guardian or advance directive, there was no statutory foundation for substitute decision making powers relating to treatment or health care that might be argued to encompass decisions about research (or specifically, research offering a prospect of therapeutic benefit).

iv. Application to the Four Scenarios in our Survey Questionnaire

Based on our analysis of provincial health care consent and guardianship laws (as well as the common law) as they stood at the time of our survey, the most defensible response to each of the four scenarios posed in the questionnaire, in all the provinces canvassed except for BC (and with the further exception of cases falling under the advance directive legislation in Alberta), was “no one has clear legal authority.” Whether an alternative response might have a reasonable chance of success in court is a more nuanced matter.

Table 1 summarizes the state of the provincial guardianship, advance directive, and health care consent laws in force at the time of the survey, as they interact with the scenarios posed in the survey questionnaire (the scenarios

themselves are located in Appendix I).¹⁴⁴ The key elements of each of the four scenarios are described in turn, followed by a province-by-province indication of whether the laws canvassed clearly authorize an LAR, are unclear on this point, or clearly fail to authorize an LAR. Where the law is classed as unclear—or, in the first scenario as it applies in Nova Scotia, where the respondent assumed the research would occur in a hospital—we add (italicized and in parentheses) a statement of the response or responses that may be considered reasonable alternative interpretations. These alternatives are less optimal than the primary response which explicitly recognizes the legal uncertainty or ambiguity on point. As noted, both Alberta and Nova Scotia introduced law reforms which came into force after our survey was completed, the possible implications of which we discuss in Part V.

Table 1. The State of Provincial Laws on LARs at the Time of the Survey

Who may authorize research participation?			
Research Scenario 1. No court-appointed guardian, no advance directive. Research involves potential benefit to individual, little risk.			
British Columbia	Alberta	Nova Scotia	Ontario
If research is REB approved, and qualifies as “minor” rather than “major” health care, clear authorization: statutory default decision maker is LAR	Clear lack of authorization	If research is to occur outside hospital, clear lack of authorization. <i>(If respondent assumes research will occur in hospital, there is a reasonable alternative response that is uncertain in law: statutory default decision maker is LAR, given pro-</i>	Authorization unclear (<i>Reasonable alternative response uncertain in law: Statutory default decision maker is LAR, given prospect of individual therapeutic benefit</i>)

¹⁴⁴ All questions in Table 1 assume (as stipulated in our questionnaire) that the research has been approved by an REB. See the Appendix for additional information.

		<i>spect of individual therapeutic benefit)</i>	
Research Scenario 2. Court-appointed guardian. Research involves potential benefit to individual, little risk.			
British Columbia	Alberta	Nova Scotia	Ontario
If the research is REB approved, and qualifies as “major” or “minor” health care that the subject “needs,” clear authorization: guardian is LAR. (Otherwise, if the research is REB approved and qualifies as “minor” health care, but there is no medical “need”: statutory default decision maker is LAR).	Authorization unclear (<i>Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual’s best interests - or, in the further alternative, if the research simply does not increase risks beyond background risks - guardian is LAR</i>)	Authorization unclear <i>(Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual’s best interests - or, in the further alternative, if the research simply does not increase risks beyond background risks - guardian is LAR)</i>	Authorization unclear (<i>Reasonable alternative response uncertain in law: if there is a prospect (reasonable likelihood?) that the research will advance the individual’s best interests so that the intervention is not deemed “a procedure whose primary purpose is research,” guardian is LAR. In the further alternative, if the research simply does not increase risks beyond background risks, guardian is LAR</i>)
Research Scenario 3. Advance directive addressing health care but not research. Research involves some risk, outweighed by potential benefit to individual.			
British Columbia	Alberta	Nova Scotia	Ontario
If the research is REB approved and is “major” or “minor” health	If there is a prospect of more than “little or no benefit,” clear	Authorization unclear (<i>Reasonable alternative response: if</i>	Authorization unclear (<i>Reasonable alternative response: if</i>

<p>care that the subject “needs,” clear authorization: proxy appointed in directive is LAR</p> <p>(Otherwise, if the research is REB approved and qualifies as “minor” health care, but there is no medical “need”: statutory default decision maker is LAR).</p>	<p>authorization: proxy appointed in directive is LAR</p>	<p><i>there is a prospect of individualized therapeutic benefit whereby research is deemed “medical treatment,” proxy appointed in directive is LAR)</i></p>	<p><i>there is a prospect of individualized therapeutic benefit whereby intervention is deemed not to be “a procedure whose primary purpose is research,” but “treatment” or “personal care,” proxy appointed in directive is LAR)</i></p>
<p>Research Scenario 4. No guardian. Research offers no prospect of benefit to individual.</p>			
<p>British Columbia</p>	<p>Alberta</p>	<p>Nova Scotia</p>	<p>Ontario</p>
<p>If research is deemed “minor” rather than “major” health care, clear authorization: statutory default decision maker (to decide in light of prior capable wishes / values, as the best interests standard will not be satisfied)</p>	<p>Clear lack of authorization</p>	<p>Clear lack of authorization</p>	<p>Clear lack of authorization</p>

Against the background of the foregoing legal analysis, we ask: how do those with a stake in the research enterprise understand the laws concerning—and frequent instances of legal ambiguity surrounding—who, if anyone, may

make a substitute decision about another adult's involvement in health research? That is the question addressed in the remaining parts of this article.

IV. The SCORES Survey

A. *Study Design, Populations and Sampling*¹⁴⁵

The data used for this article originate from a wider study of knowledge, opinions and practices regarding *Substitute Consent for Research in Elderly Subjects* (SCORES). The SCORES study included a postal survey conducted in Alberta, BC, Ontario, and Nova Scotia.

The aim of this part of the study was to compare the state of the law in the four provinces against how the law is understood by five population subgroups, differently situated in relation to research. The selected provinces represented a range of statutory approaches to resolving (or leaving unresolved) the question of who, if anyone, is legally empowered to authorize an adult's research participation. We determined, in light of a previous survey of the relevant Canadian laws,¹⁴⁶ that the laws of the four provinces selected were broadly representative of approaches taken to this issue in common law Canada.

The five groups surveyed were: i) community-dwelling adults aged 65 and over; ii) informal caregivers of cognitively-impaired older adults; iii) physicians; iv) researchers in aging; and v) Research Ethics Board (REB) members. A proportional random sample of 2,000 older adults was obtained from Human Resources and Social Development Canada. Seven hundred and two informal caregivers from Nova Scotia and Ontario were accessed through provincial Alzheimer Societies. We were unable to recruit caregivers from Alberta and BC for reasons including denial of access to membership lists, associated confidentiality concerns, and insufficient in-house personnel to support distribution of the mailings. We obtained proportional random samples of physicians from provincial medical colleges, except in BC, where we had to purchase a

¹⁴⁵ The material included in this section is substantially the same as the comparable section in other papers published as a result of this study. See Gina Bravo et al, "Are Canadians Providing Advance Directives About Health Care and Research Participation in the Event of Decisional Incapacity?" (2011) 56:4 Can J Psychiatry 209 [Bravo et al, "Advance Directives"]; Gina Bravo et al, "Research with Decisionally Incapacitated Older Adults: Practices of Canadian Research Ethics Boards" (2010) 32:6 IRB: Ethics & Human Research 1 [Bravo et al, "Practices of Canadian REBs"].

¹⁴⁶ Bravo et al, "Comparison Substitute Consent", *supra* note 7.

commercial list of physicians ($n = 3,000$). Specialities unlikely to encounter adults with cognitive impairments in their practice, such as paediatrics and pathology, were excluded. We tried to establish the most complete list of Canadian researchers in aging and REBs by searching the Internet and relevant web sites (e.g. the Canadian Institutes for Health Research, National Council on Ethics in Health Research, and universities and hospitals conducting health research). Given the relatively small size of the latter two groups (608 researchers in aging and 701 REB members), all identified members were contacted. Sample sizes for the three other groups were established to ensure that confidence intervals did not extend beyond the observed proportions by more than 0.05, and participation rates observed in a similar study conducted in Quebec were applied.¹⁴⁷

B. The Questionnaire

The postal survey included four scenarios (reproduced in Appendix I) each culminating in the question of who, if anyone, is legally authorized to make a decision about research. These scenarios track the four situations represented in Tables 1 and 4. The first scenario features no court-appointed guardian or advance directive regarding health care; the second scenario features a court-appointed guardian (with broad decision making authority); and the third scenario features an advance directive appointing a proxy in respect to health care. Scenarios 1–3 assert that the prospective benefits of research participation outweigh the risks. While perhaps artificial, this stipulation of the risk-benefit ratio is intended to clearly transmit the conditions in which the legality of third party authorization is at stake. Otherwise, it would have been even less clear whether, or to what extent, contestation about risks or benefits presented in the scenario affected responses. The fourth scenario proceeds from the same facts as scenario 3, except that the proposed research is now said to offer no benefit to the prospective subject, although it may in the future benefit others in his position (specifically, future nursing home residents).

In the final, “no-direct-benefit” scenario, our evaluation of responses was not affected by whether respondents assumed that the advance directive from the previous scenario was still in place. Also, regarding our evaluation of re-

¹⁴⁷ Bravo G, Pâquet M & Dubois MF, “Knowledge of the Legislation Governing Proxy Consent to Treatment and Research” (2003) 29 J Med Ethics 44 at 45-46; Gina Bravo et al, “Quebec Physicians’ Knowledge and Opinions Regarding Substitute Consent for Decisionally Incapacitated Older Adults” (2004) 26:5 IRB: Ethics & Human Research 12 at 14 [Bravo et al, “Physicians’ Knowledge”].

sponses from BC, both the second scenario (involving a guardianship order) and the third (involving an advance directive) supported option B (the family member) as the correct answer, whether the respondent regarded this as justified by the family member's status as guardian (scenario 2) or proxy (scenario 3), or by his or her default status as temporary decision maker. Therefore, our evaluation of the BC responses to these two scenarios was unaffected by whether or not the research was perceived to fall within the subject's health "needs" (which, as stated earlier, limits the authority of guardians and proxies). Given that the proposed research in these two scenarios satisfies the definition of "minor" health care under the BC legislation, the family member is clearly authorized to make the decision, even if only as the "temporary decision-maker."

There were two alternative responses to the scenarios (i.e. reasonable responses which differed from the ones we deemed most defensible) not addressed in the earlier discussion of how provincial laws may be interpreted generally and in their interaction with the basic elements of the scenarios.

1. Regarding scenario 3 (the "advance directive addressing health care but not research" scenario), the most defensible answer from Alberta was B. This is because, as discussed above, Alberta's *Personal Directives Act* implicitly admits of third party authorization of research where there is more than "little or no benefit" offered to the subject. However, if the respondent felt that the intervention offered "little or no" benefit (despite the statement that the likely benefits "outweigh" the risks), the appropriate answer would be E. In acknowledgment of the difficulty of quantifying prospective benefits, we recognize E as a reasonable alternative response.
2. Regarding scenario 4 (the "no-direct-benefit" scenario), the most defensible answer from BC is B. We have seen that "temporary decision makers" (family members) are empowered to decide whether an adult may participate in no-benefit research as long as the research is REB-approved. However, the BC statute requires that the decision be made in accordance with the subject's prior capable wishes or values, or in the absence of these, his or her best interests. The scenario gives no information about the subject's capable wishes or values. Nor is there any evidence of contemporaneous wishes (of important relevance to the decisions of representatives under the *Representation Agreement Act*). Therefore, while it is correct to state that the temporary decision maker is clearly authorized to make a decision about the subject's participation, there is insufficient information to know whether there is a basis

of prior capable wishes or values, or alternatively, contemporaneous wishes, on which to permit rather than refuse research participation. In recognition of the potential for confusion between the decision maker's authority to make the decision (i.e. to decide in light of the mandatory considerations) and his or her authority to permit (rather than refuse) the research in light of those considerations, we recognize E ("No one has clear legal authority") as a reasonable alternative response from BC.

Table 4, found at Appendix II, gives a summary presentation of the correct responses (including the reasonable alternative response, where one existed) to the scenarios. In all cases except the two noted above (scenario 3: Alberta and scenario 4: BC), the reasonable alternative answer identifies the family member as LAR despite the legal contestability of this answer.

A last clarification is required with regard to our evaluation of scenario 4. In this scenario, the proposed research offers no prospect of individual benefit; moreover, there is no guardianship order or advance directive with a term specific to research authorization in place. We analyzed this scenario in a manner that reflected the absence of any basis for identifying an LAR in the advance directives or more general health care consent legislation of three of the four provinces we targeted. That is, no health care consent or advance directives legislation (apart from BC's), offered a basis for identifying an LAR where the research at issue offered no prospect of benefit. Recall that Alberta's advance directives legislation contemplated such authority only where an advance directive expressly confers it.

However, some respondents may have identified this as a situation in which federal or provincial privacy legislation (applying to the collection, use, and disclosure of personal information¹⁴⁸ or personal health information¹⁴⁹) would

¹⁴⁸ See e.g. *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5 [PIPEDA]; *Personal Information Protection Act*, SBC 2003, c 63 [PIPA (BC)]; *Freedom of Information and Protection of Privacy Act*, RSBC 1996, c 165 [FIPPA (BC)]; *Personal Information Protection Act*, SA 2003, c P-6.5 [PIPA (Alta)]; *Freedom of Information and Protection of Privacy Act*, RSA 2000, c F-25 [FIPPA (Alta)]; *Freedom of Information and Protection of Privacy Act*, RSO 1990, c F.31 [FIPPA (Ont)]; *Freedom of Information and Protection of Privacy Act*, SNS 1993, c 5 [FIPPA (NS)].

¹⁴⁹ *Health Information Act*, RSA 2000, c H-5, s 2 [HIA (Alta)]; PHIPA (Ont), *supra* note 141 s 1. Also see PIPEDA, *supra* note 148 s 2(1). The scope of application of these and similar statutes is addressed by Gibson, *supra* note 66 at 263-73. At the time of

serve as the proper source of substitute decision making authority. Arguably, the interest in protection of privacy or personal information was the only legal interest implicated by the observational study described in scenario 4.¹⁵⁰ Might one or more of the set of laws relating to personal information and privacy be relied upon to identify the family member present in the scenario as LAR in scenario 4, rather than selecting the answer we identified as correct in all provinces but BC (“No one has clear legal authority”)?¹⁵¹

As noted, our analysis focused on the terms of provincial health care consent and guardianship laws. We leave the analysis of federal and provincial laws concerning personal information and privacy as they intersect with health research for another occasion. The importance of this caveat to the evaluation of scenario 4 is diminished, however, by the fact that the scenario arguably provides insufficient information to establish whether (or perhaps, which) laws aimed at the protection of privacy and personal information, or personal health information specifically,¹⁵² would apply. Among the matters relevant to that determination would be whether the nursing home featured in the scenario is a private or public body,¹⁵³ whether the research was privately or publicly funded

writing, a new law in Nova Scotia, the *Personal Health Information Act*, SNS 2010, c 41, has recently passed third reading but has not yet been proclaimed in force.

¹⁵⁰ It is also the case that a range of interventions typically understood to fall within the terms of health care consent legislation (e.g. psychological counselling, behavioural therapy, observation for diagnostic purposes) do not require bodily touching.

¹⁵¹ The substitute decision making provisions in provincial privacy legislation are discussed in Noela J Inions, “Substitute Decision-Makers in Privacy Legislation that Affects Health Information in Alberta” (2005) 14:1 Health Law Review 26.

¹⁵² *Supra* notes 148, 149.

¹⁵³ Nursing homes likely fall into the public sector (here any provincial legislation specific to the regulation of nursing homes would have to be consulted), but we do not wish to do an end-run around alternative arguments in any of the four provinces. In Nova Scotia and Ontario, the federal legislation (PIPEDA, *supra* note 148) applies to private organizations in respect to certain circumscribed activities involving the handing of personal information (although Ontario’s health-specific legislation, PHIPA (Ont), *supra* note 141, applies to public and private health providers dealing with “personal health information”). Both provinces have general public sector legislation (FIPPA (NS), *supra* note 148; FIPPA (Ont), *supra* note 148). In BC, private organizations are subject to the PIPA (BC), *supra* note 148, while public organizations are subject to the FIPPA (BC), *supra* note 148. In Alberta, private sector organizations are subject to the PIPA (Alta), *supra* note 148, while public sector organizations are subject to the FIPPA (Alta), *supra* note 148. Like Ontario, Alberta also features special legislation addressing the handling of health-specific personal information (HIA (Alta), *supra* note 149).

(i.e. did it constitute “commercial activity,” thereby engaging the federal legislation in those provinces in which that legislation may apply?),¹⁵⁴ and whether the study, involving observation of residents going about their daily routines, would qualify as collection or disclosure of personal information (or alternatively personal health information) in the control or custody of an entity regulated under one of these statutes.¹⁵⁵

These questions would require separate analyses in light of the different privacy and personal information regimes of the four provinces targeted in our study (and, at least in Nova Scotia and Ontario, possibly also the federal regime).¹⁵⁶ Beyond the problem of uncertain application (which is exacerbated by the lack of relevant details)¹⁵⁷ lies the question of whether the legislation that could apply may be understood to authorize a family member to act as LAR where, as in scenario 4, there is no guardianship order or advance directive specific to decisions concerning research (or, for that matter, the disclosure of personal information).¹⁵⁸ We may also ask what if any continuing rele-

¹⁵⁴ PIPEDA, *supra* note 148 ss 2(1), 4(1)(a).

¹⁵⁵ See e.g. PIPEDA, *ibid* s 2(1) “personal health information”, “personal information”; FIPPA (BC), *supra* note 148, Schedule 1 “personal information”; HIA (Alta), *supra* note 149, s 1(1)(k) “personal health information”; FIPPA (Alta), *supra* note 148, s 1(n) “personal information”; PHIPA (Ont), *supra* note 141, s 4(1) “personal health information”; FIPPA (NS), *supra* note 148, s 3(i) “personal information”. On the range of questions relevant to determining whether or which legislation might apply, see Hadskis, *supra* note 2 at 485; Gibson, *supra* note 66 at 286-88.

¹⁵⁶ In BC and Alberta, privacy legislation applying to private entities has been declared substantially similar to the federal legislation, which results in an exemption from the application of Part I of PIPEDA, *supra* note 148. *Organizations in the Province of Alberta Exemption Order*, SOR/2004-219; *Organizations in the Province of British Columbia Exemption Order*, SOR/2004-220. This is also true of Ontario’s health-specific privacy legislation, the *Health Information Custodians in the Province of Ontario Exemption Order*, SOR/2005-399.

¹⁵⁷ One or more of the potentially-applicable statutes relating to privacy and the protection of personal information (or personal health information specifically) might possibly provide a basis for authorizing the study featured in scenario 4 without requiring consent. However, the conditions precedent to such authorization are not addressed in the scenario, and therefore could not be said to be met. See e.g. FIPPA (BC), *supra* note 148 s 35; PHIPA (Ont), *supra* note 141 s 44.

¹⁵⁸ See PIPEDA, *supra* note 148, Schedule 1, s 4.3.6; FIPPA (BC), *supra* note 148 s 33, and BC Reg 323/93, s 3(b); HIA (Alta), *supra* note 149 s 104(1); FIPPA (Alta), *supra* note 148, s 84(1); PHIPA (Ont), *supra* note 141 ss 21, 23 & 26; FIPPA (NS), *supra* note 148 s 43.

vance health care consent legislation would have, even if privacy and personal information statutes were engaged. Finally, we must consider how likely it is that the respondents to our questionnaire (or more than a small minority of them) would be familiar with the intricacies of personal information and privacy law. In light of all these considerations, the restriction of our analysis to health care consent and guardianship legislation is of limited importance.

C. *The Postal Survey*¹⁵⁹

The postal survey arm of the SCORES project was carried out from September 2007 through April 2009. In order to maximize response rates, Dillman's suggestions on the content and design of the questionnaire, as well as the number of mailings, were followed.¹⁶⁰ In the first mailing, potential participants received a personalized cover letter, a copy of the questionnaire, an addressed stamped envelope, and a postcard bearing his or her name. The purpose of the postcard was to identify those who had returned the questionnaire without removing the anonymity of their responses, as it was to be mailed separately from the questionnaire. Letters of endorsement from the Canadian Association of Retired Persons, the Alzheimer Society of Canada, and the Royal College of Physicians and Surgeons of Canada were included in the mailings for three groups, respectively: older adults, caregivers, and physicians. Two weeks after the first mailing, a postcard was sent to non-respondents and two months later a new copy of the questionnaire was sent. All mailings to older adults, physicians, and researchers were managed by the research team. The Alzheimer Society and some REBs protected the anonymity of their members by managing the mailings themselves. The REBs of the University Institute of Geriatrics of Sherbrooke, Dalhousie University, and Sunnybrook Health Sciences Centre approved the study protocol, postal questionnaires, and accompanying letter.

The questionnaire was returned by 2,060 people, resulting in an eligible overall response rate of 32.7%. Variation in the response rate across provinces and groups can be seen in Table 2. As a result of the proportional sampling strategy, most of the respondents originated from Ontario. Respondent characteristics are given in Table 3 and complementary group-specific information is

¹⁵⁹ The material included in this section is substantially the same as the comparable section in another paper published as a result of this study: Bravo et al, "Advance Directives", *supra* note 145 at 210-11.

¹⁶⁰ See Don A Dillman, *Mail and Internet Surveys: The Tailored Design Method* (New York: John Wiley & Sons, 2000).

provided in a separate publication.¹⁶¹ 54.3% of the respondents were women, and the age of respondents ranged from 21 to 95 years. In general, this study had a heterogeneous assemblage of respondents in terms of socio-demographic status, profession, and experience with research.

Table 2. Response Rates and Sample Size per Group and Province

	NS	ON	AB	BC	Overall*
Older adults	40.2% (37)	37.5% (388)	41.3% (92)	38.8% (151)	39.0% (679)
Caregivers	54.2% (32)	60.0% (349)	--	--	59.9% (384)
Physicians	23.3% (35)	19.8% (299)	16.3% (68)	14.2% (90)	18.3% (495)
Researchers	30.0% (12)	33.6% (87)	37.4% (37)	33.1% (39)	34.3% (177)
REB members	55.6% (74)	43.1% (197)	47.2% (25)	52.3% (23)	47.3% (325)
Overall	40.1% (190)	34.4% (1320)	28.0% (222)	25.6% (303)	32.7% (2060)

* Province was missing for 25 respondents

Table 3. Respondents' Characteristics^a

	Older adults (n=679)	Informal caregivers (n=384)	Physicians (n=495)	Researchers (n=177)	REB members (n=325)
Province					
Nova Scotia	5.5%	8.4%	5.1%	6.9%	23.2%
Ontario	58.1%	91.6%	55.8%	49.7%	61.8%
Alberta	13.8%	-	16.2%	21.1%	7.8%
BC	22.6%	-	22.9%	22.3%	7.2%
Age (years)	75.2 ± 6.9 (65 to 95)	65.6 ± 12.0 (31 to 88)	51.4 ± 11.6 (29 to 94)	49.8 ± 8.8 (28 to 73)	50.7 ± 11.3 (21 to 78)
Sex (female)	56.8%	74.8%	33.7%	54.7%	56.9%

¹⁶¹ See Bravo et al, "Advance Directives", *supra* note 145 at 214-15.

Religious denomination					
Protestant	50.6%	56.5%	25.8%	29.3%	28.9%
Catholic	22.1%	25.4%	21.4%	14.4%	21.9%
Other religion	11.2%	6.3%	23.6%	11.4%	12.2%
No formal religion	16.1%	11.7%	29.2%	44.9%	37.0%
Highest level of schooling					
Less than high school	20.1%	11.8%	0	0	0
High school graduate	53.9%	45.9%	0	0	1.9%
Profess. school / college	14.0%	20.3%	0	0	22.7%
University	12.0%	22.0%	100%	100%	75.4%
Appointed on REB as					
Researcher	-	-	-	-	38.2%
Physician					26.1%
Ethics expert					11.8%
Lawyer					7.0%
Lay person					18.8%
Administrator					7.0%
Student representative					3.2%
Other					4.1%

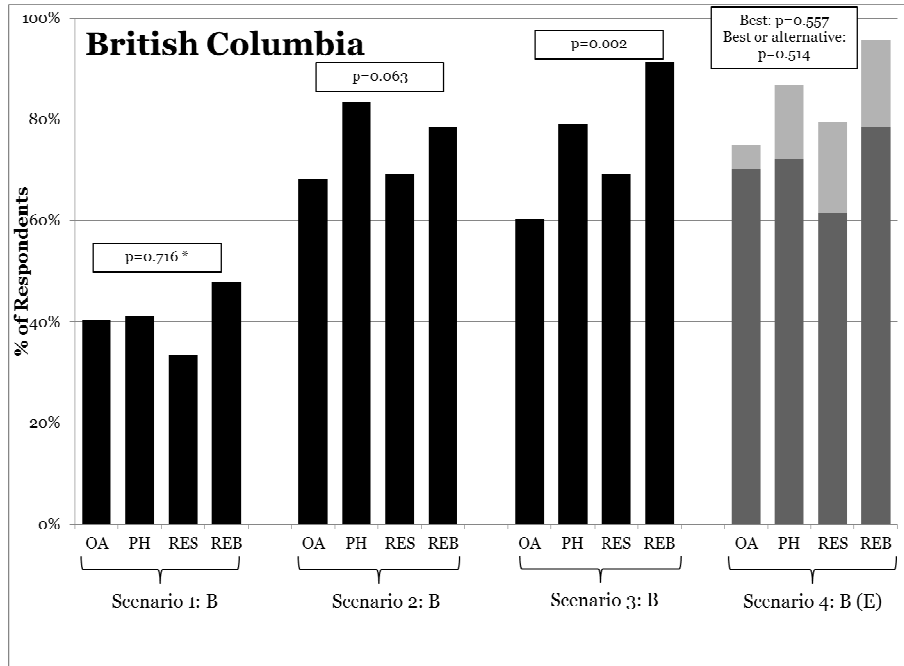
^a Data reported as percentage or mean \pm standard deviation (with the range in parentheses for some variables). These were already reported in Bravo et al, "Advance Directives", *supra* note 145 .

^b More than one answer could be given.

V. Responses to the Questionnaire

Figures 1–4 show the percentage of respondents who provided the correct–or best and alternative–responses to each scenario. In each figure, the single correct or best answer is given beside the scenario number, with its alternative in parentheses (when relevant). Like Table 4, these Figures represent our evaluation of responses in light of the health care consent (including advance directive) and guardianship laws in force at the time the survey was conducted.

Figure 1. % of Respondents with Correct or Best/Alternative Answers in British Columbia



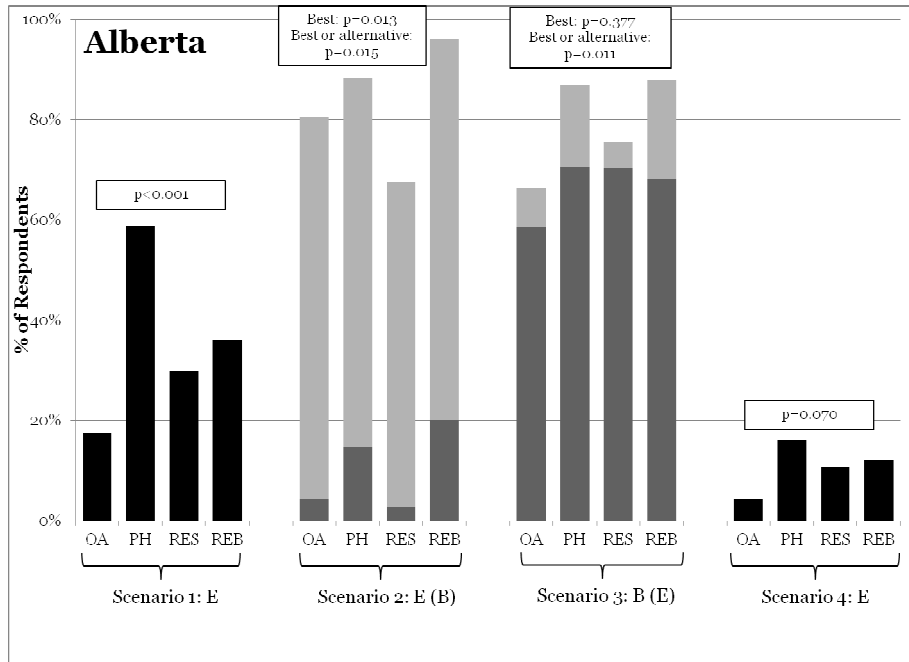
- single correct response
- best answer
- alternative answer

OA: older adults; PH: physicians; RES: researchers; REB: REB members.

* p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, $p < 0.001$ for all groups.

Figure 2. % of Respondents with Correct or Best/Alternative Answers in Alberta

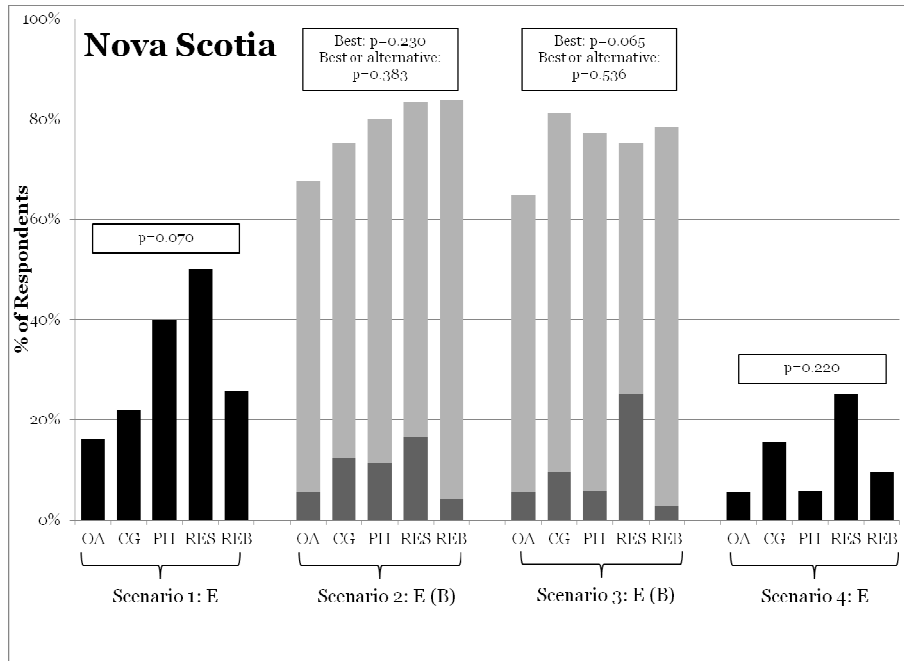


OA: older adults; PH: physicians; RES: researchers; REB: REB members.

p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, $p < 0.001$ for all groups.

Figure 3. % of Respondents with Correct or Best/Alternative Answers in Nova Scotia



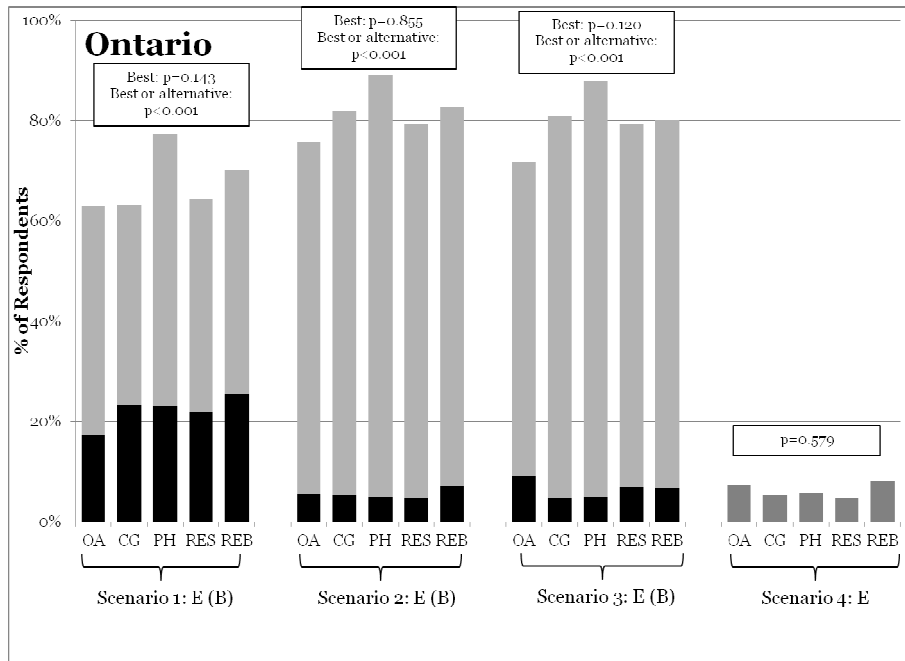
- single correct response
- best answer
- alternative answer

OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members.

p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, $p=0.088$ for OA, $p=0.241$ for CG, $p<0.001$ for PH, $p=0.029$ for RES and $p<0.001$ for REB.

Figure 4. % of Respondents with Correct or Best/Alternative Answers in Ontario



- single correct response
- best answer
- alternative answer

OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members.

p value above bars is for comparison across groups.

When comparing single correct / best answer across scenarios, p<0.001 for all groups.

These results indicate that all respondent groups, including those who conduct or oversee research, were widely mistaken about the state of the law where there was one clear answer, or alternatively, favoured an uncertain appraisal of the state of the law by identifying the family member as LAR where “no one had clear legal authority” was the optimal answer.

Figure 1 presents responses from BC. Except for scenario 3 (the “advance directive addressing health care but not research” scenario), rates of identification of the correct or best answer were similar across groups. While 11% of older adults and 5% of researchers acknowledged they did not know the answer in scenario 3 (option F), this percentage was less than 2% in the two

other groups. All respondent groups from BC were less likely to correctly identify the family member as LAR in scenario 1 as compared with the other three scenarios. This may reflect the absence of an obvious legal instrument (court-ordered guardianship or an advance directive) in this scenario.

Figure 2 presents responses from Alberta. Here the percentage of respondents with the best answer was statistically different across groups for the first two scenarios. A higher percentage of physicians and REB members identified the best or alternative response in their answers to these scenarios. In response to scenario 1, well under half of the respondents in each group, except physicians, correctly indicated that no one has clear legal authority (option E). However, this was nonetheless the most-favoured response for that scenario across all groups except the older adults, who identified the family member as LAR (option B) more frequently (42% selected B, versus 17% selecting E).¹⁶²

In response to scenario 2 (guardianship), less than 20% of each Alberta group indicated that there was no clear legal authority. The most-favoured response to this scenario across all Alberta groups was that the family member was LAR, which we recognized as a reasonable alternative response. In scenario 3, a majority of each group was correct in identifying the family member as LAR. Finally, in scenario 4, the “no-individual-benefit” scenario, under 16% of respondents from each Alberta group correctly indicated that no one had clear legal authority. The family member was the favoured selection in response to this scenario among all groups.

Figure 3 shows that, in Nova Scotia, there was no statistical difference across groups in all scenarios. Statistical power is, however, low in Nova Scotia, given the relatively small sample size. In response to scenario 1, more researchers and physicians seem to correctly indicate that no one has clear legal authority, although the difference is not statistically significant. Between 20% and 40% of the other groups selected this response; among these groups, the favoured answer was the family member. In scenarios 2–4, “no one has clear legal authority” was correctly identified by less than 20% of each group except

¹⁶² 36% of REB members and 30% of researchers selected option E (“no one has clear legal authority”) in Alberta; the next most frequent selections among the REB members, in descending order, were option B (the family member) (16%), option A (Mrs. Bristol herself) (12%), and a combination of A & B—perhaps seeking to indicate the need for a form of co-decision making or the importance of assent (12%). Among the researchers, the next most frequent selections were option B (16%), option A (16%), and options A & B (11%).

the researchers, who came in closer to 25% in scenarios 3 and 4. All groups favoured the family member in response to scenario 4.

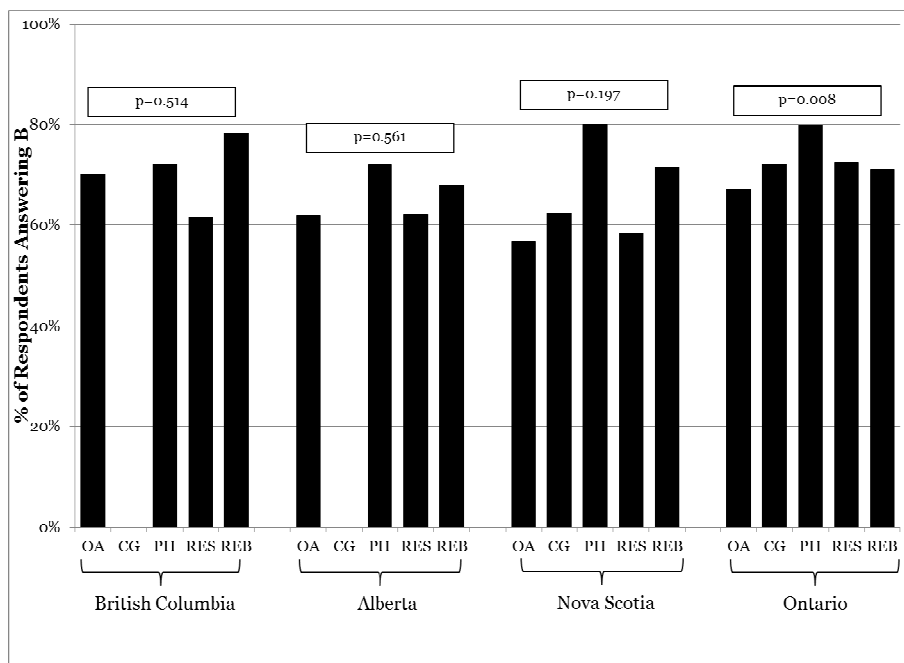
In Ontario (see Figure 4), the percentage of respondents with the best answer was not statistically different across groups for all four scenarios. Physicians however chose the alternative answer more often than other groups. The rates at which “no one has clear legal authority” was selected in Ontario were not markedly higher than in the other two provinces lacking clear statutory foundations for identification of an LAR. The favoured answer among all Ontario groups for scenarios 1–4 was that the family member was the LAR.

Figures 1–4 present only the rates at which correct answers (or best and reasonable alternative answers) were selected, but do not show the rates of other relevant responses. In connection with scenario 4 (no individual benefit), clear majorities of every group in every province indicated that the family member was the LAR. This was correct in BC, but in every other province the response had no clear basis in the laws that we have examined. Figure 5 shows this pattern.

In sum, setting aside BC (which provides a clear foundation for identifying an LAR in each of the four scenarios), and the advance directive scenario as applied in Alberta (also enabling LAR identification), the correct or best response to the remaining scenarios in Alberta and all of the scenarios in Nova Scotia and Ontario was option E “no one has clear legal authority” (See Table 4). Yet of the 52 scenario/group/province combinations proper to Alberta, Ontario, and Nova Scotia,¹⁶³ in only four instances was the most favoured response not the erroneous or, in some cases, defensible but still legally risky option B (the family member). In 45% (23 of 52) of these combinations, more than 70% of group participants identified the family member as LAR. The exceptions all arose in response to scenario 1 (no advance directive or court-appointed guardian), where “no one has clear legal authority” was favoured among the Alberta physicians (59%), Alberta REB members (36%), Alberta researchers (30%), and Nova Scotia researchers (50%).

¹⁶³ In Alberta, there were only four groups rather than five, as caregivers were not canvassed. (Three provinces) x (four scenarios) x (five groups) – (the advance directives in Alberta exception) – (Albertan caregivers in the other three scenarios) = 60 – 5 – 3 = 52.

Figure 5. Selection of B – “Family Member” – in Response to the “No-Individual-Benefit” Scenario



OA: older adults; CG: informal caregivers; PH: physicians; RES: researchers; REB: REB members

p values are for within-province comparison across groups

In other words, putting aside the divergent responses to scenario 1, the other three scenarios elicited relative agreement across provinces and population groups that the family member was the LAR—regardless of whether the applicable provincial laws were clearly supportive, unclear, or clearly contrary.

Perhaps our most striking result concerned scenario 4 (no individual benefit), in response to which a clear majority of every subgroup indicated that the family member was the LAR. In BC, this was the correct response. However, based on our analysis of health care consent and advance directives laws (there was no guardianship order in place), the response had no clear basis in law in Alberta, Nova Scotia, or Ontario. In these provinces, the proportion of respondents identifying the family member as LAR was not markedly lower than in scenarios 2 and 3, and was markedly higher than in response to the first scenario.

As noted, even those who conduct or oversee research were widely mistaken about the state of the law where there was one clear answer. Furthermore, they favoured a riskier appraisal of the state of the law when no one had clear legal authority. For example, in response to scenario 3 (featuring an advance directive for health care), the proportions of researchers asserting that the family member was the LAR for the purpose of decision making about the proposed research were 50% and 71% in Nova Scotia and Ontario, respectively. Among REB members in those two provinces, the proportions identifying the family member as LAR were 76% and 72%. In response to scenario 4 (no individual benefit), the proportions of researchers identifying the family member were 62%, 58%, and 72% in Alberta, Nova Scotia, and Ontario, respectively. Among REB members, the rates were 68%, 72%, and 71%.

VI. Discussion

In Canada, a complex set of federal and provincial laws and policies apply to the regulation of health research involving persons deemed incapable of consent. While third party authorization is a minimal legal requirement, provincial laws may fail to offer a clear or explicit basis for identifying an LAR.¹⁶⁴ In both Canada and the US, governments have been urged to devise regulatory regimes specific to this area of social policy, including but not limited to laws enabling LAR identification.¹⁶⁵ This advice is part of a broader concern to ensure that research regulation is sensitive to the dual values of advancing scientific knowledge and protecting vulnerable populations.

We put four scenarios to stakeholders in four Canadian provinces, and asked who, if anyone, was legally empowered to give third party authorization for an adult's participation in research. The key variables in the scenarios were the presence or absence of a court-appointed guardian or advance directive for health care, and the presence or absence of a prospect of individual benefit. Two provinces in which our survey was conducted featured clear legislative terms enabling LAR identification in at least one of the scenarios; the other two provinces did not. Yet, as illustrated in section IV, respondents in all provinces and across all five sub-populations surveyed tended to identify the family member as LAR, with only small minorities acknowledging the uncertainty or legal ambiguity attaching to LAR identification.

¹⁶⁴ See Bravo et al, "Comparison Substitute Consent", *supra* note 7 and Part III, above.

¹⁶⁵ In the US context, see Saks et al, *supra* note 6; in the Canadian context, see Bravo et al, "Comparison Substitute Consent", *supra* note 7.

From this tendency of respondents to identify a family member as LAR regardless of uncertain or absent legal authority, one may speculate that their understanding of the laws governing third party authorization of research may have been driven less by familiarity with provincial laws than by certain broad, culturally-shared conceptions of acceptable conventions. Based on the greater proportion of respondents across all groups who attributed decision making authority to the family member in scenarios 2 and 3 in comparison with scenario 1, one may further speculate that respondents' perceptions of authority turned in part upon the presence of an overt or obvious legal mechanism for conferring some form of substitute decision making authority (i.e. a guardianship order or advance directive), even where extension of that authority to decisions about research participation was unclear.

The utility of our study is twofold. First, it draws attention to the complexity and diversity of provincial approaches to this aspect of research regulation. While it is sometimes said that Canada's federalist order is enriched by a multiplicity of provincial legal regimes functioning as independent laboratories for policy innovation, in this instance the public interest is arguably impeded by provincial differences imposing divergent and sometimes uncertain requirements. In particular, these differences raise the possibility that research norms will be poorly understood, and that research of potential value, particularly multi-centre national research, may be impeded or chilled. Second, our study demonstrates that REB representatives, researchers, physicians, and laypersons tend to believe that a close family member may act as LAR, even in circumstances in which provincial laws are ambiguous or offer no foundation at all for third party authorization of research. This raises concerns about the adequacy of public and professional understandings of legal requirements for research involving persons deemed incapable of consent. Related concerns include harm to research subjects in the absence of clear transmission and understanding of legal requirements, as well as liability on the part of researchers, REB members, and research institutions in the absence of valid third party authorization.

A. Other Studies

In what follows, we consider our findings in light of other studies before taking up certain limitations of our study.

1. The Quebec Study

Some of the authors had conducted a similar study in Quebec prior to this one.¹⁶⁶ In Quebec, article 15 CCQ authorizes close family members to make substitute decisions about health care on behalf of a minor or an adult deemed legally incapable of consent.¹⁶⁷ In contrast, article 21 CCQ places a set of conditions upon involving persons in research where they lack capacity to consent.¹⁶⁸ One of these conditions is that, except in the situation of a parent and minor child, substitute consent must be obtained from the mandatary (in other words, the proxy appointed under an advance directive), tutor (partial or tem-

¹⁶⁶ See Bravo, Pâquet & Dubois, *supra* note 147; Bravo et al, “Physicians’ Knowledge”, *supra* note 147.

¹⁶⁷ More detailed analysis of the sources of legal regulation of medical and research interventions in Quebec is provided in Simon Verdun-Jones & David N Weisstub, “Consent to Human Experimentation in Quebec: The Application of the Civil Law Principle of Personal Inviolability to Protect Special Populations” (1995) 18:2 Int’l J of Law & Psych 163.

¹⁶⁸ Article 21 places certain restrictions on involvement in research even where capacity to consent is in place, stipulating that the benefits of the proposed research (or “experimentation”) must outweigh the risks. Commentators have remarked that this section implicitly includes societal benefits and not merely individual-specific benefits. See WF Bowker, “Experimentation on Humans and Gifts of Tissue: Articles 2-23 of the Civil Code” (1973) 19:2 McGill LJ 161 at 166-67. Article 21 para 3 CCQ states that “[c]onsent to experimentation may be given, in the case of a minor, by the person having parental authority or the tutor and, in the case of a person of full age incapable of giving consent, by the mandatary, tutor or curator.” The Code does not define “experimentation.” Some commentators have opined that these codal provisions relate only to non-therapeutic research (see Verdun-Jones & Weisstub, *supra* note 167 at 175-79). Yet this is contestable, as the Code does not explicitly distinguish therapeutic from non-therapeutic experimentation. Indeed, where a novel intervention is directed at an individual who lacks capacity to consent, art 21 para 2 CCQ requires that the “experiment” must offer a “potential to produce benefit to the person’s health”—therefore, the term is compatible with interventions that have an anticipated therapeutic effect. Article 21 para 2 CCQ also stipulates that where an experiment is directed at an identifiable group, it must have the potential “to produce results capable of conferring benefit to other persons in the same age category or having the same disease or handicap.” This allows for the possibility of non-individual-benefit research, but does not preclude application of this provision of the Code to research featuring an anticipated benefit (along with anticipated risks). Article 21 CCQ further prohibits the involvement of minors or persons incapable of consent in “experiments” involving “serious risk” to their health, and requires respect for dissent in cases in which the person “understands the nature and consequences of the experiment.”

porary guardian), or curator (plenary guardian). Each of these regimes requires a formal court process to trigger substitute decision making authority.

A majority of respondents to the Quebec survey correctly identified the individual himself or herself as having legal authority to consent to or refuse treatment if he or she is legally capable of making the decision; moreover, a majority correctly identified the LAR where the individual was deemed incapable of making a decision about treatment (under article 15 CCQ, a close family member without formal court appointment). In contrast, a minority of respondents (ranging from 2% of older adults to 44% of REB members) correctly responded that no one was legally authorized to make the decision where the scenario involved the prospective research participation of an adult who was legally incapable of consenting and who lacked a formally-appointed representative (a curator, tutor, or mandatary). The Quebec respondents tended to incorrectly identify the close family member as being automatically authorized to make a substitute decision about an adult's participation in research. Based on this result, the authors recommended increased efforts to educate the public about Quebec's laws.

In the present study, we began by determining whether and how the common law Canadian provinces and territories deal with the question of who, if anyone, may make a substitute decision about research.¹⁶⁹ We concluded that in many provinces, the matter is unsettled—yielding, at best, competing arguments rather than clear legislative or judicial statements.¹⁷⁰ Against this background, we assessed how a set of stakeholders understood the state of the law in their province. This promised to be a distinct exercise from the Quebec study, where the law on point had been explicit. It is therefore difficult to compare the results of the present study with those obtained in Quebec.

The present study therefore raises some difficult questions that were not raised in the Quebec study, namely: How do people make sense of legal uncertainty? And how should a survey of knowledge be interpreted where the object of knowledge is itself markedly ambiguous or contested? We address these questions after noting some further studies of relevance to this one.

¹⁶⁹ See Bravo et al, "Comparison Substitute Consent", *supra* note 7.

¹⁷⁰ *Ibid.*

2. Laws Relevant to Research Involving Persons Incapable of Consent

Apart from the aforementioned Quebec study, we were unable to locate any other studies, Canadian or otherwise, of people's knowledge of laws concerning substitute decision making about research.¹⁷¹ However, we were able to draw upon articles analyzing the state of the law. These included one that some of the authors of this study had previously written, commenting on the diversity and frequent ambiguity of Canadian substitute decision making laws concerning LAR identification for research purposes,¹⁷² and also the work of Tomossy & Weisstub on the uncertainty of provincial guardianship laws, particularly with respect to authorization of non-therapeutic research.¹⁷³

Another relevant study of legislative regimes was a 2008 article produced by Elyn Saks et al. That article provides a comprehensive account of US substitute decision making laws, some of which expressly address "whether proxies may consent to research, and if so, which individuals should serve as proxies, and for which sorts of research they can provide consent,"¹⁷⁴ and some of which are ambiguous in one or more of these respects. The authors conclude that a model statute may be desirable, and that in any case, "it is certainly desirable that states adopt clear, well thought out statutes that specify who may serve as a Legally Authorized Representative."¹⁷⁵ Our own conclusions, following examination of the laws in four Canadian provinces and individuals' understandings of who, if anyone, may act as LAR in research contexts, closely parallel those of Saks and her co-authors.

¹⁷¹ The authors of the Quebec study conducted a similar study in France, which arrived at similar results. See Bravo et al, "Substitute Consent for Research Involving the Elderly: a Comparison Between Quebec and France" (2008) 23:3 *Journal of Cross-Cultural Gerontology* 239. In addition, a further study has recently come to our attention: Mary Dixon-Woods & EL Angell, "Research Involving Adults who Lack Capacity: How have Research Ethics Committees Interpreted the Requirements?" (2009) 35:6 *Journal of Medical Ethics* 377. Dixon-Woods & Angell find in decision letters of research ethics committees in England and Wales evidence of confusion about recently-introduced laws concerning substitute decision making about research.

¹⁷² *Ibid.*

¹⁷³ Tomossy & Weisstub, *supra* note 7.

¹⁷⁴ Saks et al, *supra* note 6 at 79.

¹⁷⁵ *Ibid.*

3. Understanding of Substitute Decision Making Laws (Not Specific to Research)

We may also compare our study to two others, one from Scotland and the other from Australia, which assessed knowledge of substitute decision making laws relating to health care (as well as finances in the Australian study). However, because these studies did not address third party authorization of research, they are only indirectly relevant to our study.

Booth et al surveyed relatives of intensive care patients in Scotland to ascertain their knowledge of the law relating to health care interventions where the prospective patient is incapable of making a treatment decision.¹⁷⁶ At the time, there was no clear legal foundation in Scotland for third party authorization of treatment where an adult lacked legal capacity, except where a court-appointed guardian was in place.¹⁷⁷ Legislation had been introduced to address aspects of this legal state of affairs. But that law was not in force at the time of the study, and in any case, it refrained from giving substitute decision making authority to a close family member in the absence of a court-appointed guardian or an advance directive appointing the family member as proxy.¹⁷⁸

Relatives of 100 intensive care patients completed the authors' structured questionnaire. Only 10% were aware that reforms to the law on consent to

¹⁷⁶ MG Booth et al, "Relatives' Knowledge of Decision Making in Intensive Care" (2004) 30 J Med Ethics 459.

¹⁷⁷ *Ibid.* The survey was completed during a period of law reform, with the most salient reforms not coming into force until the survey was completed (the article was submitted in June, 2002; the reforms came into effect July 1, 2002). The relevant post-reform legislation is the *Adults with Incapacity (Scotland) Act 2000*, 4 ASP 2000 [*Scotland Act*]; on the coming into force of the relevant provisions, see *The Adults with Incapacity (Scotland) Act 2000 (Commencement No. 2) Order 2002*, Scot SI 2002 No 189 (c 14). It appears that the primary questions asked in the survey were not affected by the reforms.

¹⁷⁸ The *Scotland Act*, *supra* note 177 ss 47-50, brought into force after the Booth et al, *supra* note 176 study, authorizes physicians to treat patients who lack capacity in the absence of third party authorization, in order to promote their health, unless there is a proxy appointed under an advance directive or a court-appointed guardian (in which case authorization must be sought). Scottish law refrains from giving authority to the nearest relative in the absence of such a formally-appointed representative. Notably, where research is in issue, section 51 of the *Scotland Act* imposes a set of threshold risk/benefit conditions as well as a requirement of third party authorization, to be obtained from a guardian, agent under an advance directive, or—failing that—the nearest relative.

treatment were underway.¹⁷⁹ A majority (88%) incorrectly believed that prior to any law reforms, they “had the right ... to give or withhold consent on behalf of an incompetent patient.”¹⁸⁰ The authors observe that this suggests “a general lack of knowledge” about the state of the law in Scotland relating to medical treatment of persons who lack the relevant decision making capacity. They add:

Relatives’ false perception of their power to consent was probably reinforced by the almost routine practice of involving relatives in discussion concerning life sustaining treatment as a substitute for direct discussion with the patient. Certainly, getting the relative to sign a consent form would have given the impression to the relative that their opinion did have legal weight. It was our impression that not all doctors were entirely clear on this either.¹⁸¹

The study did not take up the question of third party authorization of research, only of treatment. Nonetheless, it is worth considering whether our respondents may similarly have drawn upon prior experience (in particular, common practices whereby health providers look to family members for substitute decision making about health care; in Canada, unlike Scotland, these practices are typically grounded in law) in identifying the family member as LAR, even where there was no basis, or no clear basis in law for this conclusion.

Another study of comparative interest, conducted in Queensland, Australia, explored the “knowledge and experiences of older people”¹⁸² with respect to enduring powers of attorney for financial and health care decisions. The authors found that “a majority of older people lacked a level of understanding of enduring powers of attorney concepts that would enable them to make informed legal choices.”¹⁸³ However, there was “more detailed” knowledge of the legislation on the part of family members of older persons with cognitive disabilities, which the authors attributed to “their experience of arranging and sometimes implementing an [enduring power of attorney].”¹⁸⁴

¹⁷⁹ See Booth et al, *supra* note 176 at 460.

¹⁸⁰ *Ibid.*

¹⁸¹ *Ibid.*

¹⁸² Deborah Setterlund, Cheryl Tilse & Jill Wilson, “Older People and Substitute Decision Making Legislation: Limits to Informed Choice” (2008) 21:3 *Australasian Journal on Ageing* 114 at 130.

¹⁸³ *Ibid* at 132.

¹⁸⁴ *Ibid* at 130.

It was also found that knowledge of the relevant substitute decision making laws was negatively correlated with “structural factors of lower income, [non-Anglo-Australian] cultural background, disability, rural location, nursing home residence and [female] gender.”¹⁸⁵ Lower income and disability were particularly associated with “limited understanding of the law.”¹⁸⁶ Perhaps unsurprisingly, lack of knowledge about the relevant substitute decision making laws was found to “limit the ability to make informed choices and to self monitor arrangements” about finances and health care.¹⁸⁷ The authors concluded that the government should “raise awareness in the community generally and in the older population in particular regarding both the advantages and disadvantages of substitute decision making arrangements,” while “tak[ing] account of the diversity of views that older people have of substitute decision making arrangements” and the effect of structural factors on people’s perceptions of substitute decision making laws.¹⁸⁸

In interpreting the results of our study, it is important to keep in mind that respondents may have had concrete experiences, for example, with substitute decision making about health care (or for that matter, virtual experiences, say, with television programs featuring substitute decision making about health care) that rightly or wrongly inform their understanding of substitute decision making about research. That is, despite a “limited understanding of the law,” respondents may have given answers based in their understanding of what common practices are or perhaps their opinions about what the law should permit. Yet here it is important to acknowledge that even highly educated stakeholders may be influenced by forms of misinformation or partial understanding that may be particularly entrenched in professional circles.¹⁸⁹

¹⁸⁵ *Ibid* at 132.

¹⁸⁶ *Ibid*.

¹⁸⁷ *Ibid* (focus group discussions further indicated that “the reluctance of many participants to consider substitute decision making arrangements may reflect also emotions associated with the acknowledgement of possible incapacity and mortality” at 132).

¹⁸⁸ *Ibid*.

¹⁸⁹ See e.g. Kimberly Nalder, “The Paradox of Prop. 13: The Informed Public’s Misunderstanding of California’s Third Rail” (2010) 2:3 California Journal of Politics & Policy 1. This analysis of the results of a poll assessing voter knowledge of a high profile, contentious Californian law (“Proposition 13”) found that standard predictors of better understanding of political and legal matters (in particular, higher education and wealth) were actually correlated with a higher likelihood of error in

B. Limitations¹⁹⁰

Among the limitations of our study is the fact that response rates were less favourable in some groups and provinces. The sample size, however, is relatively large. Moreover, the analyses suggest that participants were representative of their population, with the exception of the physician group, which required weighting.

A further limitation, noted earlier, is that our study did not evaluate responses in light of federal or provincial laws relating to personal information and the protection of privacy, or how the substitute decision making regimes featured therein may bear upon health research in general and our study in particular. To this we may add that our search for case law was restricted to identifying precedents directly taking up the question of who, if anyone, may function as LAR for research authorization purposes, either at common law or under the legislation canvassed. We identified no case law of direct relevance to this question. Yet there remains scope for future research involving a more searching case law review aimed, for instance, at identifying precedents involving other areas of substitute decision making authority that are of potential relevance to the research context.

In what follows, we discuss three further limitations of our study. These relate to our focus on respondents' understanding of laws that in some cases were ambiguous or were subject to law reform processes during the study period.

1. Surveying Knowledge in the Face of Uncertainty

What can be gained by surveying knowledge of the law where the law is (in many instances) markedly ambiguous or uncertain? Here we should distinguish situations in which individuals are personally uncertain about the law but there is general agreement that the law itself is clear, and situations in which the law is generally recognized as ambiguous or uncertain as between competing interpretations (and there is no case law establishing a definitive interpretation).

respect to the content of the law in question—a phenomenon that Nalder speculates may reflect high levels of public misinformation as well as interest-sensitive selectivity of understanding.

¹⁹⁰ Some of the statements on general strengths as well as limitations of our study in this part are taken from a previously published article reporting on other aspects of the study, Bravo et al, "Advance Directives", *supra* note 145 at 212-215.

In analyzing the results of the Quebec study, the authors speculated that some respondents may have lacked a defensible claim to knowledge of the law as it applied to the scenarios, but may nonetheless have provided what they thought was “the most sensible answer” rather than admit lack of knowledge.¹⁹¹ Therefore, correct survey responses might not indicate that respondents were familiar with the relevant laws (again, in Quebec the laws on point were relatively clear), but rather that the laws coincided with respondents’ intuitive judgments.

Turning to the present study, one may similarly speculate about whether people were disposed to provide the answer they deemed most sensible, or in accordance with their particular values and cultural assumptions, rather than indicate that they did not know the answer or that the law was uncertain. It is arguable, however, that information about the way that stakeholders understand the laws governing research, particularly where those understandings are rich with value-laden assumptions, may spur public reappraisal of the laws in place and the processes for promulgating and enforcing those laws.

Here we may raise a further question, going to the defensibility of our evaluation of survey responses. We distinguished situations where there was a single correct answer (meaning that we could identify no plausible alternative argument) from situations where there was a “best” answer along with a reasonable alternative. It may be argued that our characterizations of responses as correct or incorrect, or more to the point, as either “best” or a “reasonable alternative,” are inextricably bound up with our own value-laden policy preferences or subjective impressions and thus are reflective of personal bias rather than objective evaluation.

Our response is twofold. First, we have provided the bases for our interpretations in Parts II and III. Should one wish to argue that our interpretations reflect contestable premises, including contestable normative assumptions, these premises may be exposed and opposed. Second, where we privilege the claim that no one has clear legal authority—as we do in all but two situations where we recognize a best and reasonable alternative answer—this amounts to an objective acknowledgement of the presence of legal controversy. In other words, option E indicates that there are competing legal arguments, as yet unresolved by an authoritative judicial statement. This is not a matter of privileging one competing argument over another; rather, it is a matter of recognizing that there are competing arguments.

¹⁹¹ Bravo, Pâquet & Dubois, *supra* note 147 at 48.

A final, more general point must be made with respect to surveying legal knowledge in the face of uncertainty. Even where one is a legal professional, it may be unclear whether the appropriate response to an invitation to characterize an area of law that is in some respect uncertain is to acknowledge that uncertainty, or to give one's opinion about the best argument in light of the normative or policy considerations one deems most compelling or most likely to be accepted by a court.

This conundrum is illuminated by a recent study of how law students evaluate legal texts. The authors of the study distinguish internal from external approaches to legal (or specifically statutory) ambiguity.¹⁹² According to the authors, the internal approach to legal ambiguity is that which individuals tend to apply when asked simply whether a statute is ambiguous. This interpretive approach is "internal" in that it involves consulting and asserting one's own judgment about the best interpretation of the law—a process whereby, the authors suggest, individuals draw upon their particular normative predispositions or policy preferences and characterize the law as ambiguous or unambiguous (likely the latter), depending on which answer best accords with those predispositions or preferences. In contrast, an external approach to legal ambiguity tends to be elicited where the respondent is instructed to make an effort to consider whether "ordinary readers of English" would agree on the meaning of legal text.¹⁹³ Such an approach is "external," according to the authors, in that it reduces the bias of individual policy preferences in favour of a more empirically grounded attempt to predict collective opinion. Put differently, the latter approach is distinguished by an effort to take account of others' competing normative and policy orientations, rather than simply one's own, when assessing legal ambiguity.¹⁹⁴

The respondents to our survey were asked to determine who, if anyone, was authorized to make a substitute decision about research in a set of scenarios. It is possible that more respondents would have acknowledged legal uncertainty if the survey had directed them to consider whether, say, Canadians could be expected to agree on how the law applies to the problem at hand. However,

¹⁹² Ward Farnsworth, Dustin F Guzior & Anup Malani, "Ambiguity about Ambiguity: An Empirical Inquiry into Legal Interpretation" (2010) 2:1 *Journal of Legal Analysis* 257.

¹⁹³ *Ibid* at 258.

¹⁹⁴ We use this example despite the differences between the exercise grounding the study done by Farnsworth, Guzior & Malani, *ibid* (involving interpretation of specific statutory language), and our study (which asked respondents to apply their understanding of the law without providing the relevant statutory text).

asking who is legally authorized to make a substitute decision about research, while providing “no one has clear legal authority” as one option arguably engages not only respondents’ estimations of the principled or policy-based cases for one or another answer (the normative dimension of law-interpretation), but also and primarily their understanding of whether the matter is settled or contestable, and so potentially a matter for litigation (the positive dimension of law-interpretation). Of course, one may expect that many responses will be less than fully informed or considered; as noted, we speculate that some of the responses to our survey may register the common sense intuitions of respondents rather than informed assessments of the state of the law.

2. Surveying Knowledge in the Absence of Legal Consultation

A second limitation of our study is that the responses we received are not necessarily those that would inform the decisions or actions taken by the respondents in a concrete instance of proposed research. Respondents were instructed to “read each vignette carefully and answer to the best of your knowledge according to the law in your province.” If such a situation actually arose, those surveyed might consult with legal advisors or otherwise seek information about institutional policies before reaching a conclusion. Such consultation might result in a shift in respondents’ understanding from that which is recorded in the survey. This may particularly be so in the case of the REB members who completed our survey, given that each REB responsible for reviewing biomedical research within institutions that receive federal research funds is required to include a member who is knowledgeable about relevant law,¹⁹⁵ and that member’s opinion would presumably be given particular weight where problems of LAR identification arise.

The assumptions about the state of the law that our study registers, however, may conceivably inform a range of decisions and actions on the part of respondents, from the decisions of older adults about whether to engage in advance planning specific to research participation, to the activities of physicians in giving advice about advance planning, to the activities of REBs in approving research and the work of researchers in conducting it. Indeed, given that 44.3% of the researchers who participated in our study indicated that they had con-

¹⁹⁵ *TCPS2*, *supra* note 8 art 6.4(c); *TCPS1*, *supra* note 8 art 1.3(c). Both editions state that it is “advisable but not mandatory” that at least one REB member be knowledgeable about relevant law where the research under review is not biomedical research. As indicated in Table 2, REB members appointed for their legal expertise were included in our respondent pool (they comprised 7% of the REB respondents).

ducted research that involved decisionally-incapacitated older adults in the past five years, and 43.5% of the 46 REB Chairs who participated in a qualitative interview indicated that their committee had reviewed protocols involving decisionally-incapacitated older adults in the last 12 months, we may surmise that the responses from these groups sometimes reflected past practice as well as present understanding.¹⁹⁶

3. Surveying Knowledge in the Face of Legal Reforms

A third limitation of our study arises from the legal reform processes that took place in Alberta and Nova Scotia during and just after the period in which our surveys were completed. These reforms did not come into force until after all of our surveys were returned. However, some respondents were likely aware of the proposed reforms. While our survey was underway, both of the relevant statutes received Royal Assent (a stage in the legislative process that is potentially confused with coming into force). This may have led to confusion about the state of the law on the part of some Nova Scotia and Alberta respondents at the time the surveys were completed.

The first of our surveys was mailed out in September 2007; the last returned to us was received in April 2009. In Alberta, the *Dependent Adults Act*¹⁹⁷ was subject to law reform processes during the period in which we conducted our survey and was subsequently replaced by the *Adult Guardianship and Trusteeship Act*.¹⁹⁸ The latter Act received Royal Assent on 2 December 2008 and was brought into force on 30 October 2009, shortly after our survey responses were returned. Certain provisions within Alberta's *Adult Guardianship and Trusteeship Act*¹⁹⁹ would have altered our evaluation of the Alberta responses had they been in force at the time of the survey. This applies in respect to scenarios 1 (no court-ordered guardian or advance directive for health care)²⁰⁰ and 2 (court-appointed guardian).²⁰¹ Our evaluation of the Alberta re-

¹⁹⁶ Bravo et al, "Practices of Canadian REBs", *supra* note 145 at 3-6.

¹⁹⁷ *Supra* note 135.

¹⁹⁸ *Ibid.*

¹⁹⁹ *Ibid.*

²⁰⁰ In scenario 1, the correct answer under the *Dependent Adults Act* was E ("no one has clear legal authority"). However, under the *Adult Guardianship and Trusteeship Act*, the best answer shifts to B (the family member) with E as a reasonable alternative. Mrs. Bristol's son Jacob satisfies the criteria for recognition as the "specific decision maker" for "health care" under section 89 of the Act, while section 88(2)(d) excludes from the ambit of his authority "health care that involves participation ... in research"

sponses to scenarios 3 and 4 would not differ with the introduction of the new Act.

In Nova Scotia, the *Medical Consent Act*²⁰² was subject to law reform processes during the period in which we conducted our study and was subsequently replaced by the *Personal Directives Act*,²⁰³ again after our survey was complete. The new Act received Royal Assent on 27 May 2008, and was brought into force on 1 April 2010. Nova Scotia's new *Personal Directives Act* would have altered our evaluation of responses to scenario 1 (no court-appointed guardian, no advance directive) had it been in force at the time of our survey.²⁰⁴

offering “little or no potential benefit to the adult.” This provision arguably implicitly authorizes statutory decision makers (and so “Jacob”, in scenario 1) to act as LAR where research offers more than “little or no potential benefit.” We would have recognized E as a reasonable alternative, because scenario 1 states that the research study is “potentially” of “some” benefit to participants, leaving open for debate the question of whether the study satisfies the statutory threshold of offering more than “little or no potential benefit.”

²⁰¹ In the pre-reform situation in Alberta, the best answer to scenario 2 was E (“no one has clear legal authority”), with B (the family member) as a reasonable alternative, given the possibility that a court would recognize this decision as falling within the best-interests based decision making authority of the guardian. Under the *Adult Guardianship and Trusteeship Act*, B would be the best answer, with E as the reasonable alternative. In other words, Jacob (introduced in scenario 1) continues to have authority to make the decision as statutory decision maker, if not as the court-appointed guardian. As in scenario 1, E would be recognized as a reasonable alternative because of the potential for debate about whether the study (now the one described in scenario 2) meets the statutory threshold of offering more than “little or no benefit.”

²⁰² *Supra* note 126.

²⁰³ SNS 2008, c 8.

²⁰⁴ The correct pre-reform response to this scenario was E (“no one has clear legal authority”), as there was no statutory basis for substitute decision making about health care, let alone research, outside the hospital setting. Had the *Personal Directives Act*, *ibid* been in force, the best answer would still have been E, but we would have recognized B (the family member) as a reasonable alternative. This is because the *Personal Directives Act* empowers the nearest relative (stipulated in a statutory list) to make substitute decisions about “health care” whether in or beyond hospital, in the absence of a personal directive. While the Act is silent on research, it may be argued that “health care” should be interpreted to include interventions holding out a prospect of individual therapeutic benefit.

However, our evaluation of the responses to scenarios 2–4 would not shift as between the pre- and post-reform situations in Nova Scotia.²⁰⁵

Readers may therefore approach our results from Alberta with respect to scenarios 1 and 2, and Nova Scotia with respect to scenario 1, with this qualification in mind. However, we suggest that the number of respondents who were cognizant of these reforms and who would have responded in a manner that reflected awareness of the specific terms of the legislation that was not yet in force was likely small.

Conclusions and Policy Recommendations

Important interests and values are at stake in the regulation of substitute decision making about research. Contemporary pressures to increase research activity focused on health conditions correlated with aging, including conditions involving cognitive impairment, demand renewed efforts to protect prospective research subjects who are vulnerable to the designation of legal incapacity and the resulting possibility of exploitation. Yet our study found that Canadian laws are both unclear and poorly understood when it comes to the crucial matter of identifying who, if anyone, is authorized to make a substitute decision about an adult's participation in research. This finding holds even for REB members, potentially compromising their oversight role in the research process.

More specifically, our survey reveals a widespread tendency among Canadians—including older adults, researchers, and REB members—to identify a family member as authorized to make a decision about an adult's research participation, even where such authority is either uncertain or clearly lacking at law. The combined lack of clarity in, and lack of knowledge about, provincial laws relating to LAR identification that our study exposes indicates a fundamental gap in the system of research regulation. Attendant to this is a potential for harm to prospective research subjects; a potential for liability on the part of researchers, REB members, and research institutions;²⁰⁶ and a potential for impeding the progress of research on conditions involving cognitive impairment.

²⁰⁵ Scenario 4 deserves specific consideration. With the coming into force of the *Personal Directives Act*, our evaluation of Nova Scotia responses to this scenario would not shift: E remains the sole correct answer. For the *Personal Directives Act* does not introduce a statutory basis for authorizing research offering no individual benefit to the research subject—at least (and this is an important qualification), not in the absence of prior capable wishes or values deemed relevant to participation in a specific no-benefit research project. Scenario 4 features no information about prior capable wishes or values.

²⁰⁶ See Hadskis, *supra* note 2; Thomson, *supra* note 60; Gold, *supra* note 60.

These problems are compounded when considering multi-site and cross-national research.

We conclude that there is a need for coordinated efforts among the provinces and territories to develop a harmonized approach to the laws concerning the involvement in research of persons who lack capacity to consent—beginning with the question of who, if anyone, may function as LAR in the research context. Any province or territory may opt to depart from a harmonized approach where local conditions are deemed to warrant this—but such departures should be specifically justified and weighed against the merits of harmonization. We further conclude that there is a need for enhanced clarity in and enhanced awareness about existing provincial laws of relevance to the question of who, if anyone, may function as LAR. Addressing one issue without the other will not solve the problem; neither clarity without awareness nor awareness without clarity will materially improve on the current situation.

More specifically, the primary recommendations arising from our study, apart from the overarching concern for harmonization, are as follows. Where there is a clear legal basis for identifying an LAR for research purposes in a given province or territory, the provincial or territorial government should devise a program of public education targeting researchers and REB members, as well as the general public, to ensure understanding of those laws. Where the law is unclear, government should undertake processes of public deliberation on the way to law reform, followed by efforts to ensure that researchers, REB members, and the general public understand the laws enacted. Policymakers in those provinces and territories not surveyed in this study should consider whether their laws offer a clear basis for authorizing substitute decision making about research, and should make efforts to ensure public understanding if the laws are clear or initiate law reforms if they are not.

We offer in addition a few closing observations on the policy concerns that should inform law reform initiatives, apart from the important goal of bringing increased clarity, certainty, and potentially also uniformity to this area of law. First, the tendency of respondents to our questionnaire to identify a close family member as LAR, whether or not this was supported in law, requires careful consideration of whether the law should be brought into accord with this common understanding. Of course, neither common understanding nor public preference necessarily makes good policy. In its 1998 report, the US National Bioethics Advisory Commission explored the possibilities for third party authori-

zation of research.²⁰⁷ Among the possibilities noted were giving exclusive authority to court-appointed guardians or agents appointed under an advance directive. However, as the report pointed out, guardians are rarely in place and appointing a guardian is both costly and time-consuming. Additionally, the blunt instrument of full guardianship may not serve the wider interests of the individual (or family) concerned. Research directives, on the other hand, may arguably promote autonomy while advancing the important goal of encouraging deliberation and discussion regarding preferences about research participation. However, few persons have executed advance directives specifically addressing research.²⁰⁸ Moreover, research directives may raise particular challenges when applied to specific research protocols, the precise nature and consequences of which the individual may not have contemplated.²⁰⁹

Allowing a family member to function as LAR for the purpose of substitute decisions about research in the absence of a guardian or advance directive poses less of an impediment to research than either of the other two options. But is this option sufficiently protective of the interests of prospective research subjects? That is, are there good reasons to suspect that a non-appointed family member is less well-positioned than a guardian or proxy appointed under an advance directive to fulfill the function of third party authorization: namely, to ensure, as far as possible, that the rights and interests of the prospective research subject are actively defended? Or do all three types of substitute decision maker face similar challenges?

This leads us to our second closing observation: that it is important to keep in mind that third party authorization is but one of a set of arguably vital protective measures. Studies demonstrate that family members are susceptible to inaccuracies about or departure from the capable preferences of their relatives when making substitute decisions about treatment.²¹⁰ It is not unreasonable to

²⁰⁷ National Bioethics Advisory Commission (1998), *supra* note 6, Vol I (December 1998), ch 3 nn 165 and following, online: <bioethics.georgetown.edu/nbac/capacity/Advance.htm#Para26>.

²⁰⁸ Bravo et al, "Advance Directives", *supra* note 145 at 215; Appelbaum, *supra* note 5 at 122.

²⁰⁹ But see the policy proposals intended to offset such concerns in Anne Moorhouse & David N Weisstub, "Advance Directives for Research: Ethical Problems and Responses" (1996) 19:2 *Int'l JL & Psychiatry* 107; Tomossy & Weisstub, *supra* note 7 at 130-134.

²¹⁰ T Tomlinson et al, "An Empirical Study of Proxy Consent for Elderly Persons" (1990) 30:1 *Gerontologist* 54; Allison Seckler et al, "Substituted Judgment: How Accurate are Proxy Predictions?" (1991) 115:2 *Ann Intern Med* 92; David Shalowitz,

suspect that there is an even lesser likelihood that substitute decisions about research will reflect prior capable wishes.²¹¹ One response to this would be to strictly prohibit research involving persons who are incapable of consent, unless perhaps it can be established that the research offers subjects a likely health benefit,²¹² or unless the wish to be included in research is clearly indicated in an advance directive. The alternative response would require attending carefully to the adequacy of additional safeguards beyond third party authorization, including standards and practices of capacity assessment and thresholds of maximal risk, in addition to considering protective mechanisms not yet existing in Canada, such as independent advocates responsible both for advising LARs and for ongoing oversight of research.²¹³

A final point for policy consideration returns us to our earlier arguments (raised in connection with the distinction between research and treatment) on the merits of legislation that clearly addresses whether, and on what conditions, an LAR may make a substitute decision about research. Such legislation could, for example, stipulate the sort of information that must be disclosed by researchers and considered by the LAR where authorization of research is in issue. This might include information about aspects of the research that serve investigative purposes exclusively, information about how the risks and foreseeable benefits of the proposed research compare with those of available non-research-based therapies, and information about any conflicts of interest.²¹⁴ Arguably, such disclosures are essential to counteracting the therapeutic misconception and thereby promoting both the validity of third party authorization and the protection of prospective research subjects who lack decisional capacity.

These closing remarks take us beyond the confines of our study to future inquiry into this area of law and policy. Indeed, this study has touched on just

Elizabeth Garrett-Mayer & David Wendler, "The Accuracy of Surrogate Decision Makers: A Systematic Review" (2006) 166:5 *Arch Intern Med* 493.

²¹¹ Coleman, *supra* note 4 at 767.

²¹² See Lewis, *supra* note 43.

²¹³ Stefan Eriksson, "On the Need for Improved Protections of Incapacitated and Non-Benefiting Research Subjects" (2010) 24:7 *Bioethics* 1 at 6.

²¹⁴ On disclosure of conflicts of interest as a condition precedent to informed consent to participation in research, see Hadskis, *supra* note 2 at 493-95, discussing imperatives stated in Chapter 7 of the *TCPS2* in respect to researcher disclosure of conflicts of interest to REBs. Hadskis notes that among the possible dispositions that an REB may arrive at on identifying a conflict of interest is a requirement that the researcher "disclose this conflict to potential participants during the consent process" (at 495).

one piece of the research regulation puzzle: the question of who, if anyone, is authorized to make a substitute decision about health research, and how various stakeholders answer that question. Numerous additional legal and ethical concerns flow from the prospect of health research involving persons who are deemed legally incapable of consent. These range from the legal standards in light of which this capacity should be assessed, to the institutional and interpersonal practices relevant to supporting this capacity, to the means of discerning assent and dissent, to the risk-benefit thresholds to serve as conditions precedent to third party authorization, to the factors that should be disclosed to and taken into account by third party decision makers. All of these matters must continue to inspire ethical and legal inquiry, and moreover, should be pursued within the public sphere as urgent questions for collective deliberation and debate.

Appendix

I. SCORES Vignettes - Research Participation

What follows is the section of the SCORES questionnaire aimed at assessing respondents' understanding of who, if anyone, has legal authority to make a decision about an adult's participation in research. The research-related vignettes numbered 1–4 below (and in the text of our discussion) were numbered 4–7 in the questionnaire. The vignettes numbered 1–3 in the questionnaire concerned authority to make a decision about health treatment.

It is important to know that treatment vignette 3, which immediately preceded the first research vignette—and which concerned authorization to consent to or refuse a recommended hip replacement—introduced the characters of “Mrs. Bristol” and “Jacob.” In treatment vignette 3, Jacob was characterized as Mrs. Bristol's “only child,” whom she went to live with after her husband died. That vignette further stated that Mrs. Bristol “never selected a substitute decision maker while she was fully capable of making decisions,” and that “she has not been assigned a guardian by a court.”

From the SCORES Questionnaire

In this first section, we describe hypothetical situations involving an older adult who requires health care or is eligible to participate in a study. Please assume that all characters are adults, that each study has been approved by a recognized research ethics board, that all those legally authorized to give consent are willing and available, and that the risks and potential benefits are as stated. These risks and potential benefits may be psychological and social as well as physical.

Please read each vignette carefully and answer to the best of your knowledge according to the law in your province.

Research Vignettes	
1	<p>The hip replacement was successful and Mrs. Bristol is back at Jacob's home. A researcher is conducting a study to see if classical music relieves anxiety in Alzheimer patients. There is little risk and potentially some benefit to the participants. Mrs. Bristol is not capable of deciding whether to participate in the study.</p> <p>In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mrs. Bristol in the study?<i>(Check ALL the answers you think are correct)</i></p> <p>A. Mrs. Bristol herself B. Her son Jacob C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know</p>
2	<p>A court has granted guardianship of Mrs. Bristol to her son Jacob. He is now authorized to make all decisions regarding his mother's personal and health care. The guardianship order does not specifically address research. Jacob receives a call from a researcher who would like Mrs. Bristol to participate in a study. The study will test a new diet that might prevent weight loss in people with Alzheimer's disease. There is little risk and potentially some benefit to the participants.</p> <p>In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mrs. Bristol in the study?<i>(Check ALL the answers you think are correct)</i></p> <p>A. Mrs. Bristol herself B. Her son Jacob C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know</p>
3	<p>Mr. Johnson has lived in a nursing home since he was diagnosed with moderate dementia a year ago. Mrs. Johnson visits her husband every day. Many years before losing decision-making capacity, Mr. Johnson</p>

	<p>wrote a legally-binding document in which he identified his wife as the person who should make health-care decisions on his behalf if he were no longer able to do so himself. In this document, he did not make his wishes known in regard to participation in research.</p> <p>A researcher is testing a new pill that might slow memory loss due to dementia. This pill must be taken daily for 3 months. Its main side effect is a tendency to cause minor reversible liver problems. The study involves some risks to the participants but also potential benefits for them personally that outweigh the risks. Mr. Johnson is not capable of deciding whether to participate in the study.</p> <p>In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mr. Johnson in the study? (<i>Check ALL the answers you think are correct</i>)</p> <ul style="list-style-type: none"> A. Mr. Johnson himself B. His wife C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know
4	<p>Two years later, Mr. Johnson is deemed a good candidate for a study about the quality of life of nursing home residents. The study involves observing residents as they go about their daily routines. Mrs. Johnson is assured that the study involves little risk to her husband. It will not benefit him personally but might benefit future residents. Mr. Johnson is not capable of deciding whether to participate in this study.</p> <p>In your province, who is <u>legally</u> authorized to consent to or refuse an offer to involve Mr. Johnson in the study? (<i>Check ALL the answers you think are correct</i>)</p> <ul style="list-style-type: none"> A. Mr. Johnson himself B. His wife C. The researcher D. Other, please specify: _____ E. No one has clear legal authority F. I don't know

II. Correct, Best and Alternative Responses

Where there are best and alternative responses, the alternative response is given in italics in parentheses.

Table 4. The Correct, Best, and Alternative Responses to Each Scenario

Research scenario	BC	Alberta	Nova Scotia	Ontario
1. No court-appointed guardian, no advance directive. Research involves potential direct benefit, little risk.	B	E	E	E (<i>B</i>)
2. Court-appointed guardian. Research involves potential direct benefit, little risk.	B	E (<i>B</i>)	E (<i>B</i>)	E (<i>B</i>)
3. Advance directive addressing health care but not research. Research involves some risk but outweighed by potential direct benefit.	B	B (<i>E</i>)	E (<i>B</i>)	E (<i>B</i>)
4. No-direct-benefit research, no guardian.	B (<i>E</i>)	E	E	E

The McGill Journal of Law and Health wishes to acknowledge the support of the following individuals and organizations:

Fasken Martineau DuMoulin LLP
Law Students' Association, McGill University
Professor Angela Campbell, Faculty of Law, McGill University
Rx&D – Canada's Researched-Based Pharmaceutical Companies

La Revue de droit et santé de McGill remercie les individus et les organisations suivants pour leur soutien :

Association des étudiants en droit, Université McGill
Fasken Martineau DuMoulin, S.E.N.C.R.L.
Professeure Angela Campbell, Faculté de droit, Université McGill
Rx&D – Les compagnies de recherche pharmaceutique du Canada