

A REFLECTION ON THE DUTY TO WARN AFTER LÉTOURNEAU v JTI-MACDONALD: A FUTURE FOR OBESITY LITIGATION IN CANADA?

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Diet-related chronic diseases are on the rise in Canada and obesity is leading the charge. Over 60% of Canadian adults and one third of Canadian children are either overweight or obese. In 2011, it was estimated that the economic cost of obesity in Canada ranged from \$4.6 billion to \$7.1 billion annually. A “maze of policy incoherence” has resulted in a failure to identify strategies to significantly reduce the rates of obesity, with most proposals focused on state-centred solutions like the taxation of sugar-sweetened beverages or mandatory labelling. . But there have also been calls for private law interventions, most commonly, tort litigation. While some scholars argue that tort litigation is an inappropriate public health strategy, others point to tobacco litigation as a model template. Indeed, obesity has been depicted as “the next tobacco” and as the “next big thing” for litigators. In light of this claim, this article

Les maladies chroniques liées à l'alimentation sont en hausse au Canada et l'obésité mène la charge. Plus de 60 % des adultes canadiens et un tiers des enfants canadiens font de l'embonpoint ou sont obèses. En 2011, on a estimé que le coût économique de l'obésité au Canada se situait entre 4,6 et 7,1 milliards de dollars par an. Un « dédale d'incohérences politiques » a empêché d'identifier des stratégies permettant de réduire de manière significative les taux d'obésité, la plupart des propositions étant axées sur des solutions centrées sur l'État, comme la taxation des boissons sucrées ou l'étiquetage obligatoire. Mais des appels ont également été lancés en faveur d'interventions de droit privé, le plus souvent des litiges en matière de responsabilité civile. Alors que certains chercheurs affirment que le litige en responsabilité civile est une stratégie de santé publique inappropriée, d'autres soulèvent le litige en matière

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considers what lessons might be drawn from the Canadian tobacco litigation experience. In particular, it considers how the recent duty to warn case out of Québec, *Létourneau v JTI-MacDonald* (Létourneau), might shape a future for obesity litigation in Canada. It argues that Létourneau affirms the standard set out in *Buchan v Ortho Pharmaceutical*, which imposed a positive duty on manufacturers to proactively identify potential risks and harms and sets out criteria for assessing when a warning is sufficiently adequate to facilitate meaningful consumer choice.

de tabac comme un modèle exemplaire. En effet, l'obésité a été décrite comme « le prochain tabac » et comme « la prochaine grande opportunité » pour les avocats plaidants. À la lumière de cette affirmation, cet article examine les leçons que l'on peut tirer de l'expérience canadienne en matière de litiges liés au tabac. En particulier, il examine comment la récente affaire *Létourneau c JTI-MacDonald* (Létourneau), sur l'obligation d'informer au Québec, pourrait façonner l'avenir des litiges relatifs à l'obésité au Canada. Il soutient que l'affaire *Létourneau* confirme la norme établie dans l'affaire *Buchan c. Ortho Pharmaceutical*, qui a imposé aux fabricants une obligation positive d'identifier de manière proactive les risques et les préjudices potentiels et a établi des critères pour évaluer si un avertissement est suffisamment adéquat pour faciliter un choix véritable pour le consommateur.

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INTRODUCTION

It is widely recognized that diet-related chronic diseases are on the rise, and obesity is leading the charge.¹ Obesity is projected to surpass tobacco use as the leading cause of preventable deaths globally.² In 2014, Dr Ng and colleagues estimated that 2.1 billion people were overweight, more than double the worldwide prevalence of 1980,³ and the World Health Organization indicated that over 650 million adults were obese.⁴ The situation has been described as “a tsunami of obesity that will eventually affect all regions of the world.”⁵ Canada has already been affected. Over 60% of Canadian adults and one third of Canadian children are either overweight or obese,⁶ of which one in four adults and one in ten children are clinically obese.⁷ In 2011, it was estimated that the economic cost of obesity in Canada ranged

¹ See E Amine et al, *Diet, Nutrition and the Prevention of Chronic Diseases: Report of a Joint WHO/FAO Expert Consultation on Diet* (Geneva: World Health Organization, 2002) at 4–6.

² See generally Charles H Hennekens & Felicita Andreotti, “Leading Avoidable Cause of Premature Deaths Worldwide: Case for Obesity” (2013) 126:2 *Am J Med* 97.

³ See Marie Ng et al, “Global, Regional, and National Prevalence of Overweight and Obesity in Children and Adults During 1980–2013: A Systematic Analysis for the Global Burden of Disease Study 2013” (2014) 384 *Lancet* 766 at 770.

⁴ “Obesity and Overweight” (1 April 2020), online: *World Health Organization* <www.who.int/mediacentre/factsheets/fs311/en/>.

⁵ Sonia S Anand & Salim Yusuf, “Stemming the Global Tsunami of Cardiovascular Disease” (2011) 377 *Lancet Public Health* 529 at 529.

⁶ See Standing Senate Committee on Social Affairs, Science and Technology, *Obesity in Canada: A Whole-of-Society Approach for a Healthier Canada* (Ottawa: Government of Canada, 2016) at iv, 1; *Obesity in Canada: A Joint Report from the Public Health Agency of Canada and the Canadian Institute for Health Information* (Ottawa: PHAC & CIHI, 2011) at 4, online (pdf): <www.phac-aspc.gc.ca/hp-ps/hl-mvs/oic-oac/assets/pdf/oic-oac-eng.pdf> [perma.cc/7F5F-LMTN] [PHAC & CIHI].

⁷ According to the Canadian Obesity Network, “clinically obese” suggests that these individuals may “require immediate support in managing and controlling their weight”: see “Obesity in Canada” (6 June 2017), online: *Canadian Obesity Network* <www.obesitynetwork.ca/obesity-in-canada> [perma.cc/V82M-F4MC].

from \$4.6 billion to \$7.1 billion annually.⁸ There is also a high social cost associated with obesity,⁹ particularly for obese individuals who face high rates of discrimination and bias.¹⁰

It is thus unsurprising that there have been calls for multifaceted policies and interventions to address obesity. However, to date there is insufficient evidence that identified strategies will significantly reduce rates of obesity.¹¹ Instead, what exists is “a maze of policy incoherence,”¹² where competing policy solutions result in a cacophony of options that serves to confuse policymakers.¹³ As governments, international agencies, and public health organizations grapple with how to address obesity, it has been recognized that some action must be taken in order to prevent the situation from getting worse.¹⁴

⁸ See PHAC & CIHI, *supra* note 6 at 29.

⁹ See e.g. Kelly D Brownell, “The Chronicling of Obesity: Growing Awareness of its Social, Economic, and Political Contexts” (2005) 30:5 J Health Pol Pol’y & L 955.

¹⁰ See Ximena Ramos-Salas, “The Ineffectiveness and Unintended Consequences of the Public Health War on Obesity” (2015) 106:2 Can J Public Health e79 at e80.

¹¹ See Timothy Caulfield & Nola M Ries, “Obesity Policy: The Way Forward” (2014) 22:3 Health L Rev 28 at 28, citing Ng, *supra* note 3. See also Christina A Roberto et al, “Patchy Progress on Obesity Prevention: Emerging Examples, Entrenched Barriers, and New Thinking” (2015) 385 Lancet 2400 at 2400.

¹² Neil Seeman & Patrick Luciani, *XXL: Obesity and the Limits of Shame* (Toronto: University of Toronto Press, 2011) at 64.

¹³ See T Lang & G Rayner, “Overcoming Policy Cacophony on Obesity: An Ecological Public Health Framework for Policymakers” (2007) 8 Obes Rev (Supplement 1) 165 at 166.

¹⁴ See Helen L Walls et al, “Public Health Campaigns and Obesity - A Critique” (2011) 11 BMC Public Health 136 at 4, online: *BioMed Central* <www.biomedcentral.com/1471-2458/11/136> [perma.cc/2TFA-LA3X]. Some suggest that obesity rates have plateaued: see e.g. Nadeem Esmail with Patrick Basham, “Obesity in Canada: Overstated Problems, Misguided Policy Solutions” (2014), online (pdf): *Fraser Institute* <www.fraserinstitute.org/sites/default/files/obesity-in-canada.pdf> [perma.cc/86YH-5HA4]. However, Roberto et al note that the positive changes “mainly stem from a flattening of childhood obesity ... where rates [are] already high” (*supra* note 11 at 2400).

Many scholars and public health officials have called for more drastic uses of domestic and international law to combat obesity.¹⁵ By and large, the vast majority of attention has been given to the role of the state. For example, there have been calls for the taxation of sugar-sweetened beverages,¹⁶

¹⁵ See e.g. 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 [Ries & von Tigerstrom, “Legal Interventions”]; Nola M Ries, “Piling on the Laws, Shedding the Pounds? The Use of Legal Tools to Address Obesity” (2008) Health LJ 101 at 126 [Ries, “Piling on the Laws”]; Michelle Mello, “Legal and Policy Approaches to the Obesity Epidemic” (2012) 8:5 Surg Obes Relat Dis 507; Jennifer L Pomeranz et al, “Innovative Legal Approaches to Address Obesity” (2009) 87:1 Milbank Q 185 at 206–07; James G Hodge Jr, Andrea M Garcia & Supriya Shah, “Legal Themes Concerning Obesity Regulation in the United States: Theory and Practice” (2008) 5 Aust New Zealand Health Policy; Robyn Martin, “The Role of Law in the Control of Obesity in England: Looking at the Contribution of Law to a Healthy Food Culture” (2008) 5 Aust New Zealand Health Policy; Boyd A Swinburn, “Obesity Prevention: The Role of Policies, Laws and Regulations” (2008) 5 Aust New Zealand Health Policy; Lawrence O Gostin, “Law as a Tool to Facilitate Healthier Lifestyles and Prevent Obesity” (2007) 297:1 JAMA 87 at 88; Roger S Magnusson, “What’s Law Got To Do With It? Part I: A Framework for Obesity Prevention” (2008) 5 Aust New Zealand Health Policy; Roger S Magnusson, “What’s Law Got to Do With It? Part II: Legal Strategies for Healthier Nutrition and Obesity Prevention” (2008) 5 Aust New Zealand Health Policy; Jess Alderman et al, “Application of Law to the Childhood Obesity Epidemic” (2007) 35:1 JL Med & Ethics 90; Edward P Richards et al, “Innovative Legal Tools to Prevent Obesity” (2004) 32:4 JL Med & Ethics (Special Supplement) 59; Richard A Daynard, “Legal Approaches to the Obesity Epidemic” (2003) 13:5 CP Rev 154.

¹⁶ See Barbara von Tigerstrom, “Taxing Sugar-Sweetened Beverages for Public Health: Legal and Policy Issues in Canada” (2012) 50:1 Alta L Rev 37; Nola M Ries, “Legal and Policy Measures to Promote Healthy Behaviour: Using Incentives and Disincentives to Control Obesity” (2012) 6:1 McGill JL & Health 1 at 17–26; Nicole L Novak & Kelly D Brownell, “Taxation as Prevention and as a Treatment for Obesity: The Case of Sugar-Sweetened Beverages” (2011) 17:12 Curr Pharm Des 1218.

mandatory menu labelling,¹⁷ prohibitions against certain ingredients,¹⁸ and the modification of zoning by-laws to alter food environments.¹⁹ But there have also been calls for private law interventions, most commonly, tort litigation.²⁰ Tort litigation is often presented as part of a broader, multi-faceted strategy that can be used to compliment other regulatory action.²¹

¹⁷ See Barbara von Tigerstrom, "Food Labelling Regulation to Promote Healthy Eating" (2011) 20:1 Health L Rev 18 at 18–19; Barbara von Tigerstrom & Tristan Culham, "Food Labelling for Healthier Eating: Is Front-of-Package Labelling the Answer?" (2009) 33:1 Man LJ 89 at 100; Ries, "Piling on the Laws", *supra* note 15 at 114–17; Jennifer L Pomeranz & Kelly D Brownell, "Legal and Public Health Considerations Affecting the Success, Reach, and Impact of Menu-Labeling Laws" (2008) 98:9 Am J Public Health 1578.

¹⁸ See Nola M Ries, "Food, Fat and the Law: A Comment on Trans Fat Bans and Public Health" (2007) 23 Windsor Rev Legal Soc Issues 15.

¹⁹ See Marice Ashe et al, "Land Use Laws and Access to Tobacco, Alcohol, and Fast Food" (2007) 35:4 JL Med & Ethics (Special Supplement) 60 at 60; Julie Samia Mair, Matthew W Pierce & Stephen P Teret, "The Use of Zoning to Restrict Fast Food Outlets: A Potential Strategy to Combat Obesity" (October 2005), online (pdf): *The Centers for Law and the Public's Health* <www.publichealthlaw.net/Zoning%20Fast%20Food%20Outlets.pdf> [perma.cc/GNE2-KNZY].

²⁰ See Richard A Daynard, P Tim Howard & Cara L Wilking, "Private Enforcement: Litigation as a Tool to Prevent Obesity" (2004) 25:3 J Public Health Policy 408; Michelle M Mello, Eric B Rimm & David M Studdert, "The Mc-Lawsuit: The Fast-Food Industry and Legal Accountability for Obesity" (2003) 22:6 Health Aff 207 at 212; Jeremy H Rogers, "Living on the Fat of the Land: How to Have Your Burger and Sue it Too" (2003) 81:3 Wash ULQ 859; Ashley B Antler, "The Role of Litigation in Combating Obesity Among Poor Urban Minority Youth: A Critical Analysis of *Pelman v McDonald's Corp*" (2009) 15:2 Cardozo JL & Gender 275; Jason A Smith, "Setting the Stage for Public Health: The Role of Litigation in Controlling Obesity" (2006) 28:3 U Ark Little Rock L Rev 443.

²¹ For example, Gostin identifies tort law as "a strategy complementary to direct regulation," in situations "[w]here direct regulation through the political process fails": Lawrence Gostin, *Public Health Law: Power, Duty, Restraint*, 2nd ed (New York: Milbank Memorial Fund, 2008) at 202. See also WE Parmet & RA Daynard, "The New Public Health Litigation" (2000) 21 Annu Rev Public Health 437; Peter D Jacobson & Soheil Soliman, "Litigation as Public Health Policy: Theory or Reality?" (2002) 30:2 JL Med & Ethics 224; Wendy E Parmet, "Tobacco, HIV, and the Courtroom: The Role of Affirmative Litigation in the Formation of Public Health Policy" (1999) 36:5 Hous L Rev 1663; Peter D

The use of tort litigation to advance public health is not without controversy.²² For example, some scholars argue that litigation is an unjustified and inappropriate solution for addressing public health problems such as obesity²³ and that, at best, the gains promised through litigation are “unsubstantiated and speculative.”²⁴ Nevertheless, many contend that obesity litigation holds some promise, particularly given the perceived success of tobacco litigation.²⁵ While it is beyond the scope of this paper to thoroughly

Jacobson & Kenneth E Warner, “Litigation and Public Health Policy Making: The Case of Tobacco Control” (1999) 24:4 *J Health Pol Pol’y* L 769; Timothy D Lytton, “Using Litigation to Make Public Health Policy: Theoretical and Empirical Challenges in Assessing Product Liability, Tobacco, and Gun Litigation” (2004) 32:4 *JL Med & Ethics* 556.

²² See Roger Brownsword, “Public Health, Private Right, and the Common Law” (2006) 120 *Public Health* (Supplement 1) 42. See also Jacobson & Soliman, *supra* note 21; Arthur B LaFrance, “Tobacco Litigation: Smoke, Mirrors and Public Policy” (2000) 26 *Am J L & Med* 187.

²³ See Theodore H Frank, “A Taxonomy of Obesity Litigation” (2006) 28:3 *U Ark Little Rock L Rev* 427 at 429; Joseph P McMenamin & Andrea D Tiglio, “Not the Next Tobacco: Defenses to Obesity Claims” (2006) 61:3 *Food & Drug LJ* 445; Sarah Taylor Roller, Theodore Voorhees Jr & Ashley K Lunkenheimer, “Obesity, Food Marketing and Consumer Litigation: Threat or Opportunity?” (2006) 61:3 *Food & Drug LJ* 419; Richard C Ausness, “Tell Me What You Eat, and I Will Tell You Whom to Sue: Big Trouble Ahead for ‘Big Food’?” (2005) 39 *Ga L Rev* 839 at 843.

²⁴ Roller, Voorhees & Lunkenheimer, *supra* note 23 at 429. Even those supportive of the use of law to address obesity consider litigation a “wild card”: WA Bogart, “Law as a Tool in ‘The War on Obesity’: Useful Interventions, Maybe, But, First, What’s the Problem?” 2013 41:1 *JL Med & Ethics* 28 at 35.

²⁵ See e.g. Jada J Fehn, “The Assault on Bad Food: Tobacco-Style Litigation as an Element of the Comprehensive Scheme to Fight Obesity” (2012) 67:1 *Food & Drug LJ* 65 at 66–67; Richard A Daynard, “Lessons from Tobacco Control for the Obesity Control Movement” (2003) 24:3–4 *J Public Health Policy* 291 at 294; Jess Alderman & Richard A Daynard, “Applying Lessons from Tobacco Litigation to Obesity Lawsuits” (2006) 30:1 *Am J Prev Med* 82; Brooke Courtney, “Is Obesity *Really* the Next Tobacco? Lessons Learned from Tobacco for Obesity Litigation” (2006) 15:1 *Ann Health L* 61; Kelly D Brownell & Kenneth E Warner, “The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar is Big Food?” (2009) 87:1 *Milbank Q* 259 at 266–267, 286; John J Zefutue Jr, “From Butts to Big Macs—Can the Big Tobacco Litigation and Nation-Wide Settlement with States’ Attorneys General Serve as a Model for Attacking the Fast Food Industry?” (2004) 34:4 *Seton Hall L Rev*

review tobacco litigation,²⁶ obesity has been depicted as “the next tobacco”²⁷ and as the “next big thing” for litigators.²⁸ In light of this claim, this article considers what lessons might be drawn from the Canadian tobacco litigation experience. In particular, it considers whether the recent duty to warn case out of Québec, *Létourneau v JTI-MacDonald*²⁹ (*Létourneau*), might signal a future for obesity litigation in Canada.

This article proceeds in five parts. Part one provides an introduction to the duty to warn. This will be followed in part two with a review of *Buchan v Ortho Pharmaceutical*³⁰ (*Buchan*), a leading case from the Ontario Court

1383; Jonathan S Goldman, “Take That Tobacco Settlement and Super-Size It!: The Deep-Frying of the Fast Food Industry?” (2003) 13 Temp Pol & Civ Rts L Rev 113.

²⁶ For a review of tobacco litigation see Stephen E Smith, “‘Counterblasts’ to Tobacco: Five Decades of North American Tobacco Litigation” (2002) 14:1 Windsor Rev Legal Soc Issues 1; Robert L Rabin, “The Tobacco Litigation: A Tentative Assessment” (2001) 51:2 DePaul L Rev 331; LaFrance, *supra* note 22; Victor Han, “The History of Tobacco Litigation” (1988) Burson-Marsteller Position Paper, online: <www.industrydocuments.library.ucsf.edu/tobacco/docs/kpvm0105> [perma.cc/2NE2-ELZ5]; Martha A Derthick, *Up in Smoke: From Legislation to Litigation in Tobacco Politics*, 3rd ed (Washington, DC: CQ Press, 2012). For a discussion of tobacco control in Canada, see Barbara von Tigerstrom, “Tobacco Control and the Law in Canada” in Tracey M Bailey, Timothy Caulfield & Nola M Ries, eds, *Public Health Law & Policy in Canada*, 3rd ed (Markham, ON: LexisNexis, 2013) 323 [von Tigerstrom, “Tobacco Control”].

²⁷ Brownell & Warner, *supra* note 25. See also Joanna Blythman, “The New Tobacco” (2004) 34:9 Ecologist 17; Sarah Avery, “Is Big Fat the Next Big Tobacco?” *The News & Observer* (18 August 2002) A25; Shelley Branch, “Obese America: Is Food the Next Tobacco?” *Wall Street Journal* (13 June 2002) B1; Lee J Munger, “Is Ronald McDonald the Next Joe Camel? Regulating Fast Food Advertisements Targeting Children in Light of the American Overweight and Obesity Epidemic” (2004) 3:2 Conn Pub Intl LJ 456.

²⁸ Andrew M Dansicker, “The Next Big Thing for Litigators” (2004) 37:4 Maryland Bar J 12 at 14. See also Franklin E Crawford, “Fit for Its Ordinary Purpose? Tobacco, Fast Food, and the Implied Warranty of Merchantability” (2002) 63 Ohio St LJ 1165 (“[t]he history of tobacco litigation is the future of the fast food industry” at 1169).

²⁹ 2015 QCCS 2382 [*Létourneau*], *aff’d* 2019 QCCA 358.

³⁰ [1986] 25 DLR (4th) 658, 35 CCLT 1 (ONCA) [*Buchan* cited to DLR].

of Appeal on the adequacy of warnings. *Buchan*, which was affirmed by the Supreme Court of Canada in *Hollis v Dow Corning Corp*³¹, clearly articulates that manufacturers have a positive duty to proactively identify potential risks and harms, and sets out specific criteria for assessing when a warning is sufficiently adequate to facilitate meaningful consumer choice.³² This is discussed as the “*Buchan* standard”. Part three then examines the history of tobacco litigation in Canada prior to *Létourneau*. With this backdrop, part four considers how Justice Riordan of the Superior Court of Québec addressed the adequacy of the warnings provided by tobacco companies in *Létourneau*. The focus of this paper is on Justice Riordan’s decision, although it does consider the Court of Appeal of Québec’s decision. Part five concludes by considering what the decision in *Létourneau* might mean for the future of obesity litigation in Canada. This article will argue that *Létourneau* affirms the standard set out in *Buchan* in concrete terms by assessing the actions of the defendant tobacco companies. It raises important questions about how this standard of adequacy of warning might be applied in future duty to warn cases, and what it might mean for obesity litigation.³³

I. THE DUTY TO WARN

When discussing obesity litigation, the example that comes to mind for most people is the infamous “McLawsuit,”³⁴ *Pelman v McDonald’s Corp*³⁵ (*Pelman*). *Pelman* was a suit brought in New York by two teenagers who claimed that eating at McDonald’s had caused them to become obese. Despite ultimately rejecting the plaintiff’s claim that McDonald’s owed a duty

³¹ [1995] 4 SCR 634 at para 47, 129 DLR (4th) 609 [*Hollis*].

³² *Buchan*, *supra* note 30 at para 18.

³³ *Létourneau* adds to this jurisprudence in several respects. Given the multitude of issues that Justice Riordan considered in his judgment – and the length of his judgment, which is 1253 paragraphs – it is not possible to review all aspects of *Létourneau* that are relevant for the duty to warn. This article will focus on a specific aspect of the judgment – namely, the adequacy of the warnings provided by the tobacco companies. Similarly, the Court of Appeal decision goes beyond consideration of the duty to warn – and is itself a lengthy case, at 1285 paragraphs. For the purposes of this article, the focus is on the discussion about the duty to warn.

³⁴ Mello, Rimm & Studdert, *supra* note 20.

³⁵ 237 F Supp 2d 512 (SDNY 2003) [*Pelman*].

to warn about the dangers inherent in its products,³⁶ in a “highly unusual move,”³⁷ Judge Sweet suggested how the plaintiffs might amend their claim in his decision to grant McDonald’s motion to strike. He suggested the plaintiffs could allege that McDonald’s foods were so unhealthy that either they would fall outside of the reasonable expectations of consumers, for example by being highly processed, or they would be dangerous in their intended use. Speaking to the first, Judge Sweet observed, “[i]f plaintiffs were able to flesh out this argument in an amended complaint, it may establish that the dangers of [McDonald’s] products were not commonly well known and thus that [McDonald’s] had a duty to customers.”³⁸ The plaintiffs did not heed Judge Sweet’s advice, and never raised these arguments.³⁹ Judge Sweet ultimately dismissed the plaintiff’s amended claim, observing that he had “laid out in some detail the elements that a properly pleaded complaint would need to contain” and that the plaintiffs had simply failed to follow his guidance.⁴⁰ While the case did find some traction at the Second Circuit of

³⁶ Judge Sweet notes that the plaintiffs failed to establish that the dangers in McDonald’s products went beyond that which was “open and obvious” to a reasonable consumer (see *ibid* at 541).

³⁷ Matthew T Salzmann, “More Than a Fat Chance For Lard Litigation: The Viability of State Medicaid Reimbursement Actions” (2004) 56:4 Rutgers L Rev 1039 at 1052. It is commonly asserted that Judge Sweet essentially laid out a “roadmap” for the amended claim. See Alyse Meislik, “Weighing in on the Scales of Justice: The Obesity Epidemic and Litigation Against the Food Industry” (2004) 46:4 Ariz L Rev 781 at 793; Forrest Lee Andrews, “Small Bites: Obesity Lawsuits Prepare to Take on the Fast Food Industry” (2004) 15 Alb LJ Sci & Tech 153 (“the *Pelman* opinion set forth the framework for a potentially successful claim” at 175).

³⁸ *Pelman*, *supra* note 35 at 536. Judge Sweet describes Chicken McNuggets™ as a “McFrankenstein” creation that an individual would not recreate at home, and observes: “[i]t is at least a question of fact as to whether a reasonable consumer would know – without recourse to the [McDonald’s] website – that a Chicken McNugget contained so many ingredients other than chicken and provided twice the fat of a hamburger” (*Pelman*, *supra* note 35 at 535).

³⁹ See Caleb E Mason, “Doctrinal Considerations for Fast-Food Obesity Suits” (2004) 40:1 Tort Trial & Ins Prac LJ 75 at 81; William B Werner, Andrew Hale Feinstein & Christian E Hardigree, “The Risk to the American Fast-Food Industry of Obesity Litigation” (2007) 48:2 Cornell Hotel & Restaurant Administration Q 201 at 203.

⁴⁰ *Pelman v McDonald’s Corp*, 2003 WL 22052778 at 14, 2003 US Dist LEXIS 15202 (SDNY 2003).

the Court of Appeals,⁴¹ ultimately the trial “ended with a whimper”⁴² when the court refused to certify the class action in 2010.⁴³ Despite the court’s rejection of the plaintiffs’ claim in *Pelman*, the court seemed to identify the duty to warn as a promising avenue to pursue in future obesity litigation.

The duty to warn is an obligation imposed on manufacturers under product liability law.⁴⁴ The “cornerstone” of product liability law is the concept of a defect.⁴⁵ In order for liability to arise, a product must be defective in some way. The Ontario Law Reform Commission suggested that the concept of a defect “cannot be defined except in terms of what it was reasonable to expect of the product in all the circumstances.”⁴⁶ A defect indicates that a

⁴¹ In January 2005, the Second Circuit Court of Appeals surprised many by vacating the dismissal of the case. It remanded the case only for the purpose of considering the plaintiffs’ claims about deceptive advertising. This was not a resounding victory or loss for either side since the court only reversed the dismissal on the grounds that the amended complaint set out the minimal requirements. See *Pelman v McDonald’s Corp*, 396 F (3d) 508 at 511–12 (2nd Cir 2005). The court denied McDonald’s motion to strike the claim, while also striking part of the plaintiff’s claim. See *Pelman v McDonald’s Corp*, 452 F Supp (2d) 320 (SDNY 2006).

⁴² Caroline Forell, “McTorts: The Social and Legal Impact of McDonald’s Role in Tort Suits” (2011) 24:2 Loy Consumer L Rev 101 at 146

⁴³ See *Pelman v McDonald’s Corp*, 272 FRD 82 (SDNY 2010). In 2011, the plaintiffs voluntarily dismissed their suit. See *Pelman v McDonald’s Corp*, 2011 WL 1230712 (SDNY 2011) (stipulation of voluntary dismissal with prejudice), cited in Lawrence O Gostin & Lindsay F Wiley, *Public Health Law: Power, Duty, Restraint* (Oakland: University of California Press, 2016) at 693.

⁴⁴ James Cassels & Craig Jones, *The Law of Large-Scale Claims: Product Liability, Mass Torts, and Complex Litigation in Canada* (Toronto: Irwin Law, 2005) at 1. See also Douglas Harrison, *The Law of Product Warnings and Recalls in Canada* (Markham: LexisNexis, 2013) at 5. Harrison points out, however, that there are other potential claims involving warnings, such as fraudulent misrepresentations.

⁴⁵ Lawrence G Theall et al, *Product Liability: Canadian Law and Practice* (Aurora, ON: Cartwright Group, 2010) at L1-8.

⁴⁶ Ontario Law Reform Commission, *Report on Products Liability* (Ontario: Ministry of the Attorney General, 1979) at 13, cited in *Holt v PPG Industries Canada Ltd* (1983), 25 CCLT 253 at 264, [1983] AJ No 191 (QB).

product is in some way substandard or unreasonably dangerous to a user.⁴⁷ Defects generally fall into one of three categories: defective design, defective manufacturing, and defective warning.⁴⁸

A design is considered defective when a product is unduly dangerous because of the way the manufacturer designed it. Manufacturers have a duty of care when designing a product to “avoid safety risks and to make the product reasonably safe for its intended purposes.”⁴⁹ This obligation includes ensuring that the product’s design is “crashworthy.”⁵⁰ This means that manufacturers need to consider the foreseeable accidents or misuses of their products, and need to adequately test the design to safeguard against known risks.⁵¹ Manufacturing defects are said to occur when a product

⁴⁷ The language of “unreasonably dangerous” is from *Restatement (Second) of Torts* §402A (1965).

⁴⁸ See Cassels & Jones, *supra* note 44 at 32. See also Theall et al, *supra* note 45 at L1-8, who note that there is a fourth category, breach of warranty, which is based on contract law. *Arora v Whirlpool Canada Ltd* also identifies a fourth category: “manufacturers have a duty of care to compensate consumers for the cost of repairing a dangerous product that presents a real and substantial danger” (2012 ONSC 4642 at para 264 [*Arora*]).

⁴⁹ *Goodridge v Pfizer Canada Inc*, 2010 ONSC 1095 at para 81 [*Goodridge*]; *Arora*, *supra* note 48 at para 264.

⁵⁰ *Gallant v Beitz* (1983), 42 OR (2d) 86 at 90, 148 DLR (3d) 52 (Hcj). See also Theall et al, *supra* note 45 at L2-5.

⁵¹ See *LeBlanc v Marson Canada* (1995), 139 NSR (2d) 309 at para 18, [1995] NSJ No 140 (SC). Manufacturers are not expected to be able to forecast all dangers, which would essentially raise the duty to that of an insurer. See *Lem v Barotto Sports Ltd*, [1976] 69 DLR (3d) 276 at 288, 1 CCLT 180 (Alta SC) [*Lem*]. Manufacturers are expected to foresee risks identifiable according to the “state of the art” at the time of the design. For a further discussion about “state of the art”, see Dean F Edgell, *Product Liability Law in Canada* (Toronto: Butterworths, 2000) at 27–30; Theall et al, *supra* note 45 at L6-12–L6-14. Waddams suggests medical drugs are a good example of how this can apply: “A drug thought by everyone to be safe may turn out to be dangerous, but at the time of manufacture and distribution it may be that the best medical opinion could not have foreseen the danger. In such a case there would be no defence in a strict liability jurisdiction, but there might be a defence in a jurisdiction that requires proof of negligence” (Stephen Waddams, *Products Liability*, 5th ed (Toronto: Carswell, 2011) at 74).

“fail[s] to conform to their intended ... specifications.”⁵² Such is the case when a foreign object is found in a food product.⁵³ Of these two categories, design defects carry the greater liability risk⁵⁴ while manufacturing defects are more likely to occur.⁵⁵

⁵² Cassels & Jones, *supra* note 45 at 32. See also *Donoghue v Stevenson*, [1932] UKHL 100, [1932] AC 562 at 595 [*Donoghue*]; *Arora*, *supra* note 49 at para 264 and *Goodridge*, *supra* note 50 at para 81.

⁵³ There are numerous Canadian cases on point. For example, there have been cases dealing with a fly in a water bottle (*Mustapha v Culligan of Canada Ltd*, 2008 SCC 27), a dead mouse in a coke bottle (*Mathews v Coca-Cola Company of Canada Ltd*, 2 DLR 355 at 356, [1944] OR 207 (CA)), maggots in chocolate biscuits (*Farmer v Interbake Foods Ltd* (1981), 49 NSR (2d) 111 at 112, 12 ACWS (2d) 392 (SC(TD))), a piece of a hypodermic needle in a flank steak (*Kean v Sobey's Inc* (1997), Nfld & PEIR 27 at 28, ACWS (3d) 23 (Nfld SC(TD))), and shards of glass found in chocolate milk (*Shandloff v City Dairy Ltd*, [1936] 4 DLR 712 at 712–13, [1936] OR 579 [*Shandloff*]), bread (*Arendale v Canada Bread Co Ltd*, [1941] 2 DLR 41 at 42, [1941] OWN 69, (CA) [*Arendale*]), and a soft drink (*Zeppa v Coca-Cola Limited*, [1955] OR 855 at 859, 1955 CanLII 160 (CA) [*Zeppa*]). These are not the only type of manufacturing defect cases that involve food products. See e.g. *Mayburry v Ontario (Liquor Control Board)*, [2001] OJ No 1494 (QL) at para 2, [2001] OTC 271 (Sup Ct), *aff'd* 163 OAC 192, 2002 CanLII 53276 (in which the court held a manufacturer liable for damages that arose when a bottle of alcohol exploded, and glass fragments injured the plaintiff).

⁵⁴ See *Goodridge*, *supra* note 49 (“[l]iability for a blameworthy design has greater scope than the liability for a defective product because a defective product may be a single aberration, but a design defect extends to all of the products manufactured with that chosen design” at para 87).

⁵⁵ When a manufacturing defect does occur, “the inference of negligence is practically irresistible” (*McMorran v Dominion Stores Ltd* (1976), [1977] 74 DLR 186 at 191, 14 OR (2d) 559). See also *Goodridge*, *supra* note 49 at para 82; *Arendale*:

[W]hen one manufactures for human consumption, any article, fluid or solid, he putting it on the market gives an implied warranty that it contains no deleterious substance; and that if the ultimate consumer is injured by the presence of such deleterious substance he is entitled to damages unless the manufacturer proves that it was there introduced by some agency, other than his own – in other words he must prove that this deleterious article did not obtain entrance through his act or negligence but that of some other. The onus is on the manufacturer so to prove (*supra* note 54 at 41).

The final category, defective warning, is a relatively new area of tort law – at least as presently understood.⁵⁶ The basic underlying rationale for the duty to warn is that consumers rely on manufacturers to provide accurate information about the risks inherent in the use of their products.⁵⁷ As Justice La Forest held in *Hollis*, “[t]he duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.”⁵⁸ The duty exists to overcome knowledge disparities in the “relationship of reliance” between manufacturer and consumers.⁵⁹ Given that manufacturers have a self-interest in promoting their products, they may exaggerate the benefits or not disclose the risks associated with the use of the product.⁶⁰ Requiring warnings alerts consumers to the risks associated with using a product, allowing them to make informed choices. When an adequate warning is provided, it acts as a bar to recovery for the risks a consumer knowingly takes.⁶¹ A defective warning occurs when a manufacturer has knowledge, or ought to have knowledge, of an inherent danger of a product but fails to provide this information to the consumer.

The leading duty to warn case in Canada is *Lambert v Lastoplex Chemicals Co.*⁶² *Lambert* purchased a fast-drying lacquer sealer that he applied to a parquet floor in his basement. The can of lacquer had three caution notices instructing the use to keep the product away from open flames.⁶³ Despite

⁵⁶ Theall et al, *supra* note 45 at L1-4 point out that *Ross v Dunstall*, [1921] 62 SCR 393, 63 DLR 63 is an early duty to warn case as the court held that the manufacturer had a duty to warn purchasers of the dangers of rifle firing when an unlocked bolt appeared to be locked.

⁵⁷ See *Hollis*, *supra* note 31 at para 21.

⁵⁸ *Ibid* at para 21.

⁵⁹ See *ibid*.

⁶⁰ See *ibid* at para 46.

⁶¹ As Cassels & Jones, *supra* note 45 at 48, have written, “The essence of the duty to warn is the concept of an individual’s responsibility for his or her own conduct. Inseparable from the idea of fault-based liability is the idea that one should not be able to recover for a risk knowingly taken”.

⁶² [1972] SCR 569, 25 DLR (3d) 121 [*Lambert* cited to SCR]. *Per Dickson v Broan-NuTone Canada Inc*, [2007] OJ No 5114 (QL) at para 30, 2007 CarswellOnt 9931, “the leading statement on the duty to warn remains ... *Lambert*.”

⁶³ For the court’s assessment of the warnings, see *Lambert*, *supra* note 63 at 573.

these warnings, *Lambert* did not extinguish the pilot lights on his furnace or water heater. While *Lambert* neared the end of the project, a line of flame advanced across the floor and caused an explosion when it reached the open can of sealer, resulting in property damage and burns to *Lambert*. The Supreme Court of Canada found the manufacturer liable for failing to provide an adequate warning. The Court held there was a duty to provide explicit warnings commensurate with the level of danger that an ordinary consumer would encounter when using the product in the intended way. In this case, the Court unanimously agreed that the three existing warnings lacked the explicitness required.⁶⁴ Moreover, the Court held that manufacturers cannot simply pass on the risk of injury to consumers for dangers that the manufacturer is aware of, even if said injuries arise in the ordinary course of use.⁶⁵ This standard is heightened when a product is intended for human consumption.⁶⁶ The leading case on point is *Hollis*, where the Supreme Court of Canada recognized that products that are ingested, consumed, or placed in the body, necessarily require a high standard of care given that their “great capacity to cause injury to consumers” renders a plaintiff immediately vul-

⁶⁴ See *ibid* (“[a] home owner preparing to use that lacquer sealer could not reasonably be expected to realize by reading the three cautions that the product when applied as directed gives off vapours to such a degree as likely to create a risk of fire from a spark or from a pilot light in another part of the basement area” at 125).

⁶⁵ Specifically, the Court stated:

Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purposes for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer (*ibid* at 124–25).

⁶⁶ See Cassels & Jones, *supra* note 44 at 23. Interestingly, the authors note this high standard exists for “manufacturers of inherently dangerous products or products designed for human consumption.” This suggests that they consider products to be consumed and inherently dangerous products to be equivalent, or at least to impose the same obligation on manufacturers.

nerable.⁶⁷ According to *Hollis*, this heightened expectation for disclosure of risks protects public health and increases consumer choice.⁶⁸

One of the challenges in failure to warn claims is determining what level of knowledge is necessary before a consumer can be said to have voluntarily assumed the risk.⁶⁹ According to *Hollis*, the requirement is for manufacturers to provide consumers with “clear, complete and current” information, and to do so on an ongoing and continuous basis.⁷⁰ Moreover, manufacturers are required to warn consumers about foreseeable misuses of a product.⁷¹ In order for a consumer to have adequate information, a warning needs to be sufficient to substantially reduce the danger level and presented in a manner that a consumer would notice.⁷² While the precise requirements of warnings are made on a case-by-case basis,⁷³ as with general negligence claims, foreseeability of harm is considered a touchstone for determining what constitutes reasonable care. *Lem* held that foreseeability limits liability in duty to warn cases to “dangers that are known or ought reasonably to be known to the manufacturer in the use of his product, which is to say dangers that are reasonably foreseeable.”⁷⁴ At present, the trend is for manufacturers to

⁶⁷ See *Hollis*, *supra* note 31 at para 23. Although *Hollis* specifically contemplates medical products (silicone breast implants), the principle can easily be extrapolated to food products. See Cassels & Jones, *supra* note 44 at 23.

⁶⁸ See *Hollis*, *supra* note 31 at para 26.

⁶⁹ See Cassels & Jones, *supra* note 44 at 49.

⁷⁰ See *Hollis*, *supra* note 31 at para 26.

⁷¹ Manufacturers are required to warn about dangers that “might arise out of reasonably foreseeable fault on the part of the purchaser in its contemplated use” (*Lem*, *supra* note 51 at para 22). See also Cassels & Jones, *supra* note 44 at 50.

⁷² In addition to the case law discussed in this section (e.g. *Lambert*, *supra* note 63), see Jane Stapleton, *Product Liability* (Toronto: Butterworths, 1994) at 253 who points out that a plaintiff should have to prove that “warning was feasible” and “that it would have attracted the attention of a relevant party so that injury could and would have been avoided.”

⁷³ See Alvin S Weinstein et al, *Products Liability and the Reasonably Safe Product: A Guide for Management, Design, and Marketing* (Toronto: John Wiley & Sons, 1978) at 25, stating, “It is the court that must make a threshold decision on whether in any case the danger level and the nature of product use are such that society ought to consider the imposition of safety features.”

⁷⁴ *Lem*, *supra* note 51 at 287. See also *Deshane v Deere & Co*, [1993] 15 OR (3d)

provide warnings.⁷⁵ However, a warning on its own is not sufficient – as *Lambert* clearly demonstrates.⁷⁶ The obligation on manufacturers is to provide adequate warnings. The Ontario Court of Appeal in *Buchan* articulated clear guidance on when a warning will be considered adequate.

II. THE *BUCHAN* STANDARD: ADEQUACY OF WARNINGS

In August 1971, Pauline Buchan was 23 years old when she started taking Ortho-Novum 1/50, a contraceptive pill manufactured and distributed by Ortho Pharmaceutical. On 11 September, after taking the pills for just under six weeks, she suffered a stroke. The stroke left Mrs. Buchan disabled, with paralysis of her left arm and leg, and caused brain damage.⁷⁷ Justice Holland, for the Ontario High Court of Justice, found that there was a “tendency, and a clear association” between oral contraceptive use and stroke, even though the “exact mechanism” remained unknown.⁷⁸ Accepting that only a “small percentage of users will sustain serious complications from taking oral contraceptives,” Justice Holland nevertheless found the oral contraceptives to be dangerous, and that there was thus a “high duty to warn the consumer of the danger.”⁷⁹ Justice Holland found that Mrs. Buchan’s stroke was “caused or materially contributed to by taking oral contraceptives manufactured by Ortho,” that Ortho “was negligent in failing to

225 at 233, [1993] OJ No 2233 (QL) (CA) (the dissenting opinion argued that a manufacturer might have to warn about foreseeable modification of a product).

⁷⁵ Weinstein et al offer an explanation for this trend, noting that “[s]ince warnings are relatively inexpensive and require no major redesigning of the product, the natural tendency of manufacturers is to *warn* against rather than *redesign* against a foreseeable danger” (*supra* note 66 at 40). The authors further clarify that “[w]arnings are an apparently inexpensive mode of dealing with risks that cannot be designed out of a product without adding substantially to its costs or otherwise affecting its utility” (*ibid* at 62).

⁷⁶ *Lambert*, *supra* note 63.

⁷⁷ *Buchan v Ortho Pharmaceutical (Canada) Ltd*, [1984] 8 DLR (4th) 373, [1984] OJ No 3181 (QL) (HCJ), [*Buchan* H Ct J cited to DLR].

⁷⁸ *Ibid* at 382.

⁷⁹ *Ibid* at 386.

warn Mrs. Buchan directly and indirectly,” and that “[t]his failure to warn was causative of Mrs. Buchan’s injuries.”⁸⁰

In his decision, Justice Holland rejected the notion that adherence to the legislative requirements, in this case imposed by the Food and Drugs Act⁸¹, shields the manufacturer from a responsibility to warn consumers directly.⁸² Such legislative requirements, he contended, are minimums.⁸³ Justice Holland also held that warning physicians did not discharge the burden on manufacturers to warn the consumer directly,⁸⁴ although he did recognize that “[a]ctual knowledge of the risks by the doctor would break the chain of causation.”⁸⁵ In this instance, he determined that the manufacturer had not adequately warned the prescribing physician.⁸⁶ As a result, Mrs. Buchan was not adequately warned. Had she been properly warned of the risks, she stated she would not have taken the oral contraceptive, a claim Justice Holland found to be credible.⁸⁷

In reaching this conclusion, Justice Holland applied a subjective test, which was a departure from the objective test used in medical malpractice claims set out prior to *Reibl v Hughes (Reibl)*.⁸⁸ In *Reibl*, the Supreme Court of Canada recommended a modified approach to the reasonable person test, given the barriers that an objective test posed to patients.⁸⁹ Specifically, the Court asked what a reasonable person in the plaintiff’s position would have

⁸⁰ *Ibid* at 410.

⁸¹ RSC 1970, c F-27.

⁸² See *Buchan* H Ct J, *supra* note 78, at 393–95. Specifically, at 395, Justice Holland held, “The Act does not ... replace the common law duty to warn.”

⁸³ See *ibid* at 397.

⁸⁴ See *ibid* at 393.

⁸⁵ *Ibid* at 407.

⁸⁶ See *ibid* at 400.

⁸⁷ See *ibid* at 401–04. Justice Holland thought Mrs. *Buchan* to be credible and refers to her testimony that she avoids risky behaviours and was careful about her health, which led her to avoid harmful things such as smoking, at 404.

⁸⁸ *Ibid* at para 404–05, citing *Reibl v Hughes*, [1980] 2 SCR 880 at 898–99, 114 DLR (3d) 1 [*Reibl*].

⁸⁹ See *Reibl*, *supra* note 89 at 898.

done. According to Justice Holland, however, there is a distinct difference between medical malpractice and product liability suits. Whereas patients will generally follow the advice of his or her doctor, there is no “intimate relationship between the manufacturer and the ultimate consumer.”⁹⁰ Because the consumer is capable of making a fully informed decision, they have a right to be informed of all the risks.⁹¹ Justice Holland contended that if the *Reibl* test were to be applied, this would require the plaintiff to determine what a reasonable person in the plaintiff’s situation would have done. Not only would this impose on the plaintiff “a difficult evidentiary burden,” it would “render the duty to warn meaningless.”⁹² Instead, the court held that the proper test should ask whether “a reasonable person in the plaintiff’s particular position, if fully informed, would not have taken the drug.”⁹³

Ortho appealed the decision on all these points.⁹⁴ Ortho denied a direct duty to warn consumers about its products’ risks, and asserted that, to the extent that any duty was owed, such a duty was satisfied by Ortho’s adherence to the statutory standards established under the Food and Drugs Act.⁹⁵ Ortho also argued that the prescribing physician was aware of the risks, and that further warnings would have been redundant. In addition, they claimed that a reasonable person in the plaintiff’s position would have followed the advice of their prescribing physician and taken the pill even if they had been properly warned.

The Ontario Court of Appeal dismissed Ortho’s appeal, but it did so by relying on reasoning that departed from that of Justice Holland. Writing for the unanimous court, Justice Robins proceeds on “the assumption that

⁹⁰ *Buchan* H Ct J *supra* note 78 at 405.

⁹¹ See *ibid* at 405. This distinction was affirmed by the Court of Appeal in *Buchan*, *supra* note 30 at para 74, and later by the Supreme Court of Canada in *Hollis*, *supra* note 31 at 44, and has been the subject of considerable discussion, a full consideration of which is beyond present purposes. See e.g. Matthew Lewans, “Subjective Tests and Implied Warranties: Prescriptions for *Hollis* v. *Dow Corning* and *ter Neutzen v. Korn*” (1996) 60 Sask L Rev 209 at 211; Denis W Boivin, “Factual Causation in the Law of Manufacturer Failure to Warn” (1998) 30 Ottawa L Rev 47.

⁹² *Buchan* H Ct J *supra* note 78 at 406.

⁹³ *Ibid* at 406.

⁹⁴ See *Buchan*, *supra* note 30 at 665–66.

⁹⁵ *Supra* note 82.

manufacturers of contraceptive pills ... are under a duty to warn only prescribing physicians of the risks associated with the use of their products.”⁹⁶ This approach is contingent on an analysis of the learned intermediary doctrine.⁹⁷ Consequently, the court did not feel it was necessary to decide the case on the basis of whether the statutory requirements pre-empted the common law duty to warn.⁹⁸ After considering the warnings that Ortho had provided to the medical profession, Justice Robins concluded that the manufacturer “failed to give the medical profession warnings commensurate with its knowledge of the dangers inherent in the use of Ortho-Novum,” and in so doing, “breached its duty to warn.”⁹⁹

In reaching this decision, the court focused primarily on the adequacy of the warning provided. In his opening remarks about the duty to warn, Justice Robins clearly articulated what is necessary for a warning to be considered accurate. He observed that for a warning to be adequate:

[i]t should be communicated clearly and understandably in a manner calculated to inform the user of the nature of the risk and the extent of the danger; it should be in terms commensurate with the gravity of the potential hazard, and it should not be neutralized or negated by collateral efforts on the part of manufacturer.¹⁰⁰

Justice Robins also affirmed the Court’s decision in *Lambert*, noting that it provided guidance for determining the explicitness required of a

⁹⁶ *Buchan*, *supra* note 30 at 673. Justice Robins acknowledges that this approach is the most favourable position for Ortho.

⁹⁷ The learned intermediary doctrine holds that a manufacturer can discharge its obligation to warn consumers directly if they instead warn the prescribing physician. See discussion in *Buchan*, *supra* note 30 at paras 23ff.

⁹⁸ See *ibid* at 22. The Court did consider the role of statutes such as the *Food and Drugs Act*, *supra*, note 85 prior to considering the learned intermediary doctrine. See *ibid* at 670–73. Had the Court accepted Justice Holland’s approach, Justice Robins notes that “the trial judge’s conclusion that the information provided to consumers did not satisfy the duty is undoubtedly correct” (*ibid* at 672).

⁹⁹ *Buchan*, *supra* note 30 at 679.

¹⁰⁰ *Ibid* at 659.

warning.¹⁰¹ He further noted that adequacy will be determined by what is reasonable in the circumstances. For example, Justice Robins notes that in instances when there is a low probability of injury or a small class of consumers that may be harmed, “these factors must be balanced against such considerations as the nature of the drug, the necessity for taking it, and the magnitude of the increased danger to the individual consumer.”¹⁰²

The court also observed that the duty is a continuous one.¹⁰³ Justice Robins notes that manufacturers have a “duty to keep abreast of scientific developments pertaining to its products through research, adverse reaction reports, scientific literature and other available methods” and “must make all reasonable efforts to communicate the information to prescribing physicians.”¹⁰⁴ Moreover, when medical evidence exists that shows an inherent danger, “the manufacturer is not entitled to ignore or discount that information in its warnings solely because it finds it to be unconvincing.”¹⁰⁵ Rather, manufacturers are obligated to “be forthright and tell the whole story.”¹⁰⁶ Justice Robins also held that manufacturers could not justify a failure to warn by claiming that physicians could learn of the risk through other sources – “[t]he manufacturer’s duty to warn continues notwithstanding that the information may be otherwise available.”¹⁰⁷

The criterion for adequacy proposed here helps to explain why the Court of Appeal rejected the use of the objective test in *Reibl* for product liability cases. Although Justice Robins does not adhere to Justice Holland’s proposed test, he still concluded that “the *Reibl* test is inappropriate.”¹⁰⁸ Instead, it is up to the trier of fact in each case to determine whether or not a particular customer would have been influenced by a warning.¹⁰⁹ Whether

¹⁰¹ See *ibid* at 667.

¹⁰² *Ibid* at 678.

¹⁰³ See *ibid* at 667.

¹⁰⁴ *Ibid* at 678.

¹⁰⁵ *Ibid*.

¹⁰⁶ *Ibid*.

¹⁰⁷ *Ibid* at 680.

¹⁰⁸ *Ibid* at 685.

¹⁰⁹ See *ibid* at 686.

a reasonable person would heed a warning is “beside the point,” because the decision to heed a warning is an individual decision.¹¹⁰ This is why the adequacy of the warning is so important: full disclosure of the inherent risks in a product “facilitates meaningful consumer choice and promotes marketplace honesty.”¹¹¹ Moreover, as Justice Robins notes, moving away from the objective test does not impose a very serious burden on manufacturers, who are in a position to avoid liability simply by providing “a clear and forthright warning of the dangers inherent in the use of their products of which they know or ought to know.”¹¹²

Thus, *Buchan* set a standard of what is necessary for a warning to be considered adequate, identifying seven principles. These principles are reviewed in Table 1. The Supreme Court of Canada affirmed *Buchan* in *Hollis*.¹¹³ While the Court does not specifically identify all of the same principles, Justice La Forest, writing for the majority, does note that the informational advantage that manufacturers have requires them to provide “clear, complete and current informational disclosure”¹¹⁴ on an ongoing and

¹¹⁰ *Ibid* at 687. The judge continued to state that “[t]he selection of a method of preventing unwanted pregnancy in the case of a healthy woman is a matter, not of medical treatment, *but of personal choice*, and it is not unreasonable that notice of a serious potential hazard to users of oral contraceptives could influence her selection of another method of birth control” [emphasis added].

¹¹¹ *Ibid*. This is reiterated in *obiter* by Justice Robins. Noting that his comments were not necessary for his judgment, at 688, Justice Robins nevertheless explained that the aspect of choice in this case was especially germane, given that women had choices about the form of birth control they wish to use. He goes so far as to say that “[m]anufacturers of this drug should be obliged to satisfy the general common law duty to warn the ultimate consumer as well as prescribing physicians. To require this would not be to impose any real burden on drug manufacturers or to unduly interfere with the doctor-patient relationship as it exists with regard to the prescription of this drug” (*ibid* at 688–89). What it would do, however, would allow women to make “informed and intelligent decisions” about their reproductive health (*ibid* at 689).

¹¹² *Ibid* at 687.

¹¹³ In fact, to date, the only court to question the Ontario Court of Appeal’s ruling in *Buchan* was the British Columbia Court of Appeal in its decision in *Hollis v Dow Corning*, [1993] 103 DLR (4th) 520, 41 ACWS (3d) 455 [*Hollis*, BCCA cited to DLR]), which was overturned by the Supreme Court of Canada.

¹¹⁴ *Hollis*, *supra* note 31 at para 539.

forthright basis.¹¹⁵ Justice La Forest also affirms Justice Robins’s claim that manufacturers can easily avoid any undue burden by simply providing clear warnings.¹¹⁶ This high standard is justified because it “protects public health by promoting the right to bodily integrity, increasing consumer choice and facilitating a more meaningful doctor-patient relationship.”¹¹⁷

Table 1. The Buchan Standard for Adequacy of Warnings

1.	Warnings must be communicated clearly and understandably.
2.	Warnings must be communicated in a manner calculated to inform the user of the nature of the risk and extent of the danger.
3.	Warnings must be communicated in terms commensurate with the gravity of the potential hazard.
4.	Warnings must be explicit.
5.	Warnings should not be neutralized or negated by collateral efforts on the part of the manufacturer.
6.	There is a duty to keep abreast of scientific developments.
7.	There is a continuous duty to warn consumers of new risks.

One of the *Buchan* criteria not discussed in Hollis is the prohibition of collateral efforts on the part of manufacturers to negate or neutralize warnings.¹¹⁸ While several courts have referred to this prohibition when quoting

¹¹⁵ *Ibid* at para 541. Here, Justice La Forest cites *Buchan*, *supra* note 30 in holding that manufacturers cannot ignore or discount information that it finds unconvincing.

¹¹⁶ See *Hollis*, *supra* note 31 at paras 26, 44, citing *Buchan*, *supra* note 30.

¹¹⁷ *Ibid* at para 26.

¹¹⁸ The Court of Appeal’s decision does quote the entire passage from *Buchan* cited earlier, and thus does highlight that manufacturers should not negate or neutralize warnings, but it does not go into further detail on this point. See *Hollis* BCCA, *supra* note 117 at 539.

Buchan,¹¹⁹ no court has expanded on what it means for warnings. That is to say, no court has considered what types actions on the part of a manufacturer would amount to negating or neutralizing a warning. While *Létourneau* does not explicitly elaborate on this point,¹²⁰ Justice Riordan spent considerable time in his judgment discussing the collateral efforts on the part of manufacturers. As part five will demonstrate, the court in *Létourneau* was especially concerned with the efforts – or lack thereof – of tobacco manufacturers to warn users of potential harms associated with smoking. The court ultimately found that the warnings provided by the tobacco companies were inadequate. Before examining *Létourneau*, we will first review the history of tobacco litigation in Canada.

III. TOBACCO LITIGATION IN CANADA

Civil litigation is one of the many suggested ways that law can be used to assist in obesity prevention, management, and treatment. This recommendation, in large part, has been motivated by the perceived success of tobacco litigation. Tobacco litigation has played a critical role as part of a broader tobacco control strategy. Tobacco lawsuits have helped to shape the policy environment and reframe the public discourse, and have impacted the sale of tobacco products.¹²¹ However, while the experience of tobacco litigation may provide a useful template and learning opportunity for obes-

¹¹⁹ See e.g. *Pittman Estate v Bain*, [1994] 112 DLR (4th) 257 at 382, 46 ACWS (3d) 573; *Bow Valley Husky (Bermuda) Ltd v Saint John Shipbuilding Ltd*, [1995] 126 DLR (4th) 1 at 24, 56 ACWS (3d) 228 (NFLDCA); *Strata Plan N38 v Charmglow Products*, [1987] BCJ No 2776 (QL) at para 21, 8 ACWS (3d) 392 (BCSC); *Muir v Volvo Canada Ltd*, [2000] BCJ No 1970 (QL) at para 30, 2000 BCPC 96; *Walford (Litigation Guardian of) v Jacuzzi Canada Inc*, [2005] OJ No 1376 (QL) at para 120, [2005] OTC 258 (Sup Ct J) ; *Privest Properties Ltd v Foundation Co of Canada*, 128 DLR (4th) 577 at 638, [1995] 10 WWR 385 (BCSC); *More v Bauer Nike Hockey Inc*, [2011] 5 WWR 105 at para 240, 13 BCLR (5th) 61 (SC); *Can-Arc Helicopters Ltd v Textron Inc*, [1991] 86 DLR (4th) 404 at 414, [1992] 3 WWR 604 (BCSC); *Ocean Falls Corp v Worthington (Canada) Inc*, [1986] BCJ No 810 (QL) at para 52, 1986 CarswellBC 3618 (WL Can) (BCSC); *Double Bar L Ranching Ltd v Bayvet*, 1993 CanLII 6718 at 7 (SKQB).

¹²⁰ *Supra* note 29.

¹²¹ See generally Graham E Kelder Jr & Richard A Daynard, “The Role of Litigation in the Effective Control of the Sales and Use of Tobacco” (1997) 8:1 Stan L & Pol’y Rev 63; Constance A Nathanson, “Social Movements as a Catalyst

ity litigation,¹²² not all consider tobacco litigation a success.¹²³ Critics also point out that food and tobacco are distinct public health problems,¹²⁴ and that obesity presents a more complex problem since no specific behaviour (tobacco use) or product (tobacco) can be identified as the underlying cause of disease or injury.¹²⁵

Perhaps the biggest challenge with using tobacco litigation as an example for obesity litigation in Canada is the dearth of tobacco lawsuits.¹²⁶

for Policy Change: The Case of Smoking and Guns” (1999) 24:3 J of Health Politics & Law 421.

¹²² Many suggest that the experience of tobacco control can be used to avoid pitfalls. See e.g. Joshua Logan Pennel, “Big Food’s Trip Down Tobacco Road: What Tobacco’s Past Can Indicate About Food’s Future” (2008) 27:1 Buff Pub Int LJ 101.

¹²³ See e.g. R Shep Melnick, “Tobacco Litigation: Good for the Body but Not the Body Politic” (1999) 24:4 Health Pol’y & L 805; Marshall B Kapp, “Tobacco Litigation, Round Three: It’s the Money and the Principle” (1999) 24:4 Health Pol’y & L 811; McMenamin & Tiglio, *supra* note 23 at 517.

¹²⁴ McMenamin & Tiglio, *supra* note 23 (“[t]he contrast of food with tobacco is stark” at 446). The authors further note that “[t]o model tobacco litigation, proponents of obesity litigation may attempt to obscure some of the significant differences between tobacco and food” (*supra* note 23 at 463). Some of these differences are significant. For example, the sale of tobacco to minors is illegal, whereas the sale of fast-food is not. See Pennel, *supra* note 123 at 128. See also Daynard, “Lessons from Tobacco Control”, *supra* note 25 at 294–95.

¹²⁵ Additionally, consider that it is widely held that there is no safe exposure to tobacco products, which cannot be said for food products. That said, some contend this might actually render the food industry more vulnerable – after all, “while you cannot stop tobacco from being dangerous, you can make food less unhealthy.” See Bénédicte Coestier, Estelle Gozlan & Stéphan Marette, “On Food Companies Liability for Obesity” (2005) 87:1 American J Agricultural Economics 1 at 2–3.

¹²⁶ See Lara Khoury, Marie-Eve Couture-Ménard & Olga Redko, “The Role of Private Law in the Control of Risks Associated with Tobacco Smoking: The Canadian Experience” (2013) 39 Am J L & Med 442 at 443. This is not to say that the potential for tobacco litigation has not been explored. See e.g. Wendy Linden, “The Potential for a Tort Action against Tobacco Manufacturers in Canada” (1987) 6:3 Advocates’ Soc J 25; Rob Cunningham, “Tobacco Products Liability in Common Law Canada: (1990) 11:2 Health L Can 43; Megan

Tobacco litigation is a relatively recent phenomenon in Canada,¹²⁷ and only a few cases have ever made it to the courts. In part, this may stem from the fact that Canadians have publicly funded health care, and do not need to pursue civil litigation in order to recover health care costs. It is also likely relevant that, in stark contrast to American lawsuits, Canadian courts are not in the habit of handing out staggering punitive damages awards. Discussions about Canadian tobacco litigation thus far have been mostly limited to health care cost recovery actions initiated by provincial governments.¹²⁸

Evans, "Products Liability in Ontario: Is the Tobacco Industry in Trouble?" (1998) 8 Windsor Rev Legal Soc Issues 113.

¹²⁷ Tobacco litigation was still sufficiently novel in Canada in 2000 that some questioned whether or not it would be part of Canada's public health arsenal. See e.g. Barbara Sibbald, "Will Litigation Become Part of Public Health Arsenal in Canada's War Against Smoking?" (2000) 162:11 CMAJ 1608 at 1609. For an overview of tobacco litigation in Canada, see Khoury, Couture-Ménard & Redko, *supra* note 127. For a general overview of the use of law in tobacco control efforts in Canada, see von Tigerstrom, "Tobacco Control", *supra* note 26.

¹²⁸ In 1997, British Columbia enacted the *Tobacco Damages Recovery Act* (SBC 1997, c 41), later renamed the *Tobacco Damages and Health Care Cost Recovery Act* (SBC 2000, c 30). These acts enabled the province to sue tobacco companies to recover the health care costs. Both Acts were challenged by the tobacco industry. All provinces have since enacted similar legislation. For a discussion about these lawsuits, see FC DeCoste, "Smoked: Tradition and the Rule of Law in *British Columbia v. Imperial Tobacco Canada Ltd.*" (2006) 24 Windsor YB Access Just 327; Eric LeGresley, "Recovering Tobacco-Caused Public Expenditures from the Tobacco Industry: Options for Provincial Governments" (1998), online: *Non-Smoker's Rights Association* <nsra-adnf.ca/key-issue/recovering-tobacco-caused-public-expenditures-from-the-tobacco-industry-options-for-provincial-governments/> [perma.cc/GW2M-NH7S]; Elizabeth Edinger, "The Tobacco Damages and Health Care Costs Recovery Act: *JTI-Macdonald Crop. v. British Columbia (Attorney General)*" (2001) 35:1 Can Bus LJ 95; Barbara Sibbald, "All Provinces Likely to Join Tobacco Litigation" (2005) 173:11 CMAJ 1307; Devrin Froese, "Professor Raz, the Rule of Law, and the *Tobacco Act*" (2006) 19:1 Can JL & Jur 161; Robin M Elliot, "British Columbia's Tobacco Litigation and the Rule of Law" in Patricia Hughes & Patrick A Molinari, eds, *Participatory Justice in a Global Economy: The New Rule of Law* (Montreal: Canadian Institute for the Administration of Justice, 2004), online: <commons.allard.ubc.ca/cgi/viewcontent.cgi?article=1026&context=emeritus_pubs> [perma.cc/7BLJ-NNDT]; Jacob J Shelley, "The Crown's Right of Recovery Act" (2010) 18:3 Health L Rev 15.

This is not to say that there have been no tobacco lawsuits in Canada. There have been a few, but most were dismissed by the courts before the substantive claims were argued. For example, the claim in *Perron v RJR MacDonald*¹²⁹, alleging that tobacco companies neglected to determine risks associated with smoking and failed to warn users about such risks, was dismissed because the action had been commenced outside of the appropriate limitation period. *Caputo v Imperial Tobacco Ltd*¹³⁰ failed to certify a class action because the action was deemed to be inappropriate for a class proceeding. Class certifications were also denied in *Ragoonanan Estate v Imperial Tobacco Ltd*, which claimed cigarettes to be defective because they posed an unreasonable risk of igniting residential fires,¹³¹ and in *Sparkes v Imperial Tobacco Canada Limited*¹³², which claimed that tobacco companies deceived consumers by marking “light” or “mild” cigarettes. A class was certified by the British Columbia Superior Court in *Knight v Imperial Tobacco Canada Limited*¹³³, but the substantive matters of the claim have yet to be heard, as the court continues to deal with preliminary matters.¹³⁴ Individual suits have also had very limited success. For example, while Joe Battaglia was successful in bringing a case against tobacco companies to trial for damages that resulted from smoking, he ultimately lost his claim.¹³⁵

¹²⁹ [1996] BCJ No 2093 (QL) at paras 22–23, 81 BCAC 303 (CA).

¹³⁰ (2004), 236 DLR (4th) 348 at 375, 128 ACWS (3d) 874 (Ont Sup Ct J).

¹³¹ In this case, three people died when a fire started in the townhome of Davina Ragoonanan by the cigarette of one of the deceased. Although the court only refused to certify the action against two of the three named defendants initially, the plaintiffs ultimately failed to have the class certified against the third defendant. See *Ragoonanan v Imperial Tobacco*, [2005] 78 OR (3d) 98, aff’d [2008] 54 CPC (6th) 167.

¹³² 2008 NLTD 207 at paras 1, 7, 121, 282 Nfld & PEIR 177 [*Sparkes*].

¹³³ 2005 BCSC 172 at para 76, 250 DLR (4th) 347. For access to some of the litigation documents, see Physicians for a Smoke Free Canada, “*Kenneth Knight v. Imperial Tobacco Ltd.*” (last visited 7 May 2020), online: *Tobacco Litigation* <www.smoke-free.ca/litigation/webpages/Knight.htm> [perma.cc/7LPF-2GM6].

¹³⁴ See e.g. *R v Imperial Tobacco*, 2011 SCC 42, [2011] 3 SCR 45 (the Supreme Court rejected Imperial Tobacco’s attempt to add the Government of Canada as a third party to the suit).

¹³⁵ *Battaglia v Imperial Tobacco*, [2001] OJ No 5541 (QL) (Sup Ct J). This judgment is interesting for several reasons. Perhaps most striking was the fact that

While it is reported that he appealed the ruling, he did so without counsel, and died shortly thereafter.¹³⁶ Thus, in Canada, looking to tobacco litigation as an example for obesity litigation has limited value. That limited value has resulted in tobacco litigation, by and large, being ignored as a strategy that could be adopted. At most, scholars considering the role for law in obesity prevention refer to litigation in passing¹³⁷ – and often simply refer to the American experience.¹³⁸ *Létourneau* may change this.

Mr. Battaglia, who had worked for the tobacco company Rothmans, was willing to settle his case for a sum of one dollar and an apology. The defendants preferred a trial. For media coverage, see Physicians for a Smoke Free Canada, “Battaglia vs. Imperial Tobacco et al.” (last visited 7 May 2020), online: *Tobacco Litigation* <www.smoke-free.ca/litigation/webpages/Battaglia.htm> [perma.cc/BVW6-QPUL] [PSCF, “Battaglia”].

¹³⁶ See PSCF, “Battaglia”, *supra* note 136.

¹³⁷ See e.g. Ries, “Piling on the Laws”, *supra* note 15 at 104. An exception might be Nola M Ries & Barbara von Tigerstrom, “Law and the Promotion of Healthy Nutrition and Physical Activity”, in Tracey M Bailey, Timothy Caulfield & Nola M Ries, eds, *Public Health Law & Policy in Canada*, 3rd ed (Markham: LexisNexis, 2013) 323 at 367–74 [Ries & von Tigerstrom, “Law and the Promotion of Healthy Nutrition and Physical Activity”]. The authors spend several pages on litigation in this area and identify deceptive marketing as the most promising type of action.

¹³⁸ In the examples given in note 138, Ries, “Piling on the Laws”, *supra* note 15 at 104 refers only to Frank, *supra* note 23 and Daynard, Howard & Wilking, *supra* note 20. Ries & von Tigerstrom, “Law and the Promotion of Healthy Nutrition and Physical Activity”, *supra* note 138 refers almost exclusively to US authorities and cases, referencing only a class action against Vitaminwater as a Canadian example. This action has since been discontinued. See *Wilkinson v Coca-Cola Ltd* (13 November 2014), Montreal, Que CA 500-09-024570-145 (desistment), online: *Consumer Law Group* <www.clg.org/pdf/3/8/7/Discontinuance.pdf> [perma.cc/QQ54-6PMS]. Elsewhere, Ries & von Tigerstrom note that the bulk of the literature on legal interventions has focused on the legal and cultural context in the United States, but unfortunately they do not address litigation: Ries & von Tigerstrom, “Legal Interventions”, *supra* note 15 at 362.

IV. *LÉTOURNEAU C JTI-MACDONALD*

Representing 1.8 million Quebecois, and seeking damages upwards of \$27 billion,¹³⁹ *Létourneau* is the largest lawsuit of its kind in Canadian history.¹⁴⁰ It spent more than 13 years in the courts before certification was granted in 2005 – the claim suit originated in two class actions that were both filed in 1998. In May of 2015, Justice Riordan found for the plaintiffs, holding the three defendant tobacco companies, Imperial Tobacco, JTI-MacDonald, and Rothmans, Benson & Hedges, liable for over \$15 billion for several faults, including failing to warn consumers about the risks inherent in their products.

The genesis of *Létourneau* was two separate class actions. The first, the *Létourneau*¹⁴¹ file, was brought on behalf of persons in Québec who were dependent on nicotine. Ms. Létourneau originally initiated a small claims case, seeking a \$300 reimbursement for nicotine patches.¹⁴² The second, the *Blais* file,¹⁴³ was brought on behalf of smokers in Québec who had smoked

¹³⁹ See “Quebec Smokers, Tobacco Firms Face off in \$27B Lawsuit”, *CBC News* (12 March 2010), online: <www.cbc.ca/news/canada/montreal/story/2012/03/12/quebec-tobacco-lawsuit-damages-smoking-related-illness.html> [perma.cc/MQ6H-9K5K].

¹⁴⁰ See Andrew Chung, “Tobacco Lawsuit: Landmark Case Launched by Smokers Makes It to Quebec Court”, *Toronto Star* (12 March 2012), online: <www.thestar.com/news/canada/2012/03/12/tobacco_lawsuit_landmark_case_launched_by_smokers_makes_it_to_quebec_court.html> [perma.cc/2YW7-VKNE]. For a comprehensive overview of tobacco litigation in Canada, including access to original documents, statements of claims, etc., see Physicians for a Smoke Free Canada, “Litigation” (last visited 7 May 2020), online: *Tobacco Litigation* <www.smoke-free.ca/litigation> [perma.cc/FT4X-TQBX].

¹⁴¹ *Supra* note 29 at para 1. The full case name is *Cécilia Létourneau c JTI-Macdonald Corp, Imperial Tobacco Canada Ltd & Rothmans, Benson & Hedges Inc*, and the court number assigned to the case is 500-06-000070-983.

¹⁴² *Létourneau c Imperial Tobacco ltée*, 162 DLR (4th) 734 at 736, [1998] RJQ 1660.

¹⁴³ *Létourneau*, *supra* note 29 at para 1. The full case name is *Conseil Québécois sur le Tabac et la Santé and Jean-Yves Blais c JTI-Macdonald Corp, Imperial Tobacco Canada Ltd & Rothmans, Benson & Hedges Inc*, and the court number assigned to the case is 500-06-00076-980.

a minimum of five pack years, which amounts to 36,500 cigarettes,¹⁴⁴ and had been diagnosed with lung cancer, cancer of the throat, or emphysema.¹⁴⁵ These claims were brought against the three aforementioned tobacco companies. Between the two files, there were eight common questions of fact and law before the court, although the court only considered seven.¹⁴⁶ These seven questions are identified in Table 2.

Table 2. The Seven Common Questions Considered in *Létourneau*

- | | |
|----|---|
| A. | Did the Defendants manufacture, market, and sell a product that was dangerous and harmful to the health of consumers? |
| B. | Did the Defendants know, or were they presumed to know of the risks and dangers associated with the use of their products? |
| C. | Did the Defendants knowingly put on the market a product that creates dependence and did they choose not to use the parts of the tobacco containing a level of nicotine sufficiently low that it would have had the effect of terminating the dependence of a large part of the smoking population? |
| D. | Did the Defendants trivialize or deny or employ a systematic policy of non-divulgence of such risks and dangers? |
| E. | Did the Defendants employ marketing strategies conveying false information about the characteristics of the items sold? |
| F. | Did the Defendants conspire among themselves to maintain a common front in order to impede users of their products from learning of the inherent dangers of such use? |
| G. | Did the Defendants intentionally interfere with the right to life, personal security, and inviolability of the class members? |

The court was charged with determining whether the three companies were responsible for moral (compensatory) damages and punitive damages.

¹⁴⁴ The court had a formula for this: “A ‘pack year’ is the equivalent of smoking 7,300 cigarettes, as follows: 1 pack of 20 cigarettes a day over one year: $365 \times 20 = 7300$. It is also attained by 10 cigarettes a day for two years, two cigarettes a day for 10 years etc.” (*ibid* at para 2, n 4). Thus, 5 “pack years” amounts to 36,500 cigarettes ($5 \times 7,300$).

¹⁴⁵ See *ibid* at para 2 (both class descriptions are identified).

¹⁴⁶ See *ibid* at paras 3–5.

For the *Blais* file, Justice Riordan found the defendants liable for moral (compensatory) and punitive damages on four grounds.¹⁴⁷ He awarded \$6,858,864,000 in moral damages,¹⁴⁸ which, with interest and additional indemnity, amounted to \$15.5 billion.¹⁴⁹ Under the *Létourneau* file, Justice Riordan found the defendants at fault under the same heads of damage, but did not assess compensatory damages, contending that the plaintiffs failed to provide sufficient accuracy for the total amount of their claims.¹⁵⁰ For both actions together, the court awarded a total of \$131,090,000 in punitive damages. Of this, \$131,000,000 was attributed to the *Létourneau* file.¹⁵¹ Given the high damages awarded for the *Blais* file, the court reduced the punitive damage claim in this file to \$30,000 per company, representing a dollar for each Canadian death the tobacco industry causes every year.¹⁵²

Before proceeding, it is important to note that much of what the court discusses in *Létourneau* is specific to Québec.¹⁵³ The plaintiffs' claims were grounded in Québec's Consumer Protection Act¹⁵⁴ and *Charter of Human Rights and Freedoms*¹⁵⁵, and relied on the application of Québec's *Tobacco-Related Damages and Health Care Costs Recovery Act*.¹⁵⁶ Notwithstanding this, the court's articulation about the duty to warn is relevant for the rest

¹⁴⁷ See *ibid* at para 643.

¹⁴⁸ See *ibid* at para 1005.

¹⁴⁹ See *ibid* at para 1014.

¹⁵⁰ See *ibid* at para 950.

¹⁵¹ See *ibid* at para 1113. The court assessed punitive damages for both files at once, and then attributed 90% to the *Blais* file and 10% for the *Létourneau* file. See *ibid* at para 1084.

¹⁵² See *ibid* at para 1088.

¹⁵³ See *ibid* at para 668. For example, many of the findings are specific to the legislation considered, such as the discussion of the use of epidemiological evidence under the *Tobacco-Related Damages and Health Care Cost Recovery Act*, CQLR, c R-2.2.0.0.1 [*Cost Recovery Act*].

¹⁵⁴ CQLR, c P-40.1.

¹⁵⁵ CQLR, c C-12.

¹⁵⁶ *Cost Recovery Act*, *supra* note 154. The constitutionality of the legislation has been upheld by the Québec courts. See *Imperial Tobacco Canada Ltd c Québec (PG)*, 2014 QCCS 842, aff'd 2015 QCCA 1554, leave to appeal to SCC refused, 36741 (5 May 2016).

of Canada. Indeed, Justice Riordan noted that the rules relating to the duty to warn in Québec and the common law provinces are sufficiently similar, holding that “the issue of a manufacturer’s duty to warn is one where the two legal systems coexisting in Canada see the world in a similar way, and for which we see no obstacle to looking to common law decisions for inspiration.”¹⁵⁷ Moreover, as will be discussed next, much of the court’s discussion of the duty to warn in Québec is derived from and consistent with the common law.

Létourneau concerned tobacco manufacturers’ duty to warn consumers of the risks inherent in tobacco use (referred to in the case as the “obligation to inform”).¹⁵⁸ Justice Riordan identified 11 aspects of the duty to warn in the context of article 1468 of the Civil Code of Québec (see Table 3), and in so doing relies on *Hollis*, *Lambert*, and *Buchan* as authorities for several of these principles.¹⁵⁹ A comparison of these with the *Buchan* standard for adequacy demonstrates considerable overlap and general agreement.

¹⁵⁷ *Létourneau*, *supra* note 29 at para 219.

¹⁵⁸ See e.g. *ibid* at para 19.

¹⁵⁹ See *ibid* at para 227 (of the 11 principles, Justice Riordan cited *Hollis*, *supra* note 31 as the authority for principles 1, 6, 7 and 8; *Lambert*, *supra* note 63 for principles 3, 8 and 9; and *Buchan*, *supra* note 30 for principle 6). Justice Riordan then cited a summation (*ibid* at para 228) from Pierre-Gabriel Jobin & Michelle Cumyn, *La vente*, 3rd ed, (Cowansville: Éditions Yvon Blais, 2007) at 294–95.

Table 3. Eleven Principles of the Manufacturer’s Duty to Warn

1. The duty to warn “serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product”.
2. A manufacturer knows or is presumed to know the risks and dangers created by its product, as well as any manufacturing defects from which it may suffer.
3. The manufacturer is presumed to know more about the risks of using its products than is the consumer.
4. The consumer relies on the manufacturer for information about safety defects.
5. It is not enough for a manufacturer to respect regulations governing information in the case of a dangerous product.
6. The intensity of the duty to inform varies according to the circumstances, the nature of the product and the level of knowledge of the purchaser, and the degree of danger in a product’s use; the graver the danger the higher the duty to inform.
7. Manufacturers of products to be ingested or consumed in the human body have a higher duty to inform.
8. Where the ordinary use of a product brings a risk of danger, a general warning is not sufficient: the warning must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product.
9. The manufacturer’s knowledge that its product has caused bodily damage in other cases triggers the principle of precaution whereby it should warn of that possibility.
10. The obligation to inform includes the duty not to give false information; in this area, both acts and omissions may amount to fault.
11. The obligation to inform includes the duty to provide instructions as to how to use the product so as to avoid or minimize risk.

One of the central issues in the case was the point at which tobacco manufacturers’ duty to warn would be rendered unnecessary given the pre-existing knowledge of consumers. As JTI-MacDonald argued, “[t]here is no obliga-

tion to warn the warned.”¹⁶⁰ This is a common refrain for tobacco companies – that they had no duty to warn consumers that were already aware of the risks associated with smoking.¹⁶¹ To this end, they contended that the public was receiving sufficient information about the dangers of smoking from other sources, including parents, schools, doctors, and the mandatory warning labels required by the government.¹⁶² One of the important tasks set before the court was to determine when the general public would have sufficient knowledge to render warnings moot. Justice Riordan goes into considerable detail to make this determination, and ultimately identifies a “knowledge date” of 1 January 1980 for the *Blais* file and 1 March 1996 for the *Létourneau* file.¹⁶³ For both files, the manufacturer’s responsibility to warn consumers ceased as of these dates.

Thus, the conduct the court was considering for each file was that which occurred prior to the identified knowledge dates. If the companies knew during the identified class period of the increased risk of disease or dependence, they were obligated to warn consumers accordingly.¹⁶⁴ Consistent with the case law on point, if the warnings provided were incomplete or did not sufficiently identify the nature or degree of danger, then the obligation was not met.¹⁶⁵ Importantly, Justice Riordan noted that the obligation to provide a warning is not conditional. Rather, there is a “positive duty to

¹⁶⁰ *Létourneau*, *supra* note 29 at para 585 citing *Létourneau* (Notes of JTI-MacDonald’s), *supra* note 29 at para 1492..

¹⁶¹ For example, this argument has also been raised by tobacco companies in Australia. See S Champan & SM Carter, “‘Avoid Health Warnings on All Tobacco Products for Just as Long as We Can’: A History of Australian Tobacco Industry Efforts to Avoid, Delay and Dilute Health Warnings on Cigarettes” (2003) 12:SupplIII Tobacco Control iii13 at iii19.

¹⁶² See *Létourneau*, *supra* note 29 at para 185.

¹⁶³ See *ibid* at paras 121, 130. 1 March 1996 was chosen because it was 18 months after the implementation of mandatory addiction warnings were implemented on 12 September 1994, and the court assumed it would have taken one to two years for these warnings to come into effect. The 1 January 1980 date was chosen based on the testimony of experts before the court, and Justice Riordan’s conclusion that the public would have known about the dangers of smoking prior to legislated warnings being required in 1988.

¹⁶⁴ See *ibid* at para 184.

¹⁶⁵ See *ibid* (Justice Riordan noted “[t]hat is the case here” at para 232).

act.”¹⁶⁶ The duty “is not to warn the consumer ‘provided that it is reasonable to expect that the consumer will believe the warning’”¹⁶⁷ as such an expectation “would be nonsensical and impossible to enforce.”¹⁶⁸ This is consistent with the Ontario Court of Appeal’s decision in *Buchan*, which affirmed the use of the subjective test.¹⁶⁹ Moreover, Justice Riordan held that it was not necessary to show that no one would have smoked had the companies provided the appropriate information. Instead, he noted, “It suffices to find that proper knowledge was capable of influencing a person’s decision to begin or continue to smoke.”¹⁷⁰

Justice Riordan was unequivocal on his position as to whether or not the tobacco companies met their duty. He concluded that “the Companies shirked their duty to warn in a most high-handed and intentional fashion.”¹⁷¹ Indeed, his review of the tobacco companies on this point is scathing. He held that the companies had acted with a “calculated willingness to put [their] customers’ well-being, health and lives at risk for the purpose of maximizing profits,”¹⁷² behaviour that is “far outside the standards” of what is acceptable.¹⁷³ He found that their actions were not only intentional, and

¹⁶⁶ *Ibid* at para 282.

¹⁶⁷ *Ibid* at para 281.

¹⁶⁸ *Ibid*.

¹⁶⁹ See *Buchan*, *supra* note 30 at paras 77–78.

¹⁷⁰ *Létourneau*, *supra* note 29 at para 516 [emphasis added]. Justice Riordan made this declaration while considering Québec’s *Consumer Protection Act*. Thus, its applicability to the duty to warn overall may be limited. However, it resonates with other aspects of his judgment where he maintained that the obligation on the manufacturers was to provide the information that they had.

¹⁷¹ *Ibid* at para 278.

¹⁷² *Ibid* at para 338. He noted at several points in his judgment that the companies acted with “ruthless disregard for the health of their customers” (*ibid* at para 833), or appeared to have “a total absence of concern over the fact that its products were harming its consumers’ health” (*ibid* at para 579). Justice Riordan tempered some of his findings, however, noting that the companies’ actions were not necessarily motivated by malevolent desires, but simply with an aim of maximizing profits. See *ibid* at paras 485–86.

¹⁷³ *Ibid* at para 339.

“beyond irresponsible,”¹⁷⁴ but “reprehensible”¹⁷⁵ and constituted an “egregious fault.”¹⁷⁶

Of the various activities of the tobacco companies, Justice Riordan is particularly critical of the tobacco companies’ ongoing policy of silence.¹⁷⁷ By remaining silent, he noted that the companies clearly could not have met their duty to warn of the dangers.¹⁷⁸ He rejected the tobacco companies’ notion that this silence was inconsequential, refusing the assertion that consumers were adequately informed by the ongoing news and media coverage.¹⁷⁹ Similarly, he rejected the argument that warnings would not have mattered because consumers would likely not have believed any warnings provided by the tobacco companies.¹⁸⁰ Justice Riordan also did not allow the tobacco companies to use the mandated government warnings as a shield.¹⁸¹

¹⁷⁴ *Ibid* at para 288. Justice Riordan suggested that the companies were “intentionally negligent.”

¹⁷⁵ Specifically, Justice Riordan stated, “The Companies’ liability under both statutes stems from the same reprehensible conduct” (*ibid* at para 1027). He subsequently noted that “actions and attitudes were, in fact, ‘particularly reprehensible’ and must be denounced and punished in the sternest of fashions” (*ibid* at para 1038).

¹⁷⁶ *Ibid* at para 269.

¹⁷⁷ Justice Riordan used the expression “policy of silence” See e.g. *ibid* at paras 56, 271, 337, 523.

¹⁷⁸ See *ibid* at para 313.

¹⁷⁹ See *ibid* at para 86. Justice Riordan noted “[t]he Companies rely on this evidence to show that the general public was aware of the negative publicity about smoking through newspaper and magazine articles, but the knife cuts both ways” (*ibid* at para 264), and points to the “voluminous marketing material circulated” (*ibid* at para 86) by the companies.

¹⁸⁰ See *ibid* at para 271.

¹⁸¹ For example, Justice Riordan rejected the following argument:

The Companies make much of the fact that, even if they had wanted to misled the public about the dangers of smoking, which they assure that they did not, current governmental regulation of the industry creates an impermeable obstacle to any such activity. All communication between them and the public, in their submission, is prohibited, thus assuring that absolute prevention has been attained. It follows, in their logic, that there

As he observed, the tobacco companies consistently resisted the warnings and attempted to have them watered down.¹⁸² Indeed, he pointed out that the companies would have known that the warnings were insufficient to properly inform consumers and that “they actively lobbied to keep them that way.”¹⁸³ He was especially critical when discussing company documents that appear to celebrate the state of uncertainty that existed within the government when it was grappling with how to determine how to provide warnings about the risks of smoking in a meaningful way.¹⁸⁴

Part of the uncertainty the government was contending with was undoubtedly influenced by another tactic employed by the tobacco companies, namely, to actively work to create uncertainty by promulgating a scientific controversy. Justice Riordan observed that the tobacco companies were extolling a scientific controversy message, both to the broader public and its own employees.¹⁸⁵ This was more than an outright denial – although Justice Riordan noted that tobacco companies did deny the risks associated with their products¹⁸⁶ – it was a suggestion that the issues were “complicated, multi-dimensional and, especially, inconclusive, requiring much further research.”¹⁸⁷ The companies would insist that the research identifying risks

can be no justification for awarding any punitive damages (*ibid* at para 1032).

¹⁸² See *ibid* at para 272. See also *ibid* at para 463 where he noted the companies’ “efforts not only to hide the truth from the public but, as well, to delay and water down to the maximum extent possible the measures that Canada wished to implement to warn consumers of the dangers of smoking.”

¹⁸³ *Ibid* at para 287. He considered this a “most serious fault.”

¹⁸⁴ See *ibid* at paras 581–583.

¹⁸⁵ With regard to the message extolled to the public, see *ibid* at para 246. With regard to that extolled to employees, see *ibid* at para 247 (“[e]ven to its own employees, ITL was denying the existence of scientifically-endorsed link between cigarette smoking and disease and trivializing the evidence to that effect”).

¹⁸⁶ See *ibid* at para 250, where He noted that the companies “wilfully and knowingly denied those risks and trivialized the evidence showing the dangers associated with their products” (*ibid*) and that they asserted that cigarettes had “been unfairly made a scapegoat” (*ibid* at para 251).

¹⁸⁷ *Ibid* at para 252. Justice Riordan did address the fact that the companies were “technically” right. As he noted, many of the Companies’ statements were technically accurate: “Science has not, even today, been able to identify the actual physiological path that smoking follows in causing the Diseases. That,

with tobacco use was poor, and that it needed to be done by “real” scientists.¹⁸⁸ In addition to the “cynical refusal” to accept any science that identified dangers with tobacco products,¹⁸⁹ Justice Riordan found that the tobacco companies refused to do the necessary research to demonstrate otherwise.¹⁹⁰ Instead, by perpetuating the myth of a scientific controversy, the tobacco companies were attempting to “lull the public into a sense of non-urgency about the health risks.”¹⁹¹ Part of the way that the companies attempted to do this was by not disclosing – and in some instances, destroying¹⁹² – the relevant information it did have. These efforts did not impress Justice Riordan who, citing Hollis, observed that incomplete knowledge could not serve as a defence for failing to warn.¹⁹³ Thus, the tobacco companies not only failed to warn consumers, they were found to be intentionally negligent given their purposeful attempt to remain ignorant of the risks, thereby willingly putting their consumers at risk.¹⁹⁴

however, is neither a defence nor any sort of moral justification for denying the link.” (*ibid* at para 267) See also *ibid* at para 457, where he noted some of the scientific controversy points “are technically true when taken on a point-by-point basis,” but where he nevertheless declares that knowledge of harm was enough to trigger a duty to warn.

¹⁸⁸ See *ibid* at para 245.

¹⁸⁹ See *ibid* at para 474.

¹⁹⁰ See *ibid* at para 212, where Justice Riordan noted that at trial a former president of one of the companies “testified that BAT’s lawyers frowned on ITL performing scientific research to verify the health risks of smoking because that might be portrayed in lawsuits as an admission that it knew or suspected that such risks were present.” See *ibid* at para 472, where he noted that the companies were not necessarily at fault for not doing the research. But see *ibid* at para 474, “[w]here fault can be found, however, is in the failure or, worse, the cynical refusal to take account of contemporaneous, accepted scientific knowledge about the dangers of the Companies’ products and to inform consumer accordingly.”

¹⁹¹ *Ibid* at paras 458, 485.

¹⁹² For a discussion about “deadwood” and the role of lawyers in destroying evidence, see *ibid* at paras 357–78.

¹⁹³ See *ibid* at para 614, citing *Hollis*, *supra* note 31 at para 41.

¹⁹⁴ See *ibid* at para 288.

Consistent with *Buchan* and *Lambert*, *Létourneau* stands for the principle that the duty to warn does more than simply offer recourse to individuals harmed by faulty warnings – it also imposes an important obligation on manufacturers for which they ought to be held accountable independent of any finding of negligence. To put it another way, the obligations under the duty to warn exist independently of whether or not a failure to warn in a particular instance can be shown to result in harm. The potential for harm to arise is sufficient to trigger a manufacturer’s responsibility to both investigate and disclose any risks.¹⁹⁵ Moreover, as articulated in *Buchan*, warnings about risks must be adequate. In *Létourneau*, the companies failed to meet the *Buchan* standard. The tobacco companies did not provide clear and explicit warnings that informed consumers about the potential hazards associated with the use of their products, and they made no attempt to provide any new information about the risks their internal research did discover. Worse than failing to keep up with the science, the companies actively conspired to discount and undermine the science,¹⁹⁶ and they worked towards neutralizing and negating the information the public did have. As Justice Riordan observed, it is easy to understand the impulse to brand the tobacco companies’ actions as “immoral.”¹⁹⁷ The reprehensible conduct of the tobacco companies lead Justice Riordan to conclude, during his assessment of punitive damages, “[i]f the Companies are allowed to walk away unscathed now, what would be the message to other industries that today or tomorrow find themselves in a similar moral conflict?”¹⁹⁸

Following Justice Riordan’s judgment, the tobacco companies appealed to the Court of Appeal of Québec on several, often overlapping grounds.¹⁹⁹ In March 2019, a unanimous decision of five justices held that the tobacco companies “failed to demonstrate errors of law or palpable and overriding errors”, electing to make only minor corrections to Justice

¹⁹⁵ To be liable for harms that arise from a failure to warn, a plaintiff would still need to prove causation. Justice Riordan did go through this analysis, although a review of his analysis is beyond the scope of this essay. See *ibid* at paras 647–836.

¹⁹⁶ See e.g. *ibid* at paras 447, 449, 571.

¹⁹⁷ *Ibid* at para 339.

¹⁹⁸ *Ibid* at para 1037.

¹⁹⁹ For the grounds of appeal, see *Imperial Tobacco Canada Ltée c Conseil québécois sur le tabac et la santé*, 2019 QCCA 358 at paras 107–11 [*Imperial Tobacco Canada c Conseil québécois*].

Riordan's decision.²⁰⁰ These minor corrections did not pertain to Justice Riordan's articulation of the duty to warn, but rather to issues such as the date on which the class period began.²⁰¹ The unanimous upholding of Justice Riordan's judgment by the court of appeal – which, if anything, went further than Justice Riordan's judgment²⁰² – is an important signal about the obligation of manufacturers to warn consumers about the dangers in the products they sell.

With respect to the duty to warn, the court of appeal held that the “intensity of obligation imposed on the manufacturer to provide information is directly proportional to the level of the danger and the potential harm associated with the use of the product.”²⁰³ It further noted that when a product is mass produced, the obligation increases.²⁰⁴ Similarly, if a product is “intended to be ingested or implanted or introduced into the body,” such a product “requires a particularly high level of information.”²⁰⁵ This information must be “accurate and complete” and any warning must be “sufficient in order for the user to fully understand the danger and risk associated with the use of the product, as well as its possible consequences and know what to do (or not do) to avoid them or, if necessary, remedy them.”²⁰⁶ On this point, the court noted that even detailed information may not be sufficient, pointing to *Lambert* and *Hollis*, among other cases.²⁰⁷

²⁰⁰ *Ibid* at para 1277.

²⁰¹ See *ibid* at para 178.

²⁰² The court of appeal addressed matters that the plaintiffs had originally raised but that Justice Riordan had elected to not focus on in his judgment. For example, the court of appeal examined the use of scientific controversy and the targeting of children. These arguments, which are beyond the scope of this article, are not examined here.

²⁰³ *Ibid* at para 282.

²⁰⁴ See *ibid*.

²⁰⁵ *Ibid*.

²⁰⁶ *Ibid* at para 283.

²⁰⁷ See *ibid* at para 283; *Lambert*, *supra* note 63; *Hollis*, *supra* note 31. The court also identified *Mulco Inc c Garantie, compagnie d'assurance de l'Amérique du Nord*, [1990] RRA 68, 1990 CarswellQue 476; *OB Canada Inc c Lapointe*, [1987] RJQ 101, 1986 CarswellQue 248.

According to the court of appeal, informational inequality between a manufacturer and consumer justifies that a manufacturer assumes the risks that may transpire when a product is brought to market.²⁰⁸ Moreover, this inequality necessitates that information provided by the manufacture be “accurate (i.e., true), exact, understandable and complete and accurately reflect the nature and seriousness of the danger, the risks of its materialization and the significance of the harm that may result.”²⁰⁹ Importantly, the court also noted that the information that is to be provided is not limited to the information that was known at the time the product was first introduced into the market. Rather, manufacturers must provide information about the dangers that become apparent to them even after the product has been put on the market and “[i]ts obligation in this respect lasts and remains as long as the product is on the market.”²¹⁰

The court of appeal also dealt with whether a user’s knowledge of the danger of a product may negate the obligation to provide information. On this point, the court noted that general knowledge of a product may not be sufficient, particularly when there has been a “campaign of disinformation.”²¹¹ Rather, a consumer must have enough information to make an informed choice:

In other words, knowing that a product is dangerous, like knowing that an activity may be dangerous, is not sufficient: the manufacturer must prove that the victim had a precise and complete idea of the danger and risk associated with it and, in the same way, that he or she was informed of the means to be taken to deal with or avoid them, if any.²¹²

²⁰⁸ See *Imperial Tobacco Canada c Conseil Québécois*, *supra* note 200 at para 285.

²⁰⁹ *Ibid* at para 289.

²¹⁰ *Ibid* at para 298.

²¹¹ *Ibid* at para 328. The court further noted that the “extent of required knowledge is that which allows for the conclusion of the *voluntary* assumption of risk” (*ibid* at para 337) [emphasis in original].

²¹² *Ibid* at para 351.

If a consumer does not have enough information to make an informed choice, the court held that they cannot be found at fault for failing to take the precautions that they may have taken had they been properly informed.²¹³

While there is much in Justice Riordan's and the court of appeal's decisions that warrants further examination, it is sufficient for present purposes to close here with following from the court of appeal decision:

Did the appellants fail to fulfill their duty to inform? This question can only be answered in the affirmative. Not only did they intentionally conceal the pathological and addictive effects of the cigarettes they marketed from the public and users, they collectively developed and implemented at the same time a disinformation program aimed at undermining any information contrary to their interests; they maintained false scientific controversies, they hijacked debates, lied to the public (and even to public authorities), topping it all off with misleading advertising strategies contrary to their own Codes of conduct...²¹⁴

V. WHAT LÉTOURNEAU MEANS FOR OBESITY LITIGATION

If, as has been suggested, obesity litigation is a promising strategy based on the success of tobacco litigation, then it is worth considering the potential future for obesity litigation in Canada in light of the decision in *Létourneau*. As discussed above, prior to *Létourneau* there was no real success to speak of with respect to tobacco litigation in Canada – particularly for civil litigants. Thus, *Létourneau* provides the first real opportunity in Canada to assess how obesity litigation may be informed by tobacco litigation. Alongside the affirming decision of the court of appeal, Justice Riordan's decision, as the court of first instance, remains useful for evaluating the duty to warn as it might be applied to food products. This is because Justice Riordan did not attempt in his judgment to reinvent the duty, or to extend its scope or application, but instead applied the existing law concerning the duty to warn to the product in question, cigarettes. This approach gives an indication as to how obesity litigation in Canada can be framed. While there are some

²¹³ See *ibid* at para 361.

²¹⁴ *Ibid* at 477.

challenges with using *Létourneau* as a template, the decision in the Superior Court of Québec suggests that there may be a future for obesity litigation.

Before considering how Justice Riordan's decision is relevant for obesity litigation, however, it is worth noting that Canadian product liability jurisprudence is already applicable to the products associated with obesity – that is, to food and beverage products (henceforth “food products”). This is an uncontroversial claim,²¹⁵ as food products have been part of what is now product liability law since its origins.²¹⁶ Moreover, there is a long history of cases imposing liability on food manufacturers.²¹⁷ Consider, for example, the seminal negligence case, *Donoghue*, which concerned the liability of the manufacturer of ginger beer containing a decomposing snail.²¹⁸ Similarly, other early negligence cases dealt with food products. For example, in 1919, the Supreme Court of Nova Scotia allowed a plaintiff who found powdered

²¹⁵ What might be more controversial is that obesity litigation should focus on food products. While not addressed at length here, diet plays a critical role in obesity. It is estimated that 60% to 100% of obesity amongst Canadians is related to diet, specifically, excess calorie consumption. See Sara N Bleich et al, “Why is the Developed World Obese?” (2008) 29:1 Annu Rev of Public Health 273 at 283–84. Moreover, there is solid evidence to suggest that the rising prevalence in overweight and obesity occurred simultaneously with shifts in diet and the types of products available for consumption. For example, in 2002, 530 more calories per person per day were available in the Canadian food supply than in 1985. See *ibid* at 281. During this time, there was an increase in the prevalence of obesity in Canada. See generally Laurie K Twells et al, “Current and Predicted Prevalence of Obesity in Canada: A Trend Analysis” (2014) 2:1 CMAJ Open E18.

²¹⁶ For example, the *Restatement (Third) of Torts* § 1 (1998) considers the application to food, noting: “[a]s early as 1266, criminal statutes imposed liability upon victualers, vinters, brewers, butchers, cooks, and other persons who supplied contaminated food and drinks”. See also Reed Dickerson, *Products Liability and the Food Consumer* (Westport, CT: Greenwood Press, 1972) at 20, pointing to a case appearing in 1431, where it was held that if a tavern sells corrupted food, the person suffering harm would have “an action against the taverner on the case even though he makes no warranty to me.”

²¹⁷ See *ibid* at 26. Dickerson observes that “[s]ome kind of special civil responsibility undoubtedly attached to retail food sales long before the modern warranties expressed by the sales statutes were developed, and this responsibility ultimately came to be classed as a ‘warranty’ obligation” at 26.

²¹⁸ See *Donoghue*, *supra* note 52 at 562.

glass in a chocolate bar to bring an action against the manufacturer.²¹⁹ The court held that “there was a duty to the public not to put on sale such a dangerous article as the chocolate bar in question,” and found the defendant to be guilty of negligence and the proximate cause of the plaintiff’s injuries.²²⁰

Additionally, because food products are ingested, it is clear that the standard of care expected of food manufacturers is heightened.²²¹ Theall and colleagues argue that food manufacturers face among the highest standards of care, given that all of their products are ingested, suggesting that “the standard has been characterized as approximating strict liability.”²²² Consider, for example, how the matter was framed by the court in Shandloff:

The effect, as I take it, of [*Grant and Donoghue*] is to establish that a manufacturer who prepares and puts upon the market food in a container which prevents examination by the ultimate consumer is liable to the ultimate consumer for any defects which exist in the goods so marketed which arise from negligence or lack of care. The lack of care essential to the establishment of such a claim increases according to the danger to the ultimate consumer, and where the thing is in itself dangerous, the care necessary approximates to, and almost becomes, an absolute liability.²²³

The Ontario Court of Appeal in *Heimler v Calvert Caterers Ltd*²²⁴ affirmed that the burden imposed on those handling food products approxi-

²¹⁹ See *Buckley v Mott* (1919), 50 DLR 408, 1919 CarswellNS 63 (NS SC) [*Buckley v Mott* cited to DLR].

²²⁰ Edgell, *supra* note 51 at 9 citing *Buckley v Mott*, *supra* note 222 at 409.

²²¹ See Dickerson, *supra* note 219 (“[i]t is commonly said that the food manufacturer is held to a higher standard of care than other manufacturers” at 128).

²²² Theall et al, *supra* note 45 at L5-4.

²²³ *Shandloff*, *supra* note 54 at 719.

²²⁴ 56 DLR (3d) 643 at 2, 8 OR (2d) 1 [*Heimler*]. This case involved liability for food served at a wedding where a guest contracted typhoid. Although the case dealt specifically with food handlers, the court’s finding that “[t]he standard of care demanded from those engaged in the food-handling business, is an extremely high standard...”, can be applied more broadly to food manufacturers. Indeed, in its discussion of *Heimler*, the court in *Brunski v Dominion Stores Ltd* (1981), 20 CCLT 14, 13 ACWS (2d) 162 at para 25 (ON H Ct J) extends the finding to include “food producers and distributors.”

mates absolute liability. This is, in part, because of the relationship of reliance that exists between a food manufacturer and consumer.²²⁵

Thus, courts have recognized that food manufacturers have an obligation to avoid putting dangerous food products into circulation. What needs to be ascertained, then, is what counts as a dangerous food. Many of the early product liability cases involving food products concerned adulterated foods or manufacturing errors.²²⁶ Dangerous food, then, could be contrasted with “pure food” and would encompass corrupted food products. In this sense, the concept of “dangerous foods” would be restricted to food safety issues arising from manufacturing defects or from the negligence of food handlers. This class of issues is vastly different than that which arises from the continued consumption or overconsumption of food products. It has been suggested that the overconsumption of food products and, in particular, of unhealthy food products (sometimes described as “pathogenic” food or as part of a toxic food environment),²²⁷ gives rise to obesity, diabetes, and cancer, among other diet-related diseases.²²⁸

To claim that a food product is inherently dangerous would require making a claim that the food product has a defective design.²²⁹ Success in

²²⁵ See Edgell, *supra* note 51 at 17.

²²⁶ See e.g. *Donoghue*, *supra* note 52 (snail in ginger beer); *Shandloff*, *supra* note 54 (glass in chocolate milk); *Arendale*, *supra* note 54 (glass in bread); *Zeppa*, *supra* note 54 (glass in a soft drink).

²²⁷ See generally Norm RC Campbell, Kim D Raine & Lindsay McLaren, “‘Junk Foods,’ ‘Treats,’ or ‘Pathogenic Foods’? A Call for Changing Nomenclature to Fit the Risk of Today’s Diets” (2012) 28:4 Can J Cardiol 403.

²²⁸ See e.g. Jacob J Shelley, “Addressing the Policy Cacophony Does Not Require More Evidence: An Argument for Reframing Obesity as Caloric Overconsumption” (2012) 12:1 BMC Public Health 1042 at 3, online: <www.biomedcentral.com/1471-2458/12/1042> [perma.cc/3M6A-PBKS] [Shelley, “Addressing the Policy Cacophony”]. It is far beyond the scope of this chapter to review the science and evidence on this point. See also Corinna Hawkes et al, “Smart Food Policies for Obesity Prevention” (2015) 385:9985 Lancet 2410. Even food manufacturers point to overconsumption as a problem. See e.g. Katie Little, “Posts on McDonald’s Employee Site Bash Fast Food”, *CNBC* (23 December 2013), online: <www.cnn.com/2013/12/23/post-on-mcdonalds-employee-site-bashes-fast-food.html> [perma.cc/9WV8-98G6].

²²⁹ A defective design claim would argue that a food product has been designed in such a way that the risks outweigh the benefits. This is one of the arguments

a defective design claim could have grave consequences for a food manufacturer. It would require a manufacturer to redesign a product – a costly and perhaps impossible task.²³⁰ Moreover, it may have drastic consequences for some populations. It is clear that dependency on certain food products varies by neighborhood, region, and socio-economic status, among other factors.²³¹ Courts will likely be reluctant to declare an entire product line negligently designed if a community is dependent on that product.²³² Courts may also be reluctant to accept that a food product's design is defective if the product only causes harm when the harm is merely a consequence of overconsumption.²³³ A court is more likely to accept that the risk inherent in the overconsumption of a product merits some form of warning to the consumer.²³⁴ Avoiding a failure to warn claim only imposes on a manufac-

Justice Sweet identified he would accept from the plaintiffs in their amended claim in *Pelman*, *supra* note 35, but that the plaintiffs failed to submit.

²³⁰ But also consider that if all similar products carry the same risk, then the product may not be deemed defective. See Theall et al, *supra* note 45 (“[a]lthough not conclusive, evidence that the defendant’s product presented no greater risk than similar products of other manufacturers, and contained the same level of available technological innovation, can lead the court to find no defect in the defendant’s design” at L2-10).

²³¹ This thinking applies to civil liability as well. Antler, *supra* note 20 argues that *Pelman*, *supra* note 35 would have had a better chance of success had it focused on poor, urban African-American children, as their food choices were far more restricted than the plaintiffs in *Pelman*.

²³² Stapleton, *supra* note 59 (“[i]t is also one which courts may well be reluctant to uphold if grave socio-economic dislocations are thereby threatened because a firm, an industry, or a community is dependent on that product line” at 252). The author notes that “where the design is this dangerous *and* where a finding of liability would clearly threaten to precipitate major socio-economic dislocations, as it would in the product-category cases where the defect is generic and not remediable by modification to an alternative design, courts face a serious separation of powers dilemma” at 254.

²³³ This point requires consideration beyond the scope of this article. Indeed, a determination of what level of risk is sufficient to render a product defective is at the heart of the defective design analysis. Suffice it to say that manufacturers are required to, among other things, consider the foreseeable misuses of their products and to adequately test their design to safeguard against known or reasonably foreseeable risks.

²³⁴ There is considerable overlap between the two defective design and defective warnings cases, however. As Theall et al, *supra* note 45 at L1-8 note, failure

turer the minor costs associated with providing a label to warn users of the risks associated with a product. For a failure to warn claim to succeed, a consumer need only show that the product was defective because it did not have an adequate warning. He or she does not have to demonstrate that an entire product is defective.²³⁵

This is what the court ultimately found in *Létourneau*: tobacco manufacturers had an obligation to warn consumers of the risks associated with smoking cigarettes, and, by failing to provide adequate warnings to consumers, they were liable for the resulting harm. While one may disagree with Justice Riordan's interpretation of the facts or with his application of the law, *Létourneau* does not represent a departure from the existing jurisprudence. The plaintiffs were relying on well-established case law pertaining to the duty to warn. This same case law could be used by claimants who allege that food manufacturers have an obligation to provide warnings about the known and foreseeable risks associated with the consumption of their products.²³⁶

to warn claims are more akin to negligent design claims than negligent manufacturer claims. They observe that both types of cases require an assessment of "the nature and extent of the risk and then considers whether, given the level of the risk, the warnings were adequate" (*ibid* at L1-9). An important difference, however, is that while there is a need to consider the risks associated with the use of a product in a defective warning case, there is no need to find a defect *per se* in the product itself. Instead:

"[g]etting from the injury or damage to the conclusion that the warning was defective requires a consideration of whether the risk which materialized to harm the plaintiff was reasonably foreseeable. One must then consider whether the nature and extent of the risk merited a better warning, and next, whether a better warning would have prevented the harm to this plaintiff" (*ibid* at L3-2).

²³⁵ Sometimes a warning is required because a product cannot be redesigned. See *ibid* ("where prevailing technology does not allow for the manufacture of a safer product, the court may still find the manufacturer liable if the risk could have been reduced or avoided through adequate warnings to the user" at L2-9).

²³⁶ While such a discussion is beyond the scope of this article, there is an important discussion to be had about what is required to prove causation in duty to warn cases. For example, Botterell and Essert make a compelling case that "atypical cases," which arguably could include duty to warn cases, require an atypical application of normative principles. See Andrew Botterell & Christopher Essert, "Normativity, Fairness, and the Problem of Factual Uncertainty"

So, beyond being an example of how the duty to warn can be applied to a specific set of facts, what does *Létourneau* mean for obesity litigation? Perhaps most importantly, *Létourneau* affirms what is required of manufacturers to adequately warn consumers. As noted above, Justice Riordan's decision can be understood as an application of the standard of adequacy articulated in *Buchan*. In *Buchan*, the Ontario Court of Appeal held that the duty to warn requires manufacturers to provide warnings that are clearly communicated and that inform users about the nature of the risk inherent in a product. With some limited exceptions, such as food products containing allergens, food manufacturers do not provide any warning about the risks associated with the use of their products. While many food products do provide nutritional information and disclose their ingredients, as required by the *Food and Drugs Act*,²³⁷ the decision in *Buchan* suggests that food manufacturers will not be able to rely on adherence to regulatory requirements as a shield, given that such regulation represents a minimum standard of what is expected. *Létourneau* suggests that the way industry responds to regulatory initiatives may be a relevant consideration when considering liability. As noted previously, Justice Riordan was unimpressed by the tobacco industry's attempt to water down any regulatory efforts that could not be prevented outright. The Canadian government is currently reconsidering how it regulates food products as part of its "Healthy Eating Strategy,"²³⁸ and the way in which the food industry responds to these efforts presents an opportunity to gauge how receptive the food industry will be to increased regulation and oversight.

Létourneau is also unequivocal about the requirement for manufacturers to keep abreast of scientific developments. This duty is not limited to research that manufacturers undertake but extends to research undertaken by others to identify risks. *Buchan* explicitly held that manufacturers have an ongoing obligation to test products and to respond to the findings of others.

(2009) 47:4 Osgoode Hall LJ 663. See also Boivin, *supra* note 92; Vaughan Black, "Decision Causation: Pandora's Tool-Box" in Jason Neyers, Erika Chamberlain & Stephen Pitel, eds, *Emerging Issues in Tort Law* (Oxford: Hart Publishing, 2007) 309.

²³⁷ *Supra* note 82, s 5.

²³⁸ Health Canada, *Healthy Eating Strategy*, (Ottawa: Health Canada, 2016), online (pdf): *Government of Canada* <www.canada.ca/content/dam/canada/health-canada/migration/publications/eating-nutrition/healthy-eating-strategy-canada-strategie-saine-alimentation/alt/pub-eng.pdf> [perma.cc/MV98-FQC5].

Food manufacturers cannot ignore, minimize, or simply deny the risks that others identify with their products – even when the manufacturer is not convinced by the research. This is critically important in the context of obesity, where the food industry has attempted to minimize the role its products have played. As Bogart observes, the food industry

aims to convince legislators and the public that the science relating diet to health is so uncertain that regulation promoting better eating and drinking and aimed, in any way, at its products is mostly unnecessary and would, in any event, be mostly ineffective. In any event, diet and weight are a matter of personal responsibility, accountability, and discipline.²³⁹

In *Létourneau*, Justice Riordan found that rather than warn the public about the known risks, the tobacco companies attempted to discredit, downplay, and ignore the science. These tactics have been emulated by the food industry.²⁴⁰

Food manufacturers cannot hide behind ignorance. As the body of evidence grows about risks, the onus on the manufacturer also grows. This means that manufacturers cannot simply ignore the evidence they find inconvenient or unconvincing. Instead, manufacturers must provide adequate warnings in order to ensure that consumers can make an informed choice, taking into account all of the available science. On this point, food manufacturers theoretically will be cooperative. After all, the food industry has long emphasized the importance of consumer choice, particularly as it relates to obesity, championing the idea of “personal responsibility.”²⁴¹ Warnings not

²³⁹ Bogart, *supra* note 24 at 34.

²⁴⁰ For example, some media attention was brought to internal documents from the sugar industry. See Kelly Crowe, “Sugar Industry’s Secret Documents Echo Tobacco Tactics: Sugar Association’s Intent to Use Science to Defeat Critics Uncovered by Dentist”, *CBC News* (8 March 2013), online: <www.cbc.ca/news/health/story/2013/03/08/f-vp-crowe-big-sugar.html> [perma.cc/Z434-FKRQ]; Brownell & Warner, *supra* note 25.

²⁴¹ See e.g. the discussions in Kelly D Brownell et al, “Personal Responsibility and Obesity: A Constructive Approach to a Controversial Issue” (2010) 29:3 *Health Affairs* 379; Nicole L Novak & Kelly D Brownell, “Obesity: A Public Health Approach” (2011) 34:4 *Psychiatr Clin North Am* 895. Here, the industry is following the lead of the tobacco industry, who have long emphasized that smokers need to be held personally responsible for their decisions. Indeed, in *Létourneau* the tobacco companies make this point. See e.g. *Létourneau*,

only help consumers make informed choices, their legal effect is to shift responsibility for potential harms from the manufacturer to the consumer. Warnings facilitate personal responsibility – provided, of course, that they are adequate.

Justice Riordan was critical of the tobacco industry's attempt to neutralize or negate public understanding of the dangers of their products – or, as he put it, their attempt to “lull” the public into a sense of non-urgency. Consider the actions of some food manufacturers. For example, despite the known risks associated with consumption of sugar-sweetened beverages (SSB),²⁴² PepsiCo continues to market these products as “fun-for-you” without any warnings about inherent or foreseeable risks.²⁴³ Similarly, fast food restaurants make misleading claims about the healthfulness of their food products²⁴⁴ or fail to disclose the dangers of ingredients used. In fact, many individuals would not be able to even identify the ingredients used in many fast foods. Consider Judge Sweet's comments in *Pelman* that McDonald's Chicken McNuggets™ are a “McFrankenstein” creation using ingredients that an individual would not recreate at home.²⁴⁵ As Justice Sweet stated, “It is at least a question of fact as to whether a reasonable consumer would

supra note 29 at paras 305–09 (testimony by Kip Viscusi arguing that smokers had enough information to make rational decisions).

²⁴² It is beyond the scope of this article to identify all the risks associated with the consumption of SSB. However, consider the following texts, which link SSB consumption with overweight and obesity: Vasanti S Malik et al, “Sugar-Sweetened Beverages and Weight Gain in Children and Adults: A Systematic Review and Meta-Analysis” (2013) 98:4 *Am J Clin Nutr* 1084 at 1100; Vasanti S Malik et al, “Sugar Sweetened Beverages, Obesity, Type 2 Diabetes and Cardiovascular Disease Risk” (2010) 121:11 *Circulation* 1356; “Reducing Consumption of Sugar-Sweetened Beverages to Reduce the Risk of Childhood Overweight and Obesity” (last modified 11 February 2019), online: *World Health Organization* <www.who.int/elena/titles/ssbs_childhood_obesity/en/> [perma.cc/ZDN5-RU7D]; Lisa Te Morenga, Simonette Mallard & Jim Mann, “Dietary Sugars and Body Weight: Systematic Review and Meta-analyses of Randomized Control Trials and Cohort Studies” (2013) 346 *BMJ* e7492; Mark A Pereira, “Sugar-Sweetened and Artificially-Sweetened Beverages in Relation to Obesity Risk” (2014) 5:6 *Adv Nutr* 797.

²⁴³ See Novak & Brownell, “Obesity”, *supra* note 244 at 904.

²⁴⁴ See Mary O Hearts et al, “Nutritional Quality at Eight U.S. Fast-food Chains: 14-year Trends” (2013) 44 *Am J Prev Med* 589.

²⁴⁵ *Pelman*, *supra* note 35 at 535.

know without recourse to the McDonalds' website that a Chicken McNugget contained so many ingredients other than chicken and provided twice the fat of a hamburger."²⁴⁶ Products that are held out as being safe but in fact are not are, if anything, more dangerous, particularly for users that may be sensitive or vulnerable.²⁴⁷ In effect, such products become more like "a wolf in sheep's clothing instead of an obvious wolf."²⁴⁸

One of the reasons that the tobacco companies in *Létourneau* emphasized that the science was complicated, multi-dimensional, and inconclusive was to challenge the notion that their fault (i.e., failing to warn) caused people to consume their product (i.e., smoke). While there is some legitimacy to the claim about complicated science – a point Justice Riordan acknowledged, noting the "controversial scientific waters"²⁴⁹ – he rejected the idea that the science must be certain about "the cause."²⁵⁰ Instead, he found it sufficient to note that the fault of the tobacco companies was a cause.²⁵¹ As Justice Riordan noted, "Mere common sense dictates that clear warnings about the toxicity of tobacco would have had some effect on any rational person."²⁵² It is not necessary to demonstrate that warnings would influence

²⁴⁶ *Ibid.* Following *Pelman*, McDonald's did reformulate the Chicken McNuggets™, although it is not entirely clear whether this was strictly in response to the lawsuit. See Melissa Healey, "War on Fat Gets Serious" (3 January 2004) *LA Times*, online: <www.latimes.com/health/la-na-obesity24jan24b-story.html> [perma.cc/ME6N-585U].

²⁴⁷ See Waddams, *supra* note 51 at 58.

²⁴⁸ *Hodge & Sons v Anglo-American Oil Co* (1922), 12 L1 L Rep 183 at 187. While the court here was not considering the duty to warn or products held out as being safe, this sentiment seems to be applicable. This passage has been cited in failure to warn cases. See *Ruegger v Shell Oil Company of Canada*, 41 DLR (2d) 183 at 189, [1964] 1 OR 88; *Rivtow Marine Ltd v Washington Iron Works*, [1974] SCR 1189 at 1209, 40 DLR (3d) 530.

²⁴⁹ *Létourneau*, *supra* note 29 at para 766. Of course, as noted, the tobacco companies are largely responsible for creating the controversy.

²⁵⁰ *Ibid* at paras 791–809.

²⁵¹ See *ibid* at para 804, where Justice Riordan noted that the fault does not have to be "the only cause of smoking, or even the dominant one." Justice Riordan also noted, "Where the proof shows that the other causes existed, it might be necessary to apportion or reduce liability accordingly" (*ibid* at para 795).

²⁵² *Ibid* at para 803.

everyone's choice to stop smoking.²⁵³ Similarly, even though warnings on food products may not prevent the consumption of said products, common sense suggests that they will have an effect on some people. As discussed in *Buchan*, the question of what food products to consume is a personal choice. Warnings about the known or foreseeable risks in the product are necessary, because they provide consumers with adequate information to facilitate meaningful consumer choices.

Importantly, *Létourneau* also makes it clear that the mere consumption of a product may not be sufficient to impose liability. As discussed above, to be eligible for inclusion in the *Blais* file, a plaintiff had to smoke a minimum of 5 "pack years". What level of consumption of a specific food product (or class of products)²⁵⁴ would be required to give rise to liability? Consider, for example, SSBs. Is there a "litre years" threshold equivalent for SSBs? Would SSBs be too inclusive of a product category, given that, in addition to soda, it would include many juices, milk drinks, and energy drinks? In addition, for recovery under the *Blais* file, the plaintiffs had to have been diagnosed with one of the three identified diseases: lung cancer, cancer of the throat, or emphysema.²⁵⁵ For obesity litigation, would plaintiffs be required to demonstrate a specific diagnosis of obesity? This seemingly sim-

²⁵³ Justice Riordan noted that this is evidenced by the fact that "even in the presence of such warnings today, people start and continue to smoke" (*ibid*).

²⁵⁴ One of the contentious aspects of tobacco litigation has been holding various manufacturers jointly liable for a failure to warn. It is common in tobacco litigation for tobacco manufacturers to argue that plaintiffs fail to demonstrate that the harm resulted from the use of their particular product. For example, Justice Riordan addressed this in his judgment, where he ultimately determined that the three tobacco manufacturers "jointly participated in a wrongful act that resulted in an injury" (*ibid* at para 449) and referred to the collusion between the defendant companies (see *ibid* at paras 447–49, 935–36). There is an argument to be made that similar collusion has existed in some sectors of the food industry – particularly given that only a handful of companies produce the vast majority of commercially prepared foods – although this would be a matter for the court of first instance to assess on the evidence. For a breakdown of ownership in the food industry, see Kate Taylor, "These 10 Companies Control Everything You Buy", *Business Insider* (28 September 2016), online: <www.businessinsider.com/10-companies-control-the-food-industry-2016-9> [perma.cc/UE63-MPWS].

²⁵⁵ Recall that the *Létourneau* file did not address a specific disease, but instead included all those "addicted to the nicotine contained in the cigarettes" (*supra* note 29 at para 2).

ple requirement may, in fact, complicate matters. Obesity is not universally recognized as a disease,²⁵⁶ and there is no agreement even among those who do identify obesity as a disease as to when that diagnosis should be made.²⁵⁷ Additionally, there is a vociferous debate about whether or not obesity is necessarily harmful,²⁵⁸ and thus courts would likely have to consider whether obesity gives rise to an actionable loss.

In this respect, the requirements set out by the court to be included in either of the classes examined in *Létourneau* may serve as an impediment to obesity litigation. Of course, this is only the case if obesity litigation proceeds as a class action. There is good reason to suspect that this will necessarily be the case, especially given the outcome in *Létourneau*. This would come at extreme personal and financial cost to an individual claimant. Moreover, despite the large damages award in *Létourneau*, the amount claimed per individual plaintiff would be woefully inadequate to justify pursuing litigation outside of a class action. Members of the *Blais* file with lung or throat cancer sought \$100,000 and members with emphysema sought \$30,000; members of the *Létourneau* file sought \$5,000.²⁵⁹ Such damages, even if punitive damages were to be awarded, would likely be insufficient to cover the cost of litigation. While obesity litigation would undoubtedly have to proceed as a class action, it is not clear that a class will be certified. As noted above, certification has already been difficult in Canadian tobacco litigation, with certification being denied in *Ragoonanan Estate*²⁶⁰ and *Sparkes*²⁶¹. Moreover, certification was denied in the now infamous *Mc-*

²⁵⁶ See e.g. Lee Stoner et al, “Should Obesity be Considered a Disease?” (2014) 134:6 *Perspect Public Health* 314.

²⁵⁷ While traditionally based on body-mass index (BMI), there is considerable resistance to the use of BMI in clinical settings. Alternative approaches have been identified, such as the Edmonton Obesity Staging System. See AM Sharma & R Kushner, “A Proposed Clinical Staging System for Obesity” (2009) 33:3 *Int J Obes* 289.

²⁵⁸ Although a full discussion of this point is beyond the scope of this article, the debate often concerns whether or not someone who is obese can also be healthy or fit. See e.g. Joshua A Bell et al, “The Natural Course of Healthy Obesity over 20 Years” (2015) 65:1 *JACC* 101.

²⁵⁹ See *Létourneau*, *supra* note 29 at para 10.

²⁶⁰ *Supra* note 132.

²⁶¹ *Supra* note 133.

Lawsuit, *Pelman*.²⁶² While the requirements for the certification of a class are not explored here, this will present a formidable obstacle to overcome before courts would even begin to consider the merits of a failure to warn case.

There are other additional issues that warrant further consideration concerning the application of duty to warn principles to food products. For one, some thought needs to be given to what risks associated with food are so obvious and notorious that a warning will not be required.²⁶³ Additionally, there is legitimate concern that oversaturation may be a problem; if there are warnings on everything, this might only serve to confuse consumers and render warnings meaningless.²⁶⁴ Consideration needs to be given to what food products require warnings, and for what risks.²⁶⁵ Obesity is only

²⁶² *Supra* note 35.

²⁶³ Despite some of the mythology about consumers' knowledge about food, there is a large body of evidence to suggest that most people are not that informed about food products generally, including current attempts to convey nutritional information (e.g., nutrition fact panels), and thus are unlikely to be able to ascertain the true risks associated with consumption (or overconsumption) of food products. See e.g. Shelley, "Addressing the Policy Cacophony", *supra* note 231; Lisa Levy et al, "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" (2000) 14:3 Am J Health Promot 157; Fuan Li, Paul W Miniard & Michael J Barone, "The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information" (2000) 28:3 J Acad Mark Sci 425 at 427.

²⁶⁴ Waddams, *supra* note 51 at 61, for this reason, argues that courts appear to be demanding more explicit warnings for products that are really dangerous: "It is understandable that in an age where thousands of products are labelled with skulls and crossbones and other lurid symbols the consumer's sensitivity becomes a little jaded, and something more is required of a product that really is dangerous.". See also *Restatement (Third) of Torts*, which states that "[i]n some cases, excessive detail may detract from the ability of typical users and consumers to focus on the important aspects of the warnings, whereas in others reasonably full disclosure will be necessary to enable informed, efficient choices by product users." (*supra* note 219 at § 2-i).

²⁶⁵ For example, there has been some discussion about whether alfalfa sprouts require a warning, given the numerous salmonella and *E. coli* outbreaks in recent years. See Claire Leschin-Hoar, "Should Sprouts Come with a Warning Label?", *National Public Radio* (16 February 2016), online: <www.npr.org/sections/thesalt/2016/02/25/468032778/should-sprouts-come-with-a-warning-label> [perma.cc/XF74-UBXU].

one risk associated with food products. There are also legitimate procedural concerns about whether obesity litigation claims will clog the already overburdened courts, as well as speculative concerns about the impact litigation against the food industry (let alone judgments in favour of obese plaintiffs) may have on the food system (e.g., increasing the price of food, undermining incentives for the food industry to promote healthy foods,²⁶⁶ or hampering innovation²⁶⁷), given that we all rely on the food industry. These are not unimportant concerns; they are undoubtedly matters that a court will have to consider.

Notwithstanding these challenges, obesity litigation does not require the creation of a new theory of liability. Indeed, this is what is made evident through *Létourneau*. Product liability law, specifically the duty to warn, already imposes upon manufacturers an obligation to provide warnings for products that are known to cause harms, whether through proper use or misuse of the product. This obligation exists even when an industry does not accept the evidence of harm. What *Létourneau* makes clear is that manufacturers are expected to provide adequate warnings, consistent with the conditions set out in *Buchan*, to ensure that consumers are making informed choices.

CONCLUSION

Under Canadian law, it is well established that manufacturers have a duty to warn consumers about the risks inherent in their products. This duty is heightened in instances when a product is ingested or consumed. While the courts have found manufacturers liable for failing to warn about risks in situations where the risk is statistically small,²⁶⁸ as the court in *Buchan* noted, manufacturers can easily avoid liability simply by disclosing known risks to users. The underlying rationale for this duty is that it allows consumers to make informed choices about the products they consume. This duty extends to food manufacturers. Food products that have inherent risks with their consumption, including known or foreseeable risks with overconsumption, require adequate warnings to consumers. Despite this requirement, most food products do not contain such warnings.

²⁶⁶ See Roller, Voorhees & Lunkenheimer, *supra* note 23 at 420.

²⁶⁷ See McMenamin & Tiglio, *supra* note 23 at 518.

²⁶⁸ See *Hollis*, *supra* note 31 at para 41.

Many have observed that the food industry has learned from the tobacco industry, and that ultimately it has adopted the tobacco industry's playbook.²⁶⁹ This has included the food industry mimicking the tobacco industry's approach to resisting labelling and warning requirements.²⁷⁰ Like the tobacco industry, the food industry has actively undermined and thwarted attempts by the state to impose a stricter regulatory environment. It has ignored and denied the research identifying risks with its products, while simultaneously attempting to generate a scientific controversy about these risks.²⁷¹ Ultimately, despite the clear duty food manufacturers have to warn consumers, they have remained silent. Thus far, much like the tobacco industry, the food industry has benefitted from this strategy. However, the tobacco industry is starting to be held to account for their failure to adequately warn consumers. Perhaps it is time for the food industry to learn another lesson from the tobacco industry, by looking to *Létourneau*. Should it choose to ignore this lesson, *Létourneau* may very well pave the way for the future of obesity litigation in Canada.

²⁶⁹ See Linda Dorfman et al, "Soda and Tobacco Industry Corporate Social Responsibility Campaigns: How Do They Compare" (2012) 9:6 PLoS Med e1001241 at 4–5; Kelly D Brownell & Kenneth E Warner, "The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar is Big Food?" (2009) 87:1 Milbank Quarterly 259 at 262; Jess Alderman & Richard A Daynard, "Applying Lessons from Tobacco Litigation to Obesity Lawsuits" (2006) 30:1 Am J Prev Med 82 at 85–86.

²⁷⁰ See Rob Moodie et al, "Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-Processed Food and Drink Industries" (2013) 381 Lancet 670 at 674; Keith Leslie, "Ontario Bowed to the Food Industry Pressure on Menu-Labelling Legislations: Critics", *CTV News* (10 August 2016), online: <www.ctvnews.ca/health/ontario-bowed-to-food-industry-pressure-on-menu-labelling-legislation-critics-1.3022863> [perma.cc/34HA-U7GQ].

²⁷¹ See Moodie et al, *supra* note 73 at 670; Maira Bes-Rastrollo et al, "Financial Conflicts of Interest and Reporting Bias Regarding the Association between Sugar-Sweetened Beverages and Weight Gain: A Systematic Review of Systematic Reviews" (2013) 10:12 PLoS Med e1001578 at e1001578.

STRIKING THE RIGHT BALANCE: DOES THE *GENETIC NON-DISCRIMINATION ACT* PROMOTE ACCESS TO INSURANCE?

*Elizabeth Adjin-Tettey**

Effective insurance underwriting requires accurate risk assessment. Life and health insurers are concerned that widespread availability of genetic testing without requiring insurance applicants to disclose test results could result in adverse selection. The concern is that insurers could assume unreasonably high risks that might undermine the private insurance system. There are also concerns about potential genetic discrimination in access to insurance. The *Genetic Non-Discrimination Act* was enacted partly in response to these concerns. The Act prohibits insurers from demanding genetic testing as a condition for insurance or using test results in insurance underwriting without the insured's written consent. This paper argues that the Act's protection is one-sided. It also creates a false sense of security because insurers can access genetic information from health records. This paper advocates for a regime of basic insurance.

L'efficacité de la tarification d'assurance nécessite une évaluation du risque précise. Les compagnies d'assurance vie et d'assurance maladie s'inquiètent que la disponibilité croissante d'examen génétiques produise un phénomène de sélection adverse puisque les proposants n'ont pas l'obligation de divulguer leurs résultats. En conséquence, les assureurs prévoient de devoir assumer un risque déraisonnablement élevé qui pourrait potentiellement ébranler le système d'assurance privée. Une autre problématique est celle d'accès à l'assurance liée à la discrimination génétique. La Loi sur la non-discrimination génétique interdit aux assureurs d'exiger l'analyse génétique comme condition de couverture ou d'utiliser les résultats des tests pour la tarification sans le consentement écrit de l'assuré. Cet article souhaite démontrer que les protections prévues par la Loi visent uniquement le proposant. La Loi crée également un faux sentiment de sécurité puisque les assureurs pourraient

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without reference to health status and to require disclosure of health risks for policies exceeding the stated financial limit.

avoir accès à de l'information génétique se trouvant dans des dossiers médicaux. Cet article recommande un régime d'assurance de base sans référence à l'état de santé de l'assuré. La divulgation des risques de santé serait demandée seulement dans les cas où le montant de la couverture excéderait le montant maximal du régime de base.

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“The very nature of private insurance legitimates discrimination.”¹

INTRODUCTION

Advances in genetic science have made it possible to predict, diagnose, prevent, manage, and treat genetically related conditions in order to improve health outcomes and quality of life. They have also opened a potential for genetic discrimination. Persons perceived to have unfavourable genetic characteristics may face discrimination in access to employment and insurance. The Canadian public health care system provides basic but partial health care coverage. Many Canadians fill in the gaps with private health insurance policies. In addition, many Canadians depend on the private insurance system for financial planning, relying, for instance, on disability insurance, income replacement insurance, or life insurance policies. An individual's genetic status may have an impact on premiums and/or benefits provided under some policies that are related to an applicant's health status and other risk factors affecting their mortality.

Risk assessment is central to private insurance and requires applicants to disclose information regarding their risk status. An applicant must disclose risks affecting their insurability such as health status and susceptibility to illness. Breach of the disclosure duty renders the insurance contract voidable, subject to the incontestability principle regarding contracts that have been in effect for at least two years during the lifetime of the insured person, absent fraud.² Increasingly, there are concerns that the widespread availability of genetic testing and information could mean that individuals perceived to have higher-than-average susceptibility to certain illnesses will be considered undesirable insureds when applying for products such as life insurance, disability insurance, supplementary health insurance, and long-term care insurance. Specifically, the worry is that insurers may decline to insure such individuals, may offer to insure them at higher premiums that are financially prohibitive, or may offer them limited benefits. Each of these actions has the potential to deny individuals and their families access to

¹ See Law Reform Commission of Canada, *Human Dignity and Genetic Heritage: Study Paper* (1991) at 50.

² See *Insurance Act*, RSBC 2012, c 1, ss 51–52, 111–12; *Insurance Act*, RSA 2000, c I–3, ss 652–53, 719–20 ; *Insurance Act*, RSO 1990, c 1.8, ss 183–84, 308–309.

insurance, and to leave them ill-prepared for the financial consequences of unfortunate health events.

Insurance is about protecting individuals against the risk of fortuitous events. A person's risk factors are important in determining the likelihood of future health conditions and mortality, and are the basis of risk assessment in insurance underwriting. There are many unknowns in a person's future health status. Genetic test results may point to the probability of an individual suffering a particular condition compared to the general population. However, that information is not indicative of whether that person will actually suffer the condition in question.

The Parliament of Canada enacted the *Genetic Non-Discrimination Act* ("the Act")³ in 2017. Among other things, the Act prohibits insurers from (1) demanding that applicants undergo genetic testing as a condition for insurance and (2) using information yielded by genetic tests in insurance underwriting absent the applicant's written consent.⁴ This paper focuses on the Act, asking whether its prohibition on the use of genetic information in the underwriting process is the right way to allay concerns about genetic discrimination and promote equality of access to private insurance products.

Life and health insurers routinely use general health data that may also include genetic information in determining insurability. The Act's prohibition on the use of genetic information may therefore have a limited effect in protecting insurance applicants and promoting equal access to insurance. Insurers emphasize the importance of risk segregation in the underwriting process to justify consideration of an applicant's future risk factors including those that are genetically related in determining insurability. However, there may be questions about the value of genetic information in predicting future health risks. The paper proposes a regime that is attentive to the concerns of critics of genetic discrimination and the insurance industry: the provision of basic insurance up to a stated financial limit without reference to an individual's health status whether genetically related or not. For policies exceeding the stated financial limit, the paper argues that as a matter of fairness, risk assessment should be based on health conditions that are already manifest or where the predictive accuracy of the genetic information is fairly guaranteed such that there is a high probability of the person experiencing that condition, as is the case with conditions such as Huntington's disease.

³ See *Genetic Non-Discrimination Act*, SC 2017, c 3 [the Act].

⁴ See *ibid* at s 3.

Part I briefly discusses the nature of genetic testing and concerns about the potential for genetic discrimination, including access to insurance. In Part II, the paper provides a brief history of the Act. Part III canvasses some of the Canadian Life and Health Insurance Association's responses to the prohibition on using genetic test results without the individual's written consent when making underwriting decisions. In Part IV, the paper reflects on how far the Act goes in preventing discrimination in access to insurance. Finally, in Part V, the paper makes the case for a separate regulatory regime for the use of genetic information in providing insurance. It argues for promoting equity in access to insurance and offers proposals for regulating the provision of private insurance to avoid discrimination on the bases of genetic and other health statuses. Such a regime is premised on the socialization of risks, the notion that basic insurance is a social good that should be accessible to all persons regardless of their health status, and that society, or the insurance pool as a whole, rather than individual insureds, should bear the risk of providing such coverage.⁵

I. GENETIC TEST INFORMATION AND CONCERNS ABOUT GENETIC DISCRIMINATION

Genetic test results may indicate the possibility of a future condition, but cannot determine, *inter alia*, whether an individual will actually suffer the disorder in question, or when symptoms will occur and with what severity. Predictive genetic tests might reveal benign disorders or abnormalities that never materialize.⁶ Test information, especially for single gene and/or highly penetrable conditions, may indicate that a person is pre-symptomatic for a future disorder or at a higher risk of developing the disorder compared to the general population.⁷ Furthermore, testing may identify genetic

⁵ See William H Huff II, "Development of Public Policy from the Viewpoint of a State Insurance Regulator" (1975) 7 Insurance L J 393 at 395; Robert B Meyer, "Justification for Permitting Life Insurers to Continue to Underwrite on the Basis of Genetic Information and Genetic Test Results" (1993) 27 Suffolk U L Rev 1271 at 1273; Spencer L Kimball, "The Purpose of Insurance Regulation: A Preliminary Inquiry on the Theory of Insurance Law" (1960) 45 Minn L Rev 471 at 512–14.

⁶ See Nora Pashayan & Paul Pharoah, "Translating Genomic into Improved Population Screening: Hype or Hope" (2011) 130 Hum Genet 19.

⁷ See Office of the Privacy Commissioner of Canada, "The Predictive Value of Genetic Information: A Conversation with Dr. Steve Scherer, Director, the

markers that when combined with other factors, including lifestyle and environmental variables, could produce a particular disorder (non-monogenic diseases).⁸

Tests may also identify inherited abnormalities or conditions that are preventable or treatable and which may have no adverse health or mortality implications for individuals. Moreover, given the complex causes and origins (etiology) of many diseases, the predictive value of a particular test or genetic abnormality may not be significant in determining an individual's risk level. As Krajewska notes, "genetic data may vary substantially in their level of predictability, susceptibility or even potential for identification purposes, which depends on the level of relatedness to the person. The most apparent differences appear among monogenic and polygenic or multifactorial diseases."⁹ Yet, asymptomatic individuals and their relatives may be denied insurance, charged higher premiums, or provided limited benefits based on inaccurate or incomplete information regarding their susceptibility for a condition they may never experience.¹⁰

Some individuals are reluctant to undergo genetic testing or participate in research studies for fear of genetic discrimination.¹¹ There are personal,

Centre for Applied Genomics, the Hospital for Sick Children and Professor of Medicine, University of Toronto" (last modified 21 December 2012), online: *Office of the Privacy Commissioner of Canada* <www.priv.gc.ca/en/opc-actions-and-decisions/research/explore-privacy-research/2012/gi_qa/> [perma.cc/3CVB-J77C]; UK Government & Association of British Insurers, "Code on Genetic Testing and Insurance" (2018) at 4–6 (The UK Code), online (pdf): <www.abi.org.uk/globalassets/files/publications/public/genetics/code-on-genetic-testing-and-insurance_embargoed.pdf> [perma.cc/5ZFH-D33P].

⁸ See Office of the Privacy Commissioner of Canada, *supra* note 7.

⁹ Atina Krajewska, "Conceptual Quandaries about Genetic Data – A Comparative Perspective" (2009) 16 Eur J Health L 7 at 15.

¹⁰ See Margaret Otłowski, S Taylor & Yvonne Bombard, "Genetic Discrimination: International Perspectives" (2012) 13 Annu Rev Genomics Hum Genet 433 (for a discussion of the phenomenon of genetic discrimination).

¹¹ See "Statement on the Use of genetic test results by Life and Health Insurance Companies" (July 2014), online: *Office of the Privacy Commissioner of Canada* <www.priv.gc.ca/en/opc-news/news-and-announcements/2014/sd_140709/> [perma.cc/CF5F-JSV3]; "Why is Protection from Genetic Discrimination Needed?" online: *Canadian Coalition for Genetic Fairness* <ccgf-cceg.ca/en/about-genetic-discrimination/#why-protection-is-needed> [perma.

familial, and societal costs associated with this phenomenon, including not benefitting from early diagnosis, treatment, or prevention of genetically related conditions that could improve individual health outcomes and quality of life, as well as the overall health of the population.¹² Further, reluctance to undergo testing deprives individuals and society, including the insurance industry, of the benefits of scientific and medical advances that could reduce actual or perceived risk factors and improve insurability.¹³

Genetic testing also raises privacy concerns when entities such as insurers have access to individuals' test results.¹⁴ Health care professionals have described the lack of legislation protecting confidentiality of genetic test results as paralyzing. Some geneticists and medical ethicists share this view.¹⁵

cc/SC88-S4WC]; UK Government & Association of British Insurers, *supra* note 7 at Introduction; *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17 at paras 43, Karakatsani J, 109, Moldaver J, concurring, 17, Kasirer J, dissenting.

¹² See *Reference re Genetic Non-Discrimination Act*, *supra* note 11 at paras 56, 97–99, Karakatsani J, 117, 142, 146, 150, Moldaver J, concurring; Yann Joly et al, “Life Insurance: Genomic Stratification and Risk Classification” (2014) 22 Eur J Hum Genet 575 at 577; Otlowski et al, *supra* note 10 at 436, 439–41; Robert C Green et al, “GINA, Genetic Discrimination, and Genomic Medicine” (2015) 372:5 New Engl J Med 397 at 398; Kira Peikoff, “Fearing Punishment for Bad Genes”, *The New York Times* (7 April 2014), online: <www.nytimes.com/2014/04/08/science/fearing-punishment-for-bad-genes.html> [perma.cc/DEA3-BF2Q]; “Genetic Discrimination and the Genetic Non-Discrimination Act” (May 2018), online (pdf): *Huntington Society of Canada* <www.huntingtonsociety.ca/wp-content/uploads/2018/05/Genetic-Discrimination-Fact-Sheet-2018-1.pdf> [perma.cc/U5D9-4SA4].

¹³ See Robert Klitzman, Paul S Applebaum & Wendy K Chung, “Should Life Insurers Have Access to Genetic Test Results?” (2014) 313:18 JAMA 1855 at 1855.

¹⁴ See Office of the Privacy Commissioner of Canada, “Statement on the Use of Genetic Test Results by Life and Health Insurance Companies” (last modified 14 July 2014), online: <www.priv.gc.ca/en/opc-news/news-and-announcements/2014/s-d_140709/> [perma.cc/V4ZP-VUGY]; Andrea Hun-car, “Probing your DNA could Trigger Future Privacy Violations”, *CBC News* (24 April 2018), online: <www.cbc.ca/news/canada/edmonton/dna-testing-1.4632272> [perma.cc/UY9U-MV5Y]; *Reference re Genetic Non-Discrimination Act*, *supra* note 9 at paras 84–87, Karakatsani J, 144, Moldaver J, concurring.

¹⁵ See Nicole Ireland, “Genetic Discrimination Law Urgently Needed, Experts

Advocates of genetic fairness and equality of access to insurance products also argue against the use of genetic information in making underwriting decisions.¹⁶

The Act¹⁷ prohibits, *inter alia*, the use of genetic information obtained through genetic testing in insurance underwriting except with the applicant's written consent.¹⁸ The Canadian Life and Health Insurance Association (CLHIA)¹⁹ opposes legislation prohibiting the use of genetic information for insurance underwriting.²⁰ The CLHIA has expressed concern that ignoring genetic information indicating an individual's higher-than-average risk in the underwriting process could undermine the disclosure duty and risk assessment process that are central to private insurance.²¹ The prohibition could also result in insurers assuming unreasonably high risks not properly accounted for in the underwriting process, and thereby undermine the viability of the private insurance system. As Justice Steele noted in *Thorn-ton v North American Life Assurance Co*: "The [private insurance] industry

Say" *CBC News*, (30 June 2016), online: <www.cbc.ca/news/health/genetic-discrimination-bill-s201-1.3425408> [perma.cc/SHZ4-ELG4].

¹⁶ See Office of the Privacy Commissioner of Canada, *supra* note 7.

¹⁷ See the Act, *supra* note 3.

¹⁸ See *ibid* at s 5.

¹⁹ The Canadian Life and Health Insurance Association is a voluntary organization representing life and health insurers in Canada. It has 69 members, not including associated companies. CLHIA members provide 99% of life and health insurance in Canada, providing a wide range of products including life insurance, annuities and supplementary health insurance to over 28 million Canadians. See CLHIA, "Our Members", online: <www.clhia.ca/web/CLHIA_LP4W_LND_Webstation.nsf/page/155D2E272E4A7D87852578150078A752> [archived URL].

²⁰ See CLHIA, "Intervener Factum in *Canadian Coalition for Genetic Fairness v Attorney General of Quebec et al*" (3 July 2019), online: <https://www.scc-csc.ca/WebDocuments-DocumentsWeb/38478/FM060_Intervener_Canadian-Life-and-Health-Insurance-Association.pdf> [archived URL] at paras 14-15: *Reference re Genetic Non-Discrimination Act*, *supra* note 11.

²¹ See CLHIA, "Intervener Factum in *Canadian Coalition for Genetic Fairness v Attorney General of Quebec et al*", *supra* note 20 at paras 6-15. See also Meyer, *supra* note 5 at 1278-82.

operates for profit and does not provide coverage for everyone as if it were a public insurer of all citizens.”²²

However, as Joly et al note: “the damage to the public profile of insurers from insisting on access to such information for underwriting may outweigh its current commercial value.”²³ Notwithstanding the business case for accurate risk prediction, there is a public interest in some element of socialization of risks and access to insurance as a mechanism for managing risks in modern society. This calls for some level of equality in access to insurance regardless of a person’s genetic characteristics or health status. Action is required to allay concerns on both sides.

II. THE *GENETIC NON-DISCRIMINATION ACT*²⁴

A. *Developments Leading to Enactment of the Act*

Prior to the Act, the CLHIA adopted a voluntary industry regulation advising its members not to require an insurance applicant to undergo genetic testing as a condition for providing coverage.²⁵ However, where an individual had already undergone testing, the result was subject to the usual disclosure duty in an application for insurance or changes to coverage.²⁶ Thus, individuals who had taken genetic tests that indicated particular diagnoses or a higher than average susceptibility to an illness risked breach of the disclosure duty if they did not disclose the results in their application for insurance or in modifications to an existing policy. Notwithstanding the CLHIA voluntary industry regulation, there is evidence that members rou-

²² *Thornton v North American Life Assurance Co* (1995) 123 DLR (4th) 709 at para 19, [1995] OJ No 866 (Ont Ct Jus (Gen Div) Div Ct) [*Thornton*].

²³ Joly et al, *supra* note 12 at 577.

²⁴ See the Act, *supra* note 3.

²⁵ See Office of the Privacy Commissioner of Canada, “Statement on the Use of Genetic Test Results by Life and Health Insurance Companies”, *supra* note 14 (Genetic Testing and Insurance in Canada).”

²⁶ See *ibid.*

tinely ignored the policy and required applicants to undergo genetic testing to determine their insurability.²⁷

In 2015, Senator James Cowan introduced Bill S-201 as a private member's bill.²⁸ A stated purpose of the bill was to fill the "gap in our laws [...] preventing many Canadians from accessing the extraordinary advances taking place in medical science."²⁹ In his submissions in support of the bill, Senator Cowan referred to testimony before the Human Rights Committee that insurance companies routinely ignore the CLHIA policy by demanding that applicants undergo genetic tests before qualifying for insurance.³⁰

B. Overview of the Act

The Act aligns legislative protections with advancements in genetic science and medicine. It ensures that individuals can benefit from these advancements to improve their health outcomes and quality of life while safeguarding against discrimination in access to services, employment, and insurance on the basis of a person's genetic characteristics. Specifically, the Act prohibits any person from demanding that an individual undergo or disclose the results of genetic testing as a condition of providing goods or services, or of entering into employment or insurance contracts with that individual.³¹ The Act also prohibits access to and use of information obtained

²⁷ See *ibid.*

²⁸ There had been previous attempts to prohibit discrimination on the basis of genetic characteristics that required amending the federal and Ontario human rights codes. The proposals did not progress through the legislative processes. See e.g. Bill C-508, *An Act to Amend the Canadian Human Rights Act (genetic characteristics)*, 3rd sess, 40th Parl, 2011; Bill C-536, *An Act to amend the Human Rights Act (genetic characteristics)*, 3rd Sess, 40th Parl, 2010 (*Hansard*, No 062 (14 June 2010) at 1505 (Mr. Bill Biksay). See also Bill C or S - 199, *An Act to amend the Human Rights Code with respect to genetic characteristics*, 2nd Sess, 39th Leg, Ontario, 2011 (first reading 18 May 2011).

²⁹ See Senate of Canada, Honourable James S Cowan, "Genetic Non-Discrimination Bill", *Official Report of Debates (Hansard)*, (27 January 2016) at 1430, online: <sencanada.ca/en/Content/Sen/chamber/421/debates/008db_2016-01-27-e#28> [perma.cc/8493-27TE].

³⁰ See *ibid* at 1440.

³¹ The Act, *supra* note 3 at ss 3–4.

through genetic testing without the individual's consent in determining access to basic social goods.³² A person who engages in prohibited conduct is guilty of an offence punishable by a fine or a term of imprisonment.³³ In *Reference re Genetic Discrimination Act*, the Supreme Court of Canada noted that the Act's purpose is to give individuals control over whether to undergo genetic testing, who gets access to their test results and how they may be used in order to avoid the risk of genetic discrimination.³⁴

The Act makes no specific mention of the insurance industry. However, the insurance industry is within the scope of the legislation because insurance is both a service and a contract between insurers and insureds.³⁵ Further, in *Reference re Genetic Discrimination Act*, the Court acknowledged the impact of the Act on the insurance industry, in particular the obligation to disclose material health information in an application for life or health insurance.³⁶

The Canadian Coalition of Genetic Fairness (CCGF) views the Act as the law's attempt to keep pace with science and technology. The CCGF has expressed relief that individuals and families no longer have to worry about the repercussions of undergoing genetic testing, especially for diagnostic and therapeutic purposes.³⁷ The Act promotes equal access to insurance,

³² See *ibid* at s 5.

³³ See *ibid* at s 7.

³⁴ *Reference re Genetic Discrimination Act*, *supra* note 11 at paras 54–56, Karakatsanis J.

³⁵ See *Insurance Corp of British Columbia v Heerspink*, [1982] 2 SCR 145, 137 DLR (3d) 219. The Court found that insurance (specifically fire insurance) is a service customarily available to the public for purposes of the *Human Rights Code*, s 3 (now s 8) and an insurer cannot deny coverage on the basis of an enumerated ground absent reasonable cause for such denial. See also *Zurich Insurance Co v Ontario (Human Rights Commission)*, [1992] 2 SCR 321, 93 DLR (4th) 346 [Zurich] (automobile insurance). See also *J v London Life Insurance Co.*, [1999] BCHRTD 36 at para 28 (life insurance).

³⁶ See *Reference re Genetic Discrimination Act*, *supra* note 11 at paras 57–59, 60–62, Karakatsanis J, 215–17, 220, Kasirer J, dissenting.

³⁷ See Canadian Coalition for Genetic Fairness (CCGF), “Why is Protection from Genetic Discrimination Needed?”, (n.d.), online: *Canadian Coalition for Genetic Fairness* <ccgf-cccg.ca/en/about-genetic-discrimination/#why-protection-is-needed> [perma.cc/LZ6T-592L].

regardless of a person's genetic characteristics. The Act appears to accord special status to human genetic information, treating it as unique and different from other health information, and deserving of special protections compared to other health data. This special status is referred to as genetic exceptionalism.³⁸ However, the Act does not prohibit the use of genetic information in the underwriting process where the information can be obtained from a source other than a genetic test, such as the applicant's medical records or family medical history.³⁹

The Act's prohibition on the use of genetic test information absent the insured's consent is consistent with the United Nations' and Council of Europe's responses to the issue of genetic discrimination in access to insurance. These organizations recognize that discrimination on the bases of genetic characteristics raises issues of human dignity and equality and should be prohibited. For instance, the *Charter of Fundamental Rights of the European Union* prohibits discrimination on the bases of genetic features.⁴⁰ The *International Declaration on Human Genetic Data*, adopted by UNESCO's General Conference in October 2003, specifically urges states to ensure that genetic data is not disclosed or accessible to insurance companies.⁴¹ With

³⁸ See *Reference re Genetic Discrimination Act*, *supra* note 9 at para 253, Kasirer, J, dissenting; Elizabeth Adjin-Tettey, "Potential for Genetic Discrimination in Access to Insurance: Is there a Dark Side to Increased Availability of Genetic Information" (2013) 50(3) *Alta L Rev* 577 at 596–600 (for a discussion of the concept of genetic exceptionalism and arguments for and against this practice, including in insurance); Sirpa Soini, "Genetic Testing Legislation in Western Europe – a Fluctuating Regulatory Target" (2012) 3 *J Community Genet* 143 at 144–45, 151; Krajewska, *supra* note 9 at 18.

³⁹ The disclosure of such information is pursuant to the disclosure duty that requires applicants to disclose risks affecting their insurability. See *supra* note 2.

⁴⁰ See European Convention, *Charter of Fundamental Rights of the European Union*, Article 21 (2000/C 364/01) (December 18, 2000). Pursuant to the Lisbon Treaty of December 2009, the Charter is of the same binding authority similar to treaties. However, not all member states have included prohibition of discrimination on the bases of genetic features in their national laws. See e.g. Isabelle Chopin and Catharina Germaine, *A Comparative Analysis of Non-discrimination Law in Europe, 2017: The 28 EU Member States, the Former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Montenegro, Norway, Serbia and Turkey Compared* (Luxembourg: Publications Office of the European Union, 2017) at 12–14.

⁴¹ See *International Declaration on Human Genetic Data*, 32 C Res, UNESCO, 2003, art 14(b).

the Act, Canada responded to international concerns about the use of genetic testing and followed the approach of international organizations.

III. OBJECTIONS TO THE *GENETIC NON-DISCRIMINATION ACT*

The CLHIA, an organization that represents most life and health insurers in Canada, opposed enactment of the Act on two principal grounds. First, the CLHIA argued that the Act undermines the disclosure duty, accurate risk prediction in insurance underwriting, and hence the principle of utmost good faith in insurance contracts.⁴² Second, the CLHIA argued that the Act is *ultra vires* Parliament's jurisdiction because it regulates insurance, an activity within the provinces' property and civil rights power under the *Constitution Act*, 1867, s 92(13).⁴³ In *Reference re Genetic Non-Discrimination Act*, the majority of the Court upheld the constitutionality of the Act as constituting a valid exercise of Parliament's criminal law power pursuant to the *Constitution Act*, 1867, s 91(27).⁴⁴

The CLHIA's first ground of opposition arises from the basis that insurance is about transferring the risk of an uncertain future event to another person, the insurer, in exchange for consideration (i.e., premiums). Premiums and benefits are assessed based on the extent of the applicant's risk level, that is, the likelihood of the event occurring, with insurers charging a higher premium and/or providing reduced benefits where there is a higher than average risk. The disclosure duty ensures symmetry between the applicant's and insurer's knowledge of the former's health risks. Disclosure of risks allows the insurer to make actuarially sound decisions about the applicant's insurability. From insurers' perspectives, prohibition on the disclosure or use of genetic information permits informational asymmetry between applicants for insurance and insurers, which is likely to undermine the effective underwriting of risks.⁴⁵ Non-disclosure of genetic test results

⁴² See CLHIA, "Intervener Factum", *supra* note 20.

⁴³ See *Constitution Act* 1867 (UK), 30 & 31 Vict, c 3, s 92(13), reprinted in RSC 1985, App II, No 5.

⁴⁴ *Reference re Genetic Non-Discrimination Act*, *supra* note 11.

⁴⁵ See e.g., Michael Hoy & Julia Witt, "Welfare Effects of Banning Genetic Information in the Life Insurance Market: The Case of BRCA1/2 Genes" (2007) 74 J Risk Insur 526; See also Meyer, *supra* note 5 at 1274, 1278–82; Green et al, *supra* note 12 at 399; Donald H Taylor Jr et al, "Genetic Testing for Alz-

also raises concerns about the potential for adverse selection. The concern is that individuals whose genetic test results indicate a higher-than-average risk of developing an illness could take out insurance in higher amounts than they otherwise would have.⁴⁶ Meanwhile, low risk individuals may seek to obtain insurance for below average rates or, failing that, opt out of the insurance market altogether, thereby leaving too many higher risk individuals in the insurance pool.⁴⁷ The problem could be exacerbated as genetic testing becomes broadly available and more people become aware of their risk levels.⁴⁸

Canadian life and health insurers are concerned about the cost of the ban on the disclosure or use of genetic information without a person's consent in determining customers' insurability. According to the CLHIA, insurers' inability to accurately assess risks will, over time, increase their liability.⁴⁹ Insurers are likely to respond to the increased risk by raising the cost of insurance for all customers. This could in turn make insurance products unaffordable for many Canadians, taking such products beyond the reach of those who need them most.⁵⁰ Hence, many Canadians will be ill-prepared to face the financial consequences of unfortunate events.

heimer's and Long-Term Care Insurance" (2010) 29:1 Health Aff (Milwood) 102 at 105–107; Michael Hoy & Maureen Durnin, "The Potential Economic Impact of a Ban on the Use of Genetic Information for Life and Health Insurance" (2012) at 6–10, online (pdf): *Office of the Privacy Commissioner of Canada* <www.priv.gc.ca/media/1747/gi_hoy_201203_e.pdf> [perma.cc/XVP7-TECX] at 3, 6–7, 14; Susan Goldberg, "Insurers Lose Genetic Testing Fight: Canadian Insurers can no Longer ask Applicants to Disclose Genetic Test Results" (10 May 2017), online: *Advisor's Edge* <www.advisor.ca/insurance/life/insurers-lose-genetic-testing-fight/> [perma.cc/9DZ5-UWK6].

⁴⁶ See Hoy & Durnin, *supra* note 45; *Reference re Genetic Discrimination Act*, *supra* note 11 at para 88 (*per* Karakatsanis J).

⁴⁷ See *ibid.*

⁴⁸ See *ibid.*

⁴⁹ See CLHIA, "Intervener Factum", *supra* note 20 at paras 1, 15, 21; *Reference re Genetic Discrimination Act*, *supra* note 9 at para 57.

⁵⁰ See CLHIA, "Intervener Factum", *supra* note 20; Hoy & Durnin, *supra* note 45 at 5.3.

A. Responses to the Canadian Life and Health Insurers' Concerns

To date, the insurance industry has functioned relatively well with no empirical evidence of adverse selection by persons with knowledge of their higher-than-average risk status.⁵¹ The Act's prohibition on the use of genetic test information in the underwriting process is not unique. Some countries expressly prohibit the use of genetic information in making underwriting decisions.⁵² Other jurisdictions have adopted a tiered system prohibiting insurers from asking and/or using an applicant's genetic characteristics in making underwriting decisions unless an applicant seeks coverage in significant amounts or above a stated limit.⁵³ Furthermore, many insurance companies operating in Europe have agreed on a moratorium not to use genetic information in making underwriting decisions.⁵⁴

⁵¹ See Angus Macdonald, "The Actuarial Relevance of Genetic Information in the Life and Health Insurance Context" (2012), online (pdf): *Office of the Privacy Commissioner of Canada* <www.priv.gc.ca/media/1737/gi_macdonald_201107_e.pdf> [perma.cc/ZK6S-U5MT] at 1, 6–9; Hoy & Durnin, *supra* note 45 at 6–9.

⁵² See e.g. *Gene Technology Act*, 1995, art 67 (Austria).

⁵³ See e.g. United Kingdom Government & Association of British Insurers, *supra* note 7; Germany: *Gendiagnostikgesetz-GenDG* 374/09, Article 18; Sweden, Genetic Integrity Act, 2006, Article 2.1; Switzerland: *Loi fédérale sur l'analyse génétique humaine du 8 octobre 2004* (1.4.2007), Articles 26–28. Additionally, the United States *Genetic Information Nondiscrimination Act (GINA)*, Title I, prohibits genetic discrimination in the provision of health insurance. Specifically, health insurers may not require applicants or their family members to take a genetic test or use genetic information in determining eligibility, coverage or premium. However, *GINA* does not apply to long-term care insurance, life insurance or disability insurance. See also "Genetic Discrimination", online: *National Human Genome Research Institute* <www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination> [perma.cc/RH6X-TC5Q]. Three states (California, Oregon, and Vermont) had regulated genetic information in various depths with respect to insurance by 2014. In 2014, an insurance company indicated that they wanted to request genetic information but did not want to be the first to do so. See Kira Peikoff, "Fearing punishment for bad genes", *The New York Times* (7 April 2014), online: <www.nytimes.com/2014/04/08/science/fearing-punishment-for-bad-genes.html> [perma.cc/U3SL-LMJ9]; Klitzman, Applebaum & Chung, *supra* note 13 at 1856.

⁵⁴ See Soini, *supra* note 38 at 151.

Based on lessons from jurisdictions where insurers do not use genetic test information in the underwriting process, there does not appear to be evidence of strain on the insurance industry from providing life and health insurance without reference to genetic test results. However, the CLHIA points out that there are important differences between the life insurance market in Europe and in Canada. Life insurance policies in Canada can be for extended periods, such as whole life policies or policies that can last for three or four decades.⁵⁵ In contrast, policies in European markets tend to be for shorter periods. Insurers in European markets can reassess their customers' insurability on an ongoing basis with each new policy.⁵⁶ Meanwhile, Canadian insurers may be locked in for extended periods with no opportunity to reassess an individual's insurability after commencement of the policy.⁵⁷ This system makes Canadian life and health insurers susceptible to assuming risks that may be disproportionate to premiums that the insured person pays.⁵⁸

It appears that the CLHIA's concerns may stem from rapidly evolving advancements in genetic science and along with that, individuals' ability to know more about their deoxyribonucleic acid (DNA) and future health risks. However, there is not necessarily a correlation between genetic markers and diseases. Advancements in genetic science are not limited to predicting future health risks. Genetic disorders may be preventable, treatable, or manageable, with the exception of limited situations such as monogenic (single gene disorders) and high penetrance disorders. Individuals who learn of their predisposition to particular disorders would likely consider preventative measures and treatment options where available. These individuals can benefit from medical advances such as pharmacogenomics (tailoring pharmacological interventions to a patient's specific genetic profile for maximum efficacy), which can improve health outcomes and quality of life. Some individuals may obtain insurance or increase their coverage when they become aware of their genetic risks. Thus, even though there is lack of evidence about adverse selection at this time, the future potential

⁵⁵ See Goldberg, *supra* note 45.

⁵⁶ See *ibid.*

⁵⁷ See *ibid.*

⁵⁸ See *ibid.*

of this phenomenon cannot be completely dismissed as genetic testing becomes more widely available.⁵⁹

However, the insurance industry's concerns about adverse selection may be unjustified. The risk of adverse selection may be mitigated by ensuring access to a basic amount of insurance regardless of health status or risk factors. The outright prohibition approach in the Act likely goes beyond what is necessary to avoid discrimination in access to life and health insurance.

IV. REFLECTIONS ON THE CURRENT CANADIAN POSITION: HOW FAR DOES THE *GENETIC NON-DISCRIMINATION ACT* GO?

The Act adopts broad prohibitions regarding access to and use of genetic tests absent an individual's written consent. The ban includes predictive, diagnostic, prognostic and monitoring tests. The broad prohibition makes sense in the context of areas such as employment and public services, and in non-insurance contracts that do not depend on risk prediction and pooling. However, the very nature of insurance requires insurers to classify people based on risk in order to determine insurance premiums and benefits.

Enacting limits on access to and use of genetic information in the provision of all services and contracts in the same legislation fails to make the necessary distinctions between insurance and other services and contracts. Further, it fails to recognize the rationale of the disclosure duty in insurance contracts. Individuals who may be pre-symptomatic and whose test results may disclose almost certain onset (usually in relation to monogenic diseases),⁶⁰ or deterioration of a genetically related condition that may already be manifest, can obtain insurance coverage without having to disclose that information. There is some merit in not having to disclose predictive genetic test information given the uncertainty regarding their predictive

⁵⁹ See Michael Hoy, "Why Insurers are Wrong about Canada's Genetic Non-Discrimination Law" (13 September 2017), online: *The National Post* <nationalpost.com/pmn/news-pmn/why-insurers-are-wrong-about-canadas-genetic-non-discrimination-law> [perma.cc/6EGZ-FT2W]; Hoy & Durnin, *supra* note 45 at 6, 14.

⁶⁰ Monogenic conditions are caused by a single mutation in a single gene in the human DNA. See "Human Genomics in Global Health: Genes and Human Diseases" (2020), online: *World Health Organization* <www.who.int/genomics/public/geneticdiseases/en/index2.html> [perma.cc/T8Y6-U3DF] [WHO].

value.⁶¹ However, there is no justification for prohibiting the use of test results that are relatively certain in terms of the individual's risk factors.

A further concern is that by limiting the ban to predictive test results, the Act creates inequality among applicants for insurance. Specifically, applicants for insurance with genetically related conditions that elevate their risk status do not have to disclose that information. Meanwhile, applicants with other pre-existing conditions such as cardiovascular disease, chronic respiratory disease, or diabetes that may predispose them to the same or similar mortality rate do not enjoy similar protections.⁶² Nor does the Act protect applicants with immutable characteristics or other factors that predispose them to diseases.⁶³ The Canadian Institute of Actuaries has referred to the Act's differentiation between applicants for insurance based on genetic and non-genetic characteristics as irrational and discriminatory.⁶⁴

Further, the Act only speaks of written consent but does not specifically state that the consent should be informed or what the written consent might entail. The Act does not address the potential for coerced written consent with the allure of lower premiums and increased benefits which could arise in the insurance context but is perhaps less likely in other service or contract settings. Admittedly, life and health insurance companies are bound by the protections accorded to individuals in legislation that protect personal and health information. Among other things, insurers must disclose to customers the purpose for collecting that information prior to obtaining their consent.⁶⁵ It is an offence, subject to a fine, for organizations to use decep-

⁶¹ See *supra* note Part I at n 5–9 and accompanying text.

⁶² See William Burrows & Dante G Scrapel, "Disease", *Encyclopædia Britannica* (6 March 2020), online: <www.britannica.com/science/disease> [perma.cc/34QY-8GK2].

⁶³ See Ine Van Hoyweghen, "Taming the Wild Life of Genes by Law? Genes Reconfiguring Solidarity in Private Insurance" (2010) 29:4 *New Genet Soc* 431 at 441.

⁶⁴ See "Canadian Institute of Actuaries' Proposed Amendment to Bill S-201, *An Act to Prohibit and Prevent Genetic Discrimination*" (21 November 2016) at 1, online (pdf): *Canadian Institute of Actuaries* <www.ourcommons.ca/Content/Committee/421/JUST/Brief/BR8610557/br-external/CanadianInstituteofActuaries-e.pdf> [perma.cc/DZ4V-5GQ4] [CIA].

⁶⁵ See *Personal Information Protection and Electronic Documents Act*, SC 2000, c 5, s 6.1; *Personal Information Protection Act*, SBC 2003, c 63, ss 6, 7, 10

tion or coercion to collect personal information.⁶⁶ An individual affected by such conduct has a cause of action for damages against the offending organization.⁶⁷ However, given the centrality of the disclosure duty in insurance underwriting and inequality between insurers and applicants for insurance, legislation regulating access to and use of genetic information should specifically address how insurers may obtain consent and provide safeguards against deceptive or coercive practices in the insurance context.

The Act's outright ban, subject to the individual's written consent, may be contrasted with the United Kingdom *Code on Genetic Testing and Insurance* (The UK *Code*).⁶⁸ The UK *Code* permits, as a matter of fairness, the use of predictive test results in making underwriting decisions in limited circumstances, specifically in relation to single gene disorders with a high probability that a person with the gene will develop the condition, as is the case with Huntington's disease.⁶⁹ In recognition of the fact that scientific and medical knowledge is continually evolving, the UK *Code* includes a process for determining and approving conditions that may be added to the list of predictive test results that an insurer may require a customer to disclose where the sought amount exceeds the financial limit set in the UK *Code*.⁷⁰ The UK *Code* also contains a commitment to address possible changes in the genetic testing environment regarding predictive tests that may impact the insurance market more generally.⁷¹ The Act does not include such a

[BC *PIPA*]; *Personal Information Protection Act*, SA 2003, c P-6.5, ss 7, 8, 10; *Personal Health Information Protection Act*, 2004, SO 2004, c 3, Sch A, s 18.

⁶⁶ See BC *PIPA*, *supra* note 65, s 56; Alberta *Personal Information Protection Act*, *supra* note 49, s 59.

⁶⁷ See BC *PIPA*, *supra* note 65, s 57; Alberta *Personal Information Protection Act*, *supra* note 49, s 60.

⁶⁸ See UK Government & Association of British Insurers, *supra* note 7.

⁶⁹ See *ibid*, Commitment 2, Appendix I.

⁷⁰ See *ibid* at 13.

⁷¹ See *ibid* at 5, 13. Commitments in the UK *Code* is premised on the current state of knowledge about genetic testing. The Government and the ABI recognize that this is a rapidly evolving area. It is therefore possible that the current commitments could become unsustainable, for example, where the potential for adverse selection due to informational asymmetry between insurers and individuals applying for insurance becomes evident. Such a situation would necessitate the parties to the Code re-examining the nature of the Commitments

mechanism, which could give customers an unfair advantage as knowledge about genetic science evolves.

The Act prohibits insurers from requiring their customers to undergo genetic testing as a condition for providing insurance. However, insurers are not precluded from using genetic test results with the customer's written consent, presumably where such information is favourable to the customer and is submitted voluntarily.⁷² This provides an opportunity for customers to disclose genetic test results, among other things, to counteract family medical history or some other information in their medical records that may suggest they may be at an above-average risk of developing a particular condition, especially in relation to monogenic diseases.⁷³ For instance, an applicant who has one parent that has developed symptoms of an autosomal recessive disease such as Tay-Sachs, and the other parent has tested negative to the gene, might want to provide that information to an insurer to allay concerns that they may have inherited the defective genes because one must inherit two defective genes, one from each parent, in order to inherit the disease.⁷⁴ Disclosure of genetic tests by consent is intended to prevent discrimination against individual customers. However, the result is a one-sided protection of customers and a system that is not attentive to the potential for adverse selection. The potential for and consequences of adverse selection may be inconsequential where the number of policies that may be affected by the non-disclosure are relatively low. However, this could be naïve optimism given the rapidly evolving number of genetic testing and the nature of information derived from those tests.

to ensure access to insurance while also protecting the viability of the insurance industry.

⁷² See The Act, *supra* note 3, s 5.

⁷³ For example, individuals whose family medical history include a parent that has developed symptoms of an autosomal dominant genetic disorder such as Huntington's that exposes their children to a 50/50 chance of inheriting the gene. See WHO, *supra* note 60.

⁷⁴ See *ibid.* See also "Genetics Home Reference: Your Guide to Understanding Genetic Conditions" (March 2020), online: *United States National Library of Medicine* <ghr.nlm.nih.gov/primer/inheritance/inheritancepatterns> [perma.cc/Y6DF-V7CG].

A. *Permissible Discrimination by Insurers on the Bases of Identifiable Characteristics*

As already noted, risk segmentation is central to insurance underwriting and legitimates some forms of differential treatment of persons with certain characteristics.⁷⁵ All Canadian jurisdictions have human rights legislation prohibiting discrimination on enumerated grounds in the provision of services (including insurance), unless the service provider has *bona fide* and reasonable justification for making those distinctions.⁷⁶ In *Zurich Insurance Co v Ontario (Human Rights Commission)*, the Court held that insurers may engage in what would otherwise constitute discriminatory practices provided they can justify the practice as based on sound and accepted industry practice and there is no practical alternative open to the insurer.⁷⁷ To constitute discrimination, the differentiation or unequal treatment in question must be unjust or unfair in the sense that it is based on an arbitrary and irrelevant personal characteristic.⁷⁸ In *Nova Scotia (Human Rights Commission) v Canada Life Assurance Co*, the Nova Scotia Court of Appeal noted that an insurer's risk classification for life insurance based on a customer's physical disability that affected his mortality rate was not arbitrary and therefore not discriminatory.⁷⁹ The court rationalized its decision based on the centrality of risk segmentation in personal insurance contracts including life insurance. Justice Hallett stated:

Basic to a consideration of an application for life and disability insurance is the right of the insurer to assess the risk based

⁷⁵ See Knoppers, *supra* note 1 at 50. See also *Canadian Indemnity Co v Canadian Johns-Mansville Co*, [1990] 2 SCR 549, 115 NR 161 at para 144.

⁷⁶ See *Canadian Human Rights Act*, RSC 1985, c H-6, s 15(g); *Human Rights Code*, RSBC 1996, c 210, s 8; *Human Rights Act*, RSA 2000, c A-25.5, ss 4, 11; *Human Rights Code*, CCSM c H175, ss 9(2), 15(1), (2); *Human Rights Act*, RSNB 2011, c 171, ss 2.1, 2.2; *Human Rights Act*, RSY 2002, c 116, ss 7, 9(a), 10(d); *Human Rights Act*, SNWT 2002, c 18, ss 5(1), 11(1); *Human Rights Code*, RSO 1990, c H.19, s 22; *Human Rights Code*, RSS 1979, c S-24.1, s 5(1.2); *Human Rights Act*, 2010, SNL 2010 c H-13.1, s 21(3); *Human Rights Act*, SN 2003, c 12, s 12(3).

⁷⁷ See *Zurich*, *supra* note 35 at paras 23–24.

⁷⁸ See *Nova Scotia (Human Rights Commission) v Canada Life Assurance Co* (1992) 88 DLR (4th) 100, 109 NSR (2d) 40 (NS CA) at 9–10.

⁷⁹ See *ibid.*

in part on the state of the applicant's health. It is not irrelevant and therefore not unjust for an insurance company to refuse to insure at standard rates a person who fits into an above-average risk category as determined by acceptable underwriting principles. It is not discrimination to treat such a person differently than those without physical disabilities because the treating of the applicant differently is not based on an irrelevant personal difference.⁸⁰

The Act does not prohibit private insurers from making distinctions among applicants for insurance on the bases of identifiable characteristics, including genetic characteristics. Insurers can lawfully obtain information about an applicant's health or family medical history, that could be predictive of genetic diseases. Further, the Act does not protect individuals that are symptomatic. Insurers can use responses to health questionnaires, clinical observations, medical information, symptoms and diagnoses, family medical history, or lifestyle choices that may predict an individual's current or future health risks to determine a person's insurability.⁸¹ An applicant for life or supplementary health insurance who is or ought to be aware of their specific health risks is required to disclose that information, so long as that information is not exclusively contained in a genetic test result of that person or a family member. Further, the Act does not protect applicants where the genetic condition that increases their risk of illness and mortality is already manifest.

In sum, the protections that the Act accords genetic test results ignore the reality that information about a person's predisposition to particular conditions can also be obtained from other sources that do not enjoy the same protection. The Act does not prohibit insurers from charging different premiums or providing benefits based on an applicant's personal characteristics such as age, gender and health status, whether genetically related or not, in the provision of life and health insurance. The Act provides limited protections and a false sense of security for individuals experiencing or at risk of genetic diseases. It is laudable that the Act creates a regime that encourages individuals to undergo genetic testing for therapeutic purposes. However,

⁸⁰ *Ibid* at para 27. See also *Thornton*, *supra* note 22 at paras 10–12 (where the court noted that it is not unreasonable for an insurer to exclude coverage for a condition that substantially increases the chances of insured risk materializing).

⁸¹ See *Reference re Genetic Non-Discrimination Act*, *supra* note 9 at para 213, Kasirer J, dissenting.

the Act's broader goal should be to promote access to basic insurance regardless of a person's health status or predisposition to illnesses, whether genetically related or not.

V. THE CASE FOR A SEPARATE INSURANCE REGULATORY REGIME

As noted, the limitations of the Act in regulating access to and the use of genetic information in insurance underwriting partly stem from the broad scope of the legislation, which regulates different sectors without naming them or appreciating their unique contexts. Regulating access to and use of genetic data is an important step in protecting individuals, families, groups, and communities from discrimination, stigmatization, and social and economic exclusion. It may also protect the health and wellbeing of individuals. However, regulatory regimes must attend and respond to the concerns and interests of particular contexts. This section explores some factors to be considered in adopting a separate regulatory regime aimed at prohibiting discrimination in access to insurance based on genetic and health status.

Regulating the use of genetic information in insurance underwriting should include strict protocols regarding what constitutes genetic information. Genetic testing may not be the only source of predictive information regarding a particular condition. For example, the predictive information for cystic fibrosis may be obtained from a sweat test or genetic test.⁸² According to the Cystic Fibrosis Foundation, "the sweat test is considered the gold standard for diagnosing cystic fibrosis".⁸³ Protecting information obtained through one mechanism and not the other would result in an unfair privileging of genetic testing over other means of determining susceptibility for a particular condition, and result in an extreme form of exceptionalism.

⁸² See Cystic Fibrosis Foundation, "Diagnosed with Cystic Fibrosis – 3 Testing", online: <www.cff.org/What-is-CF/Diagnosed-With-Cystic-Fibrosis/> [perma.cc/EKT7-PE9W]; Suzanne Bujara, "Predicting Severity in Cystic Fibrosis with Sweat Chloride" (4 August 2017), online: *Pulmonary Advisor* <www.pulmonologyadvisor.com/home/topics/obstructive-lung-disease/predicting-severity-in-cystic-fibrosis-with-sweat-chloride/> [perma.cc/885L-FEDF].

⁸³ Cystic Fibrosis Foundation, "Sweat Test", online: <www.cff.org/What-is-CF/Testing/Sweat-Test/> [perma.cc/RS93-CQN5].

The Act's concern to prevent the use of genetic information for predicting an individual's future health status fails to protect individuals who may be at risk of health conditions unrelated to their geneomic profile. Meanwhile, there are complex interactions between genomics and other factors such as physiology, lifestyle, and environmental in predicting diseases.⁸⁴ This makes it difficult to justify distinguishing these types of information in providing insurance coverage.⁸⁵

Genetic exceptionalism may have unintended consequences, including engendering sympathy for those with "bad genes" but not for those whose risk factors are perceived as a matter of personal choice. Yet, specific pathways of some conditions allegedly caused by lifestyle choices may be the result of a combination of factors, including genetic make-up. Genes may also affect how particular conditions manifest for those individuals and their responses to therapies. This is partly why pharmacogenomics is increasingly becoming important in the management and treatment of diseases, regardless of their origins.

Further, genetic information may be available through medical records. This seriously weakens the prohibition of genetic testing and information. Genetic information may be part of a person's health records even if the actual test results are not, especially in the era of electronic storage. This information may become accessible to insurers when applicants check a box giving insurers access to their medical records, usually without the applicant fully understanding what that entails. Even if actual genetic test results are sealed and not included in medical information released to insurers, the individual's risk factors may be part of clinical notes that could lead an insurer to the same conclusion about that person's risk factors. As well, what constitutes genetic data or information and how it differs from medical data is still evolving within the medical and scientific communities. This makes the alleged distinction between genetic test results and health records for purpose of insurance underwriting practically irrelevant.

⁸⁴ See Hoyweghen, *supra* note 63 at 439–40; Green et al, *supra* note 12 at 399. See also RL Zimmern & MJ Khoury, "The Impact of Genomics on Public Health Practice: The Case for Change" (2012) 15 Public Health Genomics 118 at 119; Meyer, *supra* note 5 at 1275–77.

⁸⁵ See CIA, *supra* note 64 at 1. *Contra* Klitzman, Applebaum & Chung, *supra* note 13 at 1856 who argue in favour of genetic exceptionalism, among other things, because a person has no control over their genes, as opposed to, for example, lifestyle. The author also discusses implications of genetic information for family members.

It may be best to provide basic insurance coverage without requiring applicants to disclose any health, medical, or genetic information.⁸⁶ This will be akin to providing group insurance without the need for separate insurability regarding health status, which is based on the idea that differences in risk levels among policyholders will span across the entire spectrum and will average out in the end. This should make it possible to keep premiums reasonable and make coverage accessible while increasing the cost effectiveness of the insurance market.

Providing basic insurance without reference to health status also allays concerns about genetic essentialism, exceptionalism, and discrimination against individuals on the basis of their health status, whether genetically related or not. A regime of basic insurance also recognizes that many diseases have complex causes and origins that may include but not be limited to genetic characteristics.⁸⁷

There should be financial limits, adjusted for inflation over time, for particular types of insurance products that insurers may provide on a non-medical basis similar to the approach in the United Kingdom.⁸⁸ In the UK, limits are set at £500,000 for life insurance; £300,000 for critical illness insurance; and £30,000 for income protection, per person per annum.⁸⁹ Insurers in the UK may use predictive genetic test information in making underwriting decisions only where customers seek coverage exceeding these stated financial limits. Customers in the UK may also voluntarily provide genetic test results to counteract assumptions based on their family medical history of a higher-than-average risk of developing a particular disorder, and insurers may consider that information to provide the applicant favourable benefits.⁹⁰ Where a customer seeks insurance coverage for life insurance above the financial limit or where the cumulative value of insurance exceeds the financial limit, insurers may require disclosure of predictive genetic test

⁸⁶ See Knoppers, *supra* note 1 at 50; Joly et al, *supra* note 12 at 577.

⁸⁷ See Krajewska, *supra* note 9 at 10; Robert L Klitzman, *Am I My Genes: Confronting Fate and Family Secrets in an Age of Genetic Testing* (New York, NY: Oxford University Press, 2012) at 8–9.

⁸⁸ See UK Government & Association of British Insurers, *supra* note 7, Commitment 2.

⁸⁹ See *ibid.*

⁹⁰ See *ibid.*, Commitment 6.

results only for approved conditions, which is currently limited to Huntington's disease.⁹¹

The Canadian Institute of Actuaries unsuccessfully proposed amendments to Bill S-201, the Act, similar to the UK approach, to avoid privileging individuals predisposed to genetically related conditions and those whose predisposition derive from non-genetic conditions.⁹² Prior to the Act, the CLHIA proposed an industry regulation based on the idea of basic insurance by which its members committed not to ask applicants to undergo genetic testing or use genetic test information for life insurance coverage up to \$250,000.⁹³ The voluntary industry regulation was limited to life insurance and would not have protected applicants seeking supplementary health and disability insurance policies. The Act has rendered the voluntary regulation unnecessary. Nonetheless, the voluntary regulation indicates the private insurance industry's willingness to adopt such a regime, albeit in a limited way. It also shows that such a regime is feasible from insurers' perspective and does not threaten to undermine the private insurance system. This is further support for the idea of providing basic insurance without reference to the applicant's health status or predisposition to particular health conditions.

Providing basic insurance without reference to health status or predispositions is consistent with the socialization of risks. It promotes a sense of solidarity in managing the financial consequences of unfortunate events. Although a system of basic insurance does not guarantee equality of access to insurance, it addresses potential discrimination on the basis of genetic or other factors affecting an individual's health. Individuals will not be precluded from obtaining insurance because of unfavourable genetic and other health characteristics, whether real or perceived. Additionally, a system of basic insurance avoids the potential for indirect pressure to undergo testing. There will be no incentives for individuals to undergo testing to counteract their medical or family history of potentially higher than average risk of developing particular conditions to obtain a lower risk classification and a corresponding reduction in premiums or higher benefits.

⁹¹ See *ibid*, Commitment 2, Appendix I.

⁹² See CIA, *supra* note 64 at 1.

⁹³ CLHIA, "Canada's Life and Health Insurers Announce Commitment on Use of Genetic Testing Information" (January 2017), online: <www.newswire.ca/news-releases/canadas-life-and-health-insurers-announce-commitment-on-use-of-genetic-testing-information-610363125.html> [perma.cc/2TNL-JN3N].

The tiered approach recognizes that there are limits to the socialization of risks. It is intended to promote financial security for individuals and families confronted with unfortunate life circumstances and justifies an exception to the disclosure duty in relation to health information. However, that justification does not support departure from the disclosure duty where individuals seek insurance in large amounts.⁹⁴

Provincial and territorial governments and the CLHIA should work to establish a pan-Canadian regulatory or supervisory body funded by life and health insurers to oversee the proposed regime and ensure compliance. The parties should adopt protocols for determining genetic test results for conditions that insurers may use where a customer seeks coverage above the stated amount for basic insurance, similar to the UK approach.⁹⁵ This must be limited to tests that an applicant has already taken. There should be guidelines on acceptable test providers, in order to ensure the accuracy and reliability of the information. The use of medical information including genetic data, if it must occur, must be limited to testing done by accredited companies or under certain conditions.⁹⁶ There should be strict protocols for protecting customers' confidentiality, including not retaining such information within insurers' databases after it has been used in the underwriting process, to avoid concerns about subsequent improper use or potential data breaches.

⁹⁴ The financial limits of basic insurance should be determined based on data from the insurance industry to ensure most individuals seeking life and health-related insurance can obtain coverage within the financial limits. For example, when the CLHIA adopted a voluntary industry code, it set a \$250,000 limit for life insurance policies. According to CLHIA, that amount was large enough to have ensured more than 85% of life insurance of policies could have been issued without the duty to disclose genetic test results. See Goldberg, *supra* note 45.

⁹⁵ Where a customer seeks insurance coverage for life insurance above the financial limit or where the cumulative value of insurance exceeds the financial limit, insurers may require disclosure of predictive genetic test results only for approved conditions; currently, the only approved test is for Huntington's disease. See UK Government & Association of British Insurers, *supra* note 7, Commitment 2, Appendix I.

⁹⁶ There is a proliferation of companies offering genetic testing, including mail order testing (direct-to-consumer). Among other things, these tests may not be necessarily diagnostic, and the quality of the testing protocol as well as the accuracy of the results may be questionable.

Insurers should not rely on predictive test results in making underwriting decisions regarding individuals who are asymptomatic. The uncertainty regarding the manifestation of genetically related disorders at a future time, the possibility of future advancement in science and medicine that may prevent or provide treatment for the condition, and the reality that the causes of diseases are often multi-factorial justify such a prohibition. Moreover, while rare, the risk factor associated with a gene variant may be reclassified, as happened in relation to a mutation on a BRCA gene carried by members of one family previously considered “pathogenic” but subsequently changed to “unknown significance.”⁹⁷

Further, the predictive capacity of genetically derived information is limited to X-linked (dominant or recessive) and monogenic disorders such as thalassaemia, sickle cell anemia, haemophilia, cystic fibrosis, Tay-Sachs disease, fragile X syndrome, and Huntington’s disease.⁹⁸ While some common disorders may be influenced by genetic factors, the correlation between genes and disease is more complicated compared to single gene disorders.⁹⁹ Admittedly, risk predictions are based on probabilities not certainties. However, given the complex etiology of diseases, the shift to systems biology, and the rejection of genetic essentialism, there is no justification for insurers to rely on predictive tests for risk assessments where individuals are asymptomatic. These considerations also support the idea of providing basic insurance without reference to health statuses discussed above.¹⁰⁰

The parties should follow the UK’s approach of limiting the use of predictive tests in underwriting to untreatable single-gene disorders with

⁹⁷ Amy Dockser Marcus, “A Genetic Test Led Seven Women in One Family to Have Major Surgery. Then the Odds Changed”, *The Wall Street Journal* (20 December 2019), online: <www.wsj.com/articles/seven-women-in-a-family-chose-surgery-after-a-genetic-test-then-the-results-changed-11576860210> [perma.cc/B2LP-9GDP]. Meanwhile, several of the women who tested positive had taken drastic measures including double mastectomy and removal of their ovaries before being informed of the reclassification. The author notes that the reclassification of the gene variant in question is not unanimous and that other labs continue to classify it as “harmful” or “likely pathogenic.”

⁹⁸ See WHO, *supra* note 60; Krajewska, *supra* note 9 at 10.

⁹⁹ See Macdonald, *supra* note 51 at 10.

¹⁰⁰ See WHO, *supra* note 60.

a high probability of manifesting.¹⁰¹ These conditions should be identified with input from genetic policy experts in a transparent process, and through population-based studies. Such an approach should be pursued with great caution and must be evidence-based given the rejection of genetic determinism and the possibility of scientific and medical advances mitigating the effects of certain conditions. In fact, there is some optimism in the scientific community that, given rapidly evolving advances in genomic medicine and the shift towards systems biology, the notion of immutable genetic risks may become obsolete.¹⁰²

Based on the UK example, genetic test results that may be approved for disclosure in insurance applications for coverage above the basic amount are likely to be small in number and limited to non-preventable and non-treatable disorders.¹⁰³ Thus, only a small number of insurance applicants are likely to be affected by the need to disclose genetic test results when seeking coverage above the basic amounts. Isolating such a small number of individuals for differential treatment in the application for insurance is potentially discriminatory on the basis of genetic characteristics. Further, such an approach is inconsistent with equality of access to insurance and the socialization of risks.

VI. A DIFFERENT WAY OF THINKING: PROMOTING EQUITY IN ACCESS TO INSURANCE

Perhaps we should think differently about life and health insurance policies. Given that the Canadian public health care system does not cover all health services, individuals and families are left to seek coverage for extended health benefits through supplementary health insurance policies. Similarly, many Canadians seek financial security through insurance products such as life, disability, or income replacement insurance. Individuals and their families may be insured under individual or group policies. There is usually no separate insurability for persons insured under group insur-

¹⁰¹ See Klitzman, Applebaum & Chung, *supra* note 13 at 1856.

¹⁰² See Green et al, *supra* note 12 at 399.

¹⁰³ The use of predictive test results for insurance coverage above the basic amount is limited to monogenic, late-onset and high penetrance disorders. So far, the only test that has been approved for disclosure for life insurance is for Huntington's Disease. See UK Government & Association of British Insurers, *supra* note 7 at Commitment 2, Appendix I.

ance or creditors' group insurance policies, and no disclosure duty unless specifically requested by the insurer at the time of application in relation to a specific group member.¹⁰⁴ The rationale is that in a group of people who are sufficiently healthy to be working, it is likely that some group members will have lower risk profiles and above-average health, while others will have higher risk profiles and below average health. The risk level of the entire group will even out to be average, making it unnecessary for the insurer to require evidence of the insurability of individual group members.¹⁰⁵ This means that those with group policies, usually through avenues such as their employment, professional associations, or unions, and their dependants, do not risk denial of coverage because of their genetic or health characteristics. In contrast, individual insurance policies are provided based on the personal information of the life insured. Those who purchase policies for themselves or their families must supply proof of insurability under the disclosure duty. Anyone, including individuals with group insurance policies, may also purchase individual policies requiring disclosure of medical information.

According to the CLHIA, 60% of life insurance policies in 2016 were individual policies, up from 54% in 2006.¹⁰⁶ Individuals applying for life insurance face the same disclosure duty and are often insured on the basis of their personal risk status. Presumably, those with group policies who are above-average risk, whether genetically related or not, are less likely to purchase individual insurance coverage – at least not to the same extent as those without such policies. These individuals may not have to worry about the potential for higher premiums or lower benefits because of their risk status. The statistics on extended health insurance appear to confirm this. According to the CLHIA, 90% of supplementary health insurance is provided through group plans. Furthermore, specialized drugs made up 2% of prescription drug claims in 2016, but accounted for 30% of prescrip-

¹⁰⁴ See BC *Insurance Act*, *supra* note 2, ss 52(3) (life), 112(2) (A&S); Alberta *Insurance Act*, *supra* note 2, ss 653(3), 720(2); Ont *Insurance Act*, *supra* note 2, ss 184(3), 309(2).

¹⁰⁵ See David Norwood & John P Weir, *Norwood on Life Insurance Law in Canada*, 3rd ed (Toronto: Carswell, 2002) at 211–12; Craig Brown & Andrew Mercer, *Introduction to Canadian Insurance Law*, 3rd ed (Markham, Ont: Lexis-Nexis, 2013) at 145–46.

¹⁰⁶ See Canadian Life and Health Insurance Association, “Canadian Life and Health Insurance Facts 2017 Edition” (2017) at 8–9, online (pdf): CLHIA <[www.clhia.ca/web/CLHIA_LP4W_LND_Webstation.nsf/resources/Factbook_2/\\$file/2017+FB+ENGLISH.pdf](http://www.clhia.ca/web/CLHIA_LP4W_LND_Webstation.nsf/resources/Factbook_2/$file/2017+FB+ENGLISH.pdf)> [perma.cc/55KC-K7TB].

tion drug costs. The cost of specialized drugs is expected to rise to 40% of prescription drug costs by 2022.¹⁰⁷ These figures are significant because conditions that may affect an individual's insurability, whether genetically related or not, could require specialized drugs. Given the high percentage of supplementary insurance provided through group plans, it is likely that many individuals who may be classified as above-average risk based on their anticipated use of insurance benefits may be insured without the need for individual insurability.

Individuals without the benefit of group plans, such as those with non-standard and precarious employment,¹⁰⁸ are susceptible to higher premiums or lower coverage levels compared to those with standard employment who are likely to benefit from group policies. This is an equity issue as those with precarious employment are often members of marginalized groups.¹⁰⁹ Conditions that may give rise to discrimination in access to supplementary health, disability, income replacement, or life insurance, including those that

¹⁰⁷ See *ibid* at 12–13.

¹⁰⁸ See Wayne Lewchuk, & Michelynn Laflèche, "Precarious employment: what it means for workers and their families" in Ronald Burke & Kathryn M Page, eds, *Research Handbook on Work and Well-Being* (Cheltenham: Edward Elgar Publishing, 2017) 150 at 156–157, online: < books.google.ca/books?hl=en&lr=&id=i-wTDgAAQBAJ&oi=fnd&pg=PA150&dq=precarious+employment+race+canada&ots=C2Xyj7NjJb&sig=p9QCBjdSWqxSl8dSPIS-6pHpEn8#v=onepage&q=precarious%20employment%20race%20canada&f=false> [perma.cc/PM6K-BTVZ]. Lewchuk & Laflèche note that fewer than 10% of workers in precarious employment receive extended health benefits such as drug or dental and just about 15% have an employer-funded pension plan.

¹⁰⁹ See *ibid* at 153–55; Nicole S Bernhardt, "Racialized Precarious Employment and the Inadequacies of the Canadian Welfare State" (2015) 5:2 J Workplace Rights 1 at 5; Sheila Block & Grace-Edward Galabuzi, "Colour Coded Labour Market" in Tania Das Gupta et al, eds, *Race and Racialization: Essential Readings*, 2nd ed (Toronto, Ontario Canadian Scholars, 2018) at 394; Susan Ferguson & David McNally, "Precarious Migrants: Gender, Race and the Social Reproduction of the Global Working Class" (2015) 51 Socialist Register, online (pdf): <pdfs.semanticscholar.org/6755/2dec9b65db7598c2adfladfe7964d811465b.pdf> [perma.cc/ET9T-MR6R]; Adjin-Tettey, *supra* note 38 at 590–91. For a general commentary on the rise in non-standard and precarious employment in contemporary society and implications for workers, see Lewchuk, & Laflèche, *supra* note 108.

are genetically related, are often beyond an individual's control. A regime of basic insurance within specified financial limits protects such individuals.

CONCLUSION

The Act prohibits insurers from using genetic test information in insurance underwriting absent an individual's written consent. Among other things, the ban is intended to encourage individuals to undergo genetic testing without being concerned about the potential for genetic discrimination when accessing insurance and other basic social goods. Canadian life and health insurers are concerned that such a ban on the use of genetic test results undermines the disclosure duty that enables insurers to accurately assess an individual's risk, which is central to insurance underwriting. There is further concern that informational asymmetry between applicants for insurance and insurers has the potential to cause adverse selection as genetic testing becomes widely available and individuals' knowledge of their future health risks increases. Insurers are concerned that this could cause them to assume unreasonably high risks that are not properly accounted for in the underwriting process with detrimental consequences for the private insurance market.

This paper has argued that insurers' concern about adverse selection is not justified. Nevertheless, the Act's ban on the use of genetic test results from insurance underwriting, save with the individual's written consent, may provide a false sense of security to applicants. The Act does not prohibit insurers from accessing medical records or family medical history that may equally point to an individual's risk factors for future diseases, including those relating to their genetic profile. Additionally, the Act's approach unfairly discriminates against individuals with non-genetic health risks. Given the complex origins and causes of diseases, the rejection of genetic determinism, and the adoption of systems biology, there is no justification for separating genetically related risks from other health risks. Consequently, this paper has argued for promoting equality of access to insurance regardless of a person's risk factors, whether genetically related or not. It has advocated for the provision of basic insurance without reference to an individual's health risks up to a stated amount, adjusted for inflation over time, as a way of socializing risks.

Faire jouer un rôle élargi aux infirmières dans une approche individualisée de dépistage du cancer du sein : analyse des options juridiques

*Emmanuelle Lévesque et Bartha Maria Knoppers **

Une approche novatrice permettant d'adapter le dépistage du cancer du sein au risque de chaque femme pourrait bientôt faire son entrée dans la pratique clinique au Québec. Nécessitant à la fois une analyse génétique et une estimation par un algorithme de calcul, l'implantation de cette approche pourrait toutefois se heurter à un manque de professionnels de la santé spécialisés. Pour y remédier, des acteurs du milieu ont suggéré d'élargir le rôle de l'infirmière afin qu'elle puisse initier le test génétique, recommander des options de suivi et prescrire des examens d'imagerie. Comment ce rôle à la frontière de l'exercice de la médecine pourrait-il s'insérer dans le cadre juridique actuel? Nous avons identifié quatre options juridiques qui pourraient permettre à l'infirmière de jouer un rôle élargi : A) le Programme national de santé publique, B) le partage d'activités réservées aux médecins, C) l'ordonnance collective, et D) le recours aux infirmières praticiennes spécialisées. Après avoir examiné chacune de ces avenues au regard de la légalité des actes que devrait poser l'infirmière, nous en arrivons à la conclusion que chaque option est susceptible d'être utilisée, et que les options pourraient même être combinées.

An innovative approach to adapt breast cancer screening to the individual risk level of each woman may soon be implemented in the Québec clinical context. Requiring both a genetic analysis as well as an estimation using a calculation algorithm, this approach may well reveal a lack of specialized health professionals to implement such changes. To address this issue, stakeholders suggested increasing the involvement of nurses by allowing them to initiate genetic testing, advise on follow-up options and order imaging exams. Can this increased involvement of nurses –at the frontier of the practice of medicine– could be embodied in the current legal framework? We identified four legal options that would allow increasing the involvement of nurses: A) the National Public Health Program, B) the sharing of functions reserved to doctors, C) the use of collective prescription, and D) delegation to specialized nurse practitioners. After examining each of these options with regards to their legality under the current legal framework regulating the practice of nursing, we concluded that each option could be pursued individually or together with one or more of the other proposed options to achieve an increased involvement of nurses.

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Note aux lectrices et lecteurs: dans ce texte, l'emploi du féminin ou du masculin pour désigner des personnes n'a d'autres fins que d'alléger le texte.

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Introduction

Pour diminuer la mortalité due au cancer du sein, le dépistage par mammographie est offert dans plusieurs pays. Ce dépistage prend souvent la forme d'un programme offrant une radiographie des seins à toutes les femmes de plus de 50 ans, à des intervalles de deux ou trois ans¹. Ces mammographies visent à identifier la tumeur alors qu'elle est petite et ne cause pas encore de symptômes. Bien que ce dépistage n'empêche pas le cancer de survenir, il permet de s'attaquer à la tumeur de façon précoce.

Le rapport entre les bénéfices et les inconvénients de ce dépistage à large échelle est toutefois critiqué. Certains remettent en question les gains sur l'espérance de vie, et beaucoup s'interrogent sur les conséquences néfastes qu'il engendre². Parmi les inconvénients, on inclut le surdiagnostic (c.-à-d. la médicalisation d'un cancer qui n'aurait jamais eu d'impact s'il n'avait pas été dépisté), les fausses alarmes (c.-à-d. une anomalie dépistée qui se révèle finalement ne pas être un cancer), et les cancers qui sont découverts entre les intervalles de mammographie³. Afin de diminuer ces inconvénients, les chercheurs sont à mettre au point une approche individualisée qui adapterait le dépistage en fonction du risque de cancer de chaque femme (l'« Approche individualisée »). Le risque individuel serait estimé en combinant de nombreux facteurs, comme l'histoire médicale et familiale, les habitudes de vie et le résultat d'un test génétique. Ainsi, les femmes à risque plus élevé se verraient offrir un dépistage adapté à leur condition, comme des mammographies plus tôt et plus souvent, ou encore un examen d'imagerie supplémentaire par résonance magnétique⁴.

¹ Voir Scott Klarenbach et al, « Recommendations on Screening for Breast Cancer in Women Aged 40–74 Years who are not at Increased Risk for Breast Cancer » (2018) 190:49 CMAJ E1441 aux pp E1443, E1448–49.

² Voir *ibid* à la p E1441.

³ Voir Sylvia H Heywang-Köbrunner, Astrid Hacker et Stefan Sedlacek, « Advantages and Disadvantages of Mammography Screening » (2011) 6:3 Breast Care 199 aux pp 201–03.

⁴ Voir J Gagnon et al, « Recommendations on Breast Cancer Screening and Prevention in the Context of Implementing Risk Stratification: Impending Changes to Current Policies » (2016) 23:6 Current Oncology e615 à la p e616.

Cette approche est présentement appliquée auprès de milliers de femmes dans des projets de recherche au Canada (PERSPECTIVE I&I⁵), aux États-Unis (WISDOM⁶), au Royaume-Uni (BRIDGES⁷) et en Europe (MyPeBS⁸ et FORECEE⁹). On pourrait assister à son implantation dans la pratique clinique dans les années qui suivront.

À l'instar d'autres pays, le Québec s'est doté en 1998 d'un programme national de dépistage par mammographie¹⁰. Nos travaux antérieurs ont démontré qu'intégrer l'Approche individualisée dans le programme québécois de dépistage soulèverait plusieurs enjeux organisationnels pour le système de santé, notamment en ce qui concerne l'accès à certains professionnels de la santé¹¹. Par exemple, l'implantation de cette approche à l'échelle du

⁵ Génome Québec, « Évaluation personnalisée du risque pour la prévention et le dépistage précoces du cancer du sein : intégration et mise en œuvre » (dernière consultation le 21 janvier 2021), en ligne : *Génome Québec* <www.genomequebec.com/211-projet/evaluation-personnalisee-du-risque-pour-la-prevention-et-le-depistage-precoces-du-cancer-du-sein-integration-et-mise-en-oeuvre/> [https://perma.cc/K9WH-BKT4]; Étude PERSPECTIVE (dernière consultation le 21 janvier 2021), en ligne : *PERSPECTIVE* <www.etudeperspective.ca/> [https://perma.cc/2LSB-7CRU].

⁶ WISDOM, « WISDOM Study » (dernière consultation le 21 janvier 2021), en ligne : *Wisdom Study* <www.athenacarenetwork.org/wisdom-study> [perma.cc/56RZ-KFR7].

⁷ BRIDGES, « Breast Cancer Risk after Diagnostic Gene Sequencing » (dernière consultation le 21 janvier 2021), en ligne : *BRIDGES* <bridges-research.eu/> [perma.cc/Z7YD-7CLW].

⁸ MyPeBS, « My Personal Breast Screening » (dernière consultation le 21 janvier 2021), en ligne : *MyPeBS* <mypebs.eu/the-project/> [perma.cc/3F8S-3M35].

⁹ FORECEE Consortium, « Female Cancer Prediction Using Cervical Omics to Individualise Screening and Prevention (FORECEE) », en ligne : <www.ucl.ac.uk/womens-health/research/forecee>.

¹⁰ Voir Québec, Ministère de la Santé et des Services sociaux, « Bilan 1998-2003 - Programme québécois de dépistage du cancer du sein », (2004) à la p 10, en ligne (pdf) : *MSSS* <publications.msss.gouv.qc.ca/msss/fichiers/2004/04-204-02.pdf> [perma.cc/4SAQ-JPQJ].

¹¹ Voir Julie Hagan, Emmanuelle Lévesque et Bartha M Knoppers, « Influence des facteurs organisationnels sur l'implantation d'une approche personnelle de dépistage du cancer du sein » (2016) 28:3 *Santé Publique* 353 aux pp 356-57; Emmanuelle Lévesque et al, « Organizational Challenges to Equity in

Québec pourrait nécessiter que l'on offre une estimation du risque individualisée chaque année aux 59 000 femmes qui atteignent l'âge de 40 ans¹². Si l'Approche individualisée était implantée en calquant l'organisation des soins dans les départements d'oncogénétique (c.-à-d. une consultation individuelle avec une conseillère en génétique ou un généticien à chaque patiente), il manquerait nécessairement de ces professionnels de la santé pour répondre aux besoins¹³. En effet, le Québec compte 34 médecins généticiens¹⁴ et une cinquantaine de conseillères en génétique¹⁵. Par ailleurs, si l'unique porte d'entrée de l'Approche individualisée était le médecin de famille, l'accès par de nombreuses femmes sans médecin de famille pourrait être compromis. Récemment, encore 18% des personnes n'avaient pas de médecin de famille¹⁶.

Nos travaux subséquents ont permis d'identifier, avec des acteurs du milieu de la santé, des pistes de solution à ces enjeux d'accessibilité. Parmi celles-ci, il a été clairement préconisé de **faire jouer un rôle de premier plan à l'infirmière dans l'Approche individualisée**: son rôle devrait être maximisé en utilisant les mécanismes offerts par le cadre juridique actuel¹⁷.

the Delivery of Services within a New Personalized Risk-Based Approach to Breast Cancer Screening » (2018) 38:1 *New Genetics and Society* 38 à la p 45 [Lévesque et al, « Organizational Challenges »].

¹² Voir Institut de la statistique du Québec, « Le bilan démographique du Québec, Québec » (2020) à la p 28, en ligne (pdf) : *Institut de la statistique du Québec* <statistique.quebec.ca/en/fichier/bilan-demographique-du-quebec-edition-2020.pdf> [perma.cc/5CY6-J5LK].

¹³ Voir généralement Hagan, Lévesque et Knoppers, *supra* note 11; Lévesque et al, « Organizational Challenges », *supra* note 11 à la p 48.

¹⁴ Voir Fédération des médecins spécialistes du Québec, « Effectifs médicaux » (dernière consultation le 24 janvier 2021), en ligne : *FMSQ* <www.fmsq.org/fr/profession/repartition-des-effectifs-medicaux> [perma.cc/9VWV-XCDT].

¹⁵ Voir Institut canadien d'information sur la santé, « Les dispensateurs de soins de santé au Canada : profils provinciaux, 2008 à 2017 — Tableaux de données », (2019) au tableau 6, en ligne : *Institut canadien d'information sur la santé* <www.cihi.ca/sites/default/files/document/hcp-2017-data-tables-fr-web.xlsx>.

¹⁶ Voir Ministère de la Santé et des Services Sociaux, « Mesure de l'accès aux soins de santé et aux services sociaux: indicateurs » (octobre 2020) à la p 13, en ligne (pdf) : *MSSS* <www.vgq.qc.ca/Fichiers/Publications/rapport-annuel/165/vgq_ch03_sante_web.pdf> [perma.cc/8642-286C].

¹⁷ Voir Daphne Esquivel-Sada et al, « Envisioning Implementation of a Person-

Parmi les tâches que l'infirmière devrait assumer, et qui sortiraient de la conception traditionnelle de son champ d'activité, il a été proposé d'inclure : la prescription du test génétique, la recommandation d'options de suivi à la patiente et la prescription d'examens d'imagerie. Or, cette proposition soulève des enjeux importants liés à la légalité des actes qui seraient posés par les infirmières¹⁸. Considérant que ces actes sont traditionnellement exercés par le médecin, l'infirmière pourrait-elle aussi les exercer? Devant l'absence de littérature sur les enjeux juridiques soulevés par cette piste de solution dans un contexte québécois, nous proposons la présente analyse.

Notre analyse juridique a identifié quatre avenues juridiques qui pourraient permettre à l'infirmière de jouer un rôle élargi dans l'Approche individualisée : A) le Programme national de santé publique, B) le partage d'activités réservées aux médecins, C) l'ordonnance collective, et D) le recours aux infirmières praticiennes spécialisées. Nous présentons dans cet article chacune de ces avenues, en commençant toutefois par une mise en contexte des aspects scientifiques et pratiques de l'Approche individualisée (I. La science et la pratique) et d'une qualification juridique du rôle élargi de l'infirmière (II. Le rôle élargi de l'infirmière). Enfin, il faut noter que notre analyse juridique ne couvre évidemment pas l'examen de la faisabilité organisationnelle d'un élargissement du rôle des infirmières, par exemple d'évaluer si le nombre d'infirmières serait suffisant. Toutefois, il est intéressant de savoir que le Québec compte plus de 71 000 infirmières et infirmiers en emploi, et la croissance des nouveaux membres est la plus forte depuis une dizaine d'années¹⁹. Le président de l'Ordre des infirmières et infirmiers

alized Approach in Breast Cancer Screening Programs: Stakeholder Perspectives », (2019) 15:2 Healthcare Policy 39 à la p 41 (le présent texte constitue une analyse juridique d'une piste de solution évoquée dans nos précédents travaux: il ne constitue pas une analyse de la pertinence organisationnelle ni de l'efficacité d'élargir le rôle de l'infirmière).

¹⁸ Dans une perspective européenne, voir aussi Emmanuelle Lévesque et al, « Ethical, Legal, and Regulatory Issues for the Implementation of Omics-Based Risk Prediction of Women's Cancer: Points to Consider » (2018) 21:37 Public Health Genomics 37.

¹⁹ Voir Daniel Marleau, « Rapport statistique sur l'effectif infirmier 2018-2019. Le Québec et ses régions » (2019) aux pp 9 et 11, en ligne (pdf) : *Ordre des infirmières du Québec* <www.oiq.org/documents/20147/3410233/Rapport_statistique_2018-2019.pdf> [perma.cc/XB52-AETL] [OIIQ, « Rapport statistique »].

du Québec écrivait en novembre 2018 qu'il était difficile de conclure à une pénurie²⁰.

I. La science et la pratique

Effectuer une estimation du risque individuel de développer une maladie n'est pas une approche cantonnée au cancer du sein ni une méthode complètement nouvelle en santé préventive. L'évaluation du risque dans le but de proposer des stratégies de prévention et de dépistage adaptées s'effectue déjà dans la pratique clinique pour de nombreux problèmes de santé. Au Québec, les médecins sont invités à le faire de routine pour le diabète, les maladies cardiovasculaires, les infections transmissibles sexuellement et par le sang, et enfin pour les fractures de fragilisation dues à l'ostéoporose²¹. Le cancer du poumon est une autre maladie pour laquelle de nombreux modèles d'évaluation du risque ont été développés afin d'établir l'admissibilité au dépistage²². Bien que l'évaluation du risque pour ces conditions ne nécessite pas d'analyse génétique, plusieurs exemples dans la recherche démontrent que l'ajout de facteurs génétiques dans l'évaluation du risque arrivera bientôt dans la pratique. Des modèles d'évaluation du risque prenant en compte des facteurs génétiques sont prometteurs, comme pour la maladie

²⁰ Voir Luc Mathieu, « Pénurie d'effectifs infirmiers au Québec? Le temps est venu de faire le point » (16 novembre 2018), en ligne : *Ordre des Infirmières et Infirmiers du Québec* < www.oiq.org/en/nouvelles/-/asset_publisher/DlzUSyQo6S6/content/penurie-d-effectifs-infirmiers-au-quebec-le-temps-est-venu-de-faire-le-point-> [perma.cc/Q2DU-UDX9].

²¹ Voir Collège des médecins du Québec et Ministère de la Santé et des Services sociaux, « Fiche de prévention clinique » (2020), en ligne (pdf) : *Collège des médecins du Québec* <www.cmq.org/publications-pdf/p-1-2020-05-29-fr-fiche-de-prevention-clinique-adultes.pdf?t=1596402696157> [perma.cc/U7B8-AR4L].

²² Voir Kevin ten Haaf et al, « Risk Prediction Models for Selection of Lung Cancer Screening Candidates: A Retrospective Validation Study » (2017) 14:4PLoS Med aux pp 3–5.

coronarienne²³, le cancer de l'ovaire²⁴, le cancer de la prostate²⁵, le cancer colorectal²⁶, ainsi que le cancer du col utérin et de l'endomètre²⁷.

L'élargissement du rôle de l'infirmière aux fins de l'évaluation du risque est donc un enjeu qui dépasse le dépistage du cancer du sein. Le questionnement des bases juridiques d'un rôle élargi de l'infirmière en cancer du sein trouve aussi sa pertinence dans les approches similaires qui sont à nos portes à l'égard de nombreuses maladies.

L'Approche individualisée en cancer du sein vise à estimer les probabilités qu'une femme développe cette maladie au cours de sa vie, dans l'objectif de lui proposer des stratégies de dépistage adaptées (voir Figure 1).

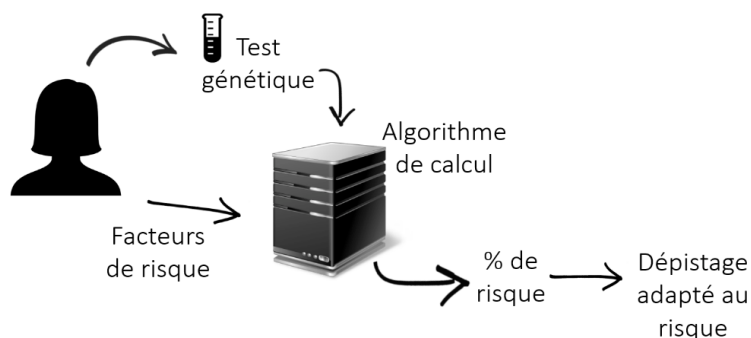
²³ Voir Florian Wünnemann et al, « Validation of Genome-Wide Polygenic Risk Scores for Coronary Artery Disease in French Canadians » (2019) *Circ Genom Precis Med* 243 à la p 244; Mario Luca Morieri et al, « Genetic Tools for Coronary Risk Assessment in Type 2 Diabetes: A Cohort Study from the ACCORD Clinical Trial » (2018) 41:11 *Diabetes Care* 2404 aux pp 2404–05.

²⁴ Voir The Eve Appeal, « Predicting-Risk of Ovarian Malignancies Improved Screening and Early detection (PROMISE) », en ligne : *The Eve Appeal* <www.eveappeal.org.uk/our-research/our-research-programmes/promise-2016/> [perma.cc/QVJ9-KCGK]; FORECEE Consortium, *supra* note 9.

²⁵ Voir Sam Li-Sheng Chen et al, « Risk Prediction of Prostate Cancer with Single Nucleotide Polymorphisms and Prostate Specific Antigen » (2019) 201:3 *JUrol* 486.

²⁶ Voir Jihyoun Jeon et al, « Determining Risk of Colorectal Cancer and Starting Age of Screening Based on Lifestyle, Environmental, and Genetic Factors » (2018) 154:8 *Gastroenterology* 2152.

²⁷ Voir FORECEE Consortium, *supra* note 9.

Figure 1. L'estimation du risque dans l'approche individualisée

Sources des images: image de serveur par Icons-Land, en ligne : <www.icons-land.com> ; image de femme par Free Icons Library, en ligne : <<http://chittagongit.com/>> ; et image de tube par Endless Icon, en ligne : <<http://www.endlessicons.com>>.

Différents algorithmes de calcul et tests génétiques existent pour effectuer cette estimation. Faisant partie de l'équipe du programme de recherche PERSPECTIVE5, notre analyse s'est basée sur l'utilisation des outils spécifiques qui y sont développés. Cela signifie que l'estimation du risque s'effectuerait avec l'algorithme de calcul BOADICEA à partir de nombreux facteurs, comme les antécédents personnels et familiaux, l'histoire reproductive (ex. nombre d'accouchements) et certaines habitudes de vie (ex. consommation d'alcool)²⁸. À ces facteurs s'ajouterait le résultat d'une analyse de laboratoire sur environ 300 variants génétiques²⁹. Ce test génétique peut s'effectuer à partir d'un échantillon de salive ou de sang. Une fois le risque estimé, les options de suivi proposées à la patiente seraient celles

²⁸ Voir Andrew Lee et al, « BOADICEA: A Comprehensive Breast Cancer Risk Prediction Model Incorporating Genetic and Nongenetic Risk Factors » (2019) 21:6 *Genetics in Medicine* 1708 à la p 1709.

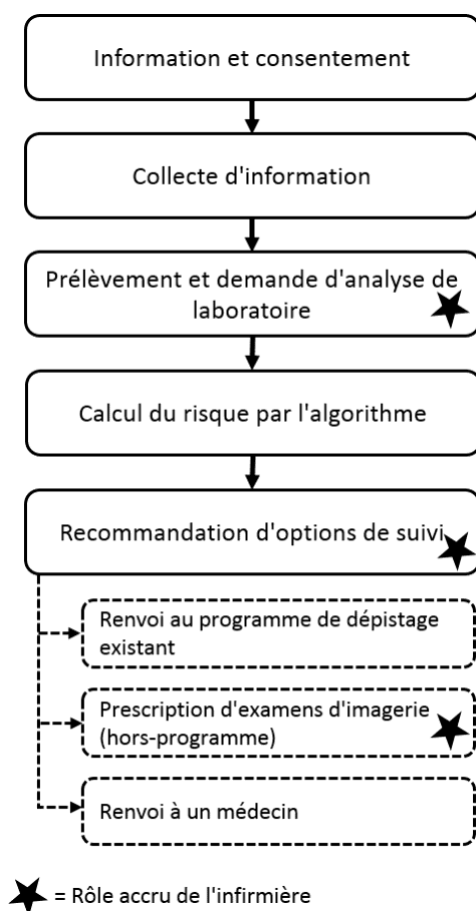
²⁹ Voir Nasim Mavaddat et al, « Polygenic Risk Scores for Prediction of Breast Cancer and Breast Cancer Subtypes », (2019) 104:1 *Am J Hum Genet* 21 (il s'agit d'un test qui examine uniquement des variants génétiques qui augmentent légèrement le risque, contrairement aux tests identifiant des mutations génétiques augmentant de façon importante le risque et qui sont utilisés à l'échelle individuelle en clinique spécialisée).

établies par les lignes directrices développées au cours du programme de recherche PERSPECTIVE. Celles-ci consistent principalement à offrir aux patientes les plus à risque certaines mesures en dehors du programme provincial de dépistage, soit des mammographies plus fréquemment ou plus tôt, l'examen par résonnance magnétique, ou une consultation avec un médecin (spécialisé en génétique ou dans les maladies du sein)³⁰.

L'Approche individualisée peut être schématisée en une série d'étapes ordonnées, lesquelles peuvent impliquer différents professionnels de la santé selon l'organisation des soins qui est choisie au moment de son implantation. La Figure 2 détaille ces étapes et identifie par une étoile celles où l'infirmière devrait y jouer un rôle élargi selon la proposition découlant de nos travaux précédents³¹. Notre analyse juridique portera spécifiquement sur ces étapes impliquant un rôle élargi.

³⁰ Voir Gagnon et al, supra note 4 à la p E619-E621.

³¹ Voir Esquivel-Sada et al, supra note 17.

Figure 2. Schéma des étapes de l'approche individualisée

Au Québec, la prestation de soins se conçoit juridiquement en termes d'activités bien segmentées, comme « diagnostiquer les maladies »³², « effectuer l'assistance respiratoire »³³, ou « évaluer la fonction neuromusculosquelettique »³⁴. Chacune représente une activité professionnelle dite « réservée ». Les activités professionnelles réservées doivent être exercées uniquement par les personnes membres d'un ordre professionnel autorisé, à moins d'une exception de la loi. Par exemple, malgré que l'injection de médicament soit normalement réservée aux professionnels de la santé, tout

³² Loi médicale, RLRQ c M-9, art 31.

³³ Code des professions, RLRQ c C-26, art 37.1(7)(a).

³⁴ Ibid, art 37.1(4)(b).

citoyen peut faire une injection de naloxone en situation d'urgence à une personne ayant trop consommé d'opioïdes³⁵. Par ailleurs, l'exercice de certaines activités professionnelles réservées peut être partagé entre les membres de plusieurs ordres professionnels. Ainsi, l'exercice de la médecine englobe toutes les activités professionnelles de l'infirmière³⁶.

Les infirmières sont classifiées par la loi selon leurs spécialisations. Cette classification détermine notamment le type d'activité professionnelle que chacune est autorisée à exercer. Habituellement, plus le niveau de diplomation de l'infirmière est élevé, plus ses activités professionnelles sont étendues.

Lorsque le mot « infirmière » est utilisé seul dans notre texte, nous référons à l'infirmière dont le champ d'exercice est décrit dans la *Loi sur les infirmières et les infirmiers* :

L'exercice infirmier consiste à évaluer l'état de santé, à déterminer et à assurer la réalisation du plan de soins et de traitements infirmiers, à prodiguer les soins et les traitements infirmiers et médicaux dans le but de maintenir et de rétablir la santé de l'être humain en interaction avec son environnement et de prévenir la maladie ainsi qu'à fournir les soins palliatifs³⁷.

L'infirmière dont il est question dans cette disposition détient un diplôme d'études collégiales ou universitaires³⁸. Plusieurs activités professionnelles lui sont réservées, notamment :

³⁵ Voir Règlement sur les activités professionnelles pouvant être exercées dans le cadre des services et soins préhospitaliers d'urgence, RLRQ c M-9, r 2.1, art 3(2).

³⁶ Voir Ordre des infirmières et infirmiers du Québec, « Le champ d'exercice et les activités réservées des infirmières et infirmiers, 3e édition » (2016) à la p 6, en ligne (pdf) : Ordre des infirmières et infirmiers du Québec <www.oiiq.org/documents/20147/1306047/1466-exercice-infirmier-activites-reservees-web+%282%29.pdf/84aaaa05-af1d-680a-9be1-29fcde8075e3> [perma.cc/2EVJ-C6VL] [Le champ d'exercice].

³⁷ *Loi sur les infirmières et les infirmiers*, RLRQ c I-8, art 36 [*Loi sur les infirmières*].

³⁸ Voir *Règlement sur les diplômes délivrés par les établissements d'enseignement désignés qui donnent droit aux permis et aux certificats de spécialistes des*

- « évaluer la condition physique et mentale d'une personne symptomatique; [...]
- initier des mesures diagnostiques et thérapeutiques, selon une ordonnance; [...]
- effectuer des examens et des tests diagnostiques invasifs, selon une ordonnance, et; [...]
- administrer et ajuster des médicaments ou d'autres substances, lorsqu'ils font l'objet d'une ordonnance³⁹. »

À certaines conditions, l'infirmière peut acquérir un certificat de spécialiste et avoir le titre d'infirmière praticienne spécialisée (« IPS »)⁴⁰. L'IPS peut exercer des activités réservées additionnelles, comme la prescription d'examens diagnostiques⁴¹. Nous analyserons le champ d'activité particulier de l'IPS en lien avec l'Approche individualisée dans la section D.

Bien qu'il existe d'autres spécialisations chez les infirmières, elles ne seront pas analysées ici puisqu'elles ne sont pas pertinentes avec l'Approche individualisée. Enfin, il faut préciser que notre analyse ne porte pas sur « l'infirmière auxiliaire ». Celle-ci détient un diplôme d'études professionnelles de niveau secondaire⁴². Son champ d'exercice est moins large que celui de l'infirmière : elle joue un rôle de support dans l'évaluation de l'état de santé et la réalisation du plan de soins infirmier⁴³.

ordres professionnels, RLRQ c C-26, r 2, arts 1.17, 2.02 [Règlement sur les diplômes].

³⁹ *Loi sur les infirmières*, *supra* note 38, art 36.

⁴⁰ Voir *Règlement sur les classes de spécialités d'infirmière praticienne spécialisée*, RLRQ c I-8, r 8, arts 3, 22.1.

⁴¹ Voir *Loi sur les infirmières*, *supra* note 38, art 36.1.

⁴² *Règlement sur les diplômes*, *supra* note 39, art 3.01.

⁴³ Voir *Code des professions*, *supra* note 34, arts 37(p), 37.1(5).

II. Le rôle élargi de l'infirmière

Avant d'examiner les mécanismes juridiques qui pourraient permettre à l'infirmière de jouer un rôle élargi dans l'Approche individualisée, il est nécessaire de se demander si ce rôle constituerait effectivement un élargissement de son champ d'activité professionnelle.

La première étape où ce rôle élargi serait joué touche **le prélèvement et la demande d'analyse de laboratoire** (voir la Figure 2). Bien que le test génétique puisse être réalisé avec de la salive ou du sang, notre analyse porte sur les situations où un prélèvement sanguin devrait être effectué par une infirmière⁴⁴.

L'insertion d'un instrument, comme une aiguille, au-delà de la peau, est une technique invasive⁴⁵. Or, l'infirmière doit avoir une ordonnance pour effectuer des examens et des tests invasifs, ou pour appliquer des techniques invasives⁴⁶. Comme un prélèvement sanguin est un examen/test invasif⁴⁷, une ordonnance devrait exister pour qu'une infirmière puisse effectuer un prélèvement sanguin destiné à une analyse de laboratoire. De plus, toute analyse faite par un laboratoire de biologie médicale hors d'un centre hospitalier⁴⁸ doit être précédée d'une ordonnance signée par un professionnel habilité⁴⁹.

Par ailleurs, demander qu'un laboratoire médical effectue une analyse génétique sur ce prélèvement nécessite d'être habilité à entreprendre des

⁴⁴ Il faut préciser qu'il ne serait pas nécessaire que l'infirmière effectue un prélèvement sanguin si l'auto-prélèvement était la méthode adoptée par les autorités de santé. En effet, avec l'auto-prélèvement, la patiente pourrait effectuer elle-même son prélèvement de salive ou de sang capillaire (par ex. sur son doigt).

⁴⁵ *Le champ d'exercice*, supra note 37, à la p 54.

⁴⁶ Voir *Loi sur les infirmières*, supra note 38, arts 36(2), (5), (8).

⁴⁷ Voir *Le champ d'exercice*, supra note 37, à la p 55.

⁴⁸ Pour une définition d'un laboratoire, voir *Loi sur les laboratoires médicaux, la conservation des organes et des tissus et la disposition des cadavres*, RLRQ 2019, c L-0.2, art 1(b).

⁴⁹ Voir *Règlement d'application de la Loi sur les laboratoires médicaux, la conservation des organes et des tissus et la disposition des cadavres*, RLRQ 2020, c L-0.2, r 1, art 136.

analyses ou des examens qui sont de nature diagnostique. La notion de diagnostic a été définie ainsi par la jurisprudence dans le contexte de la délimitation des activités réservées au médecin :

Un diagnostic est essentiellement une démarche consistant à identifier une maladie, une pathologie ou des troubles de la santé. Cette démarche consiste en l'examen de symptômes ou en l'examen par appareil ou méthode scientifique. Le diagnostic concerne aussi l'identification de la nature d'un dysfonctionnement ou d'une difficulté. Le diagnostic s'entend aussi de prévisions de malaises probables suivant l'état d'une personne⁵⁰.

Certains auteurs décrivent le diagnostic comme étant « 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 »⁵¹. Pour un autre auteur, l'évaluation du risque qu'effectue une conseillère en génétique (c.-à-d. la probabilité d'occurrence d'une maladie génétique) s'apparente à la formulation d'un diagnostic⁵². Le fait que le résultat d'une telle évaluation génétique soit sous forme de pourcentage et n'offre pas de réponse tranchée ne l'empêcherait pas de constituer un diagnostic⁵³. Ainsi, dans l'Approche individualisée, le test génétique – effectué dans l'objectif d'estimer le risque de cancer du sein, – et les examens d'imagerie, – effectués pour détecter une tumeur – devraient être considérés des mesures diagnostiques⁵⁴.

⁵⁰ *Collège des médecins du Québec c Provencher*, 2005 CanLII 3754 (QC CQ) au para 28.

⁵¹ Jean-Louis Baudouin, Patrice Deslauriers et Benoît Moore, *La responsabilité civile*, 8e éd, Cowansville, Édition Yvon Blais, 2014 à la p 78.

⁵² Voir Ma'n Zawati, « Les conseillers en génétique et les professions médicales et infirmières au Québec: des frontières brouillées? » (2012) 6:1 RDSM 137 à la p 160.

⁵³ Voir *ibid.*

⁵⁴ Il n'est pas apparu nécessaire de se demander si le calcul du risque par l'outil BOADICEA constituait en soi une mesure diagnostique (qui exigerait une habilitation à initier des mesures diagnostiques). Comme l'infirmière devrait déjà être habilitée à initier des mesures diagnostiques pour demander le test génétique, la question ne se poserait pas. D'autres travaux seront d'ailleurs nécessaires pour déterminer si l'utilisation d'outils de calcul du risque comme BOADICEA constitue une mesure diagnostique, surtout considérant que des

L'infirmière peut « initier des mesures diagnostiques », mais elle peut seulement le faire à partir d'une ordonnance médicale⁵⁵ ou dans le cadre de la *Loi sur la santé publique*⁵⁶. La prescription d'examen diagnostiques est une activité professionnelle réservée notamment au médecin⁵⁷.

Les deux ordres professionnels représentant les médecins et les infirmières ont conjointement établi des balises aux tests que l'infirmière peut demander sans ordonnance. Ils ont exigé des tests « non invasifs », « disponibles sur les lieux d'intervention de l'infirmière », « sans risque de préjudice », et toujours effectués sur un patient « symptomatique »⁵⁸. Mais il est difficile de comprendre comment ces ordres professionnels ont interprété leurs critères puisqu'ils ont inclus la glycémie capillaire (nécessitant une aiguille) parmi les tests que l'infirmière peut effectuer sans ordonnance⁵⁹. Il nous paraît que leur position reflète la reconduction de pratiques consensuelles établies, mais que notre analyse doit plutôt être guidée par les critères de la *Loi sur les infirmières et infirmiers*⁶⁰ vus plus haut. Ainsi, à notre avis, dans l'Approche individualisée, le prélèvement sanguin et la demande d'analyse de laboratoire ne font pas partie du champ d'activité professionnelle de l'infirmière lorsqu'aucune ordonnance n'existe.

La deuxième étape où l'infirmière jouerait un rôle élargi concerne **la recommandation d'options de suivi** (voir la Figure 2). Avec l'arrivée d'une médecine qui repose sur des algorithmes sophistiqués utilisant des centaines

outils de ce type pourraient se qualifier d'« instruments médicaux » (voir généralement Adrian Thorogood et al, « Genetic Database Software as Medical Devices » (2018) 39:11 Hum Mutat 1702) et être encadrés par la réglementation fédérale sur les instruments médicaux (voir généralement *Règlement sur les instruments médicaux*, DORS/98-282).

⁵⁵ *Loi sur les infirmières*, *supra* note 38, art 36(3).

⁵⁶ *Loi sur la santé publique*, RLRQ c S-2.2, art 7 et 9. Voir *Ibid* art 36(4).

⁵⁷ Voir *Loi médicale*, *supra* note 33, art 31(2).

⁵⁸ Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, « Avis conjoint. Non-pertinence d'assujettir certains tests à une obligation d'ordonnance » (2017), en ligne (pdf) : *Collège des Médecins du Québec* <www.cmq.org/pdf/activites-partage/avis-oiq-cmq-non-pertinence-ord-20170418.pdf?t=1507766400023> [perma.cc/4QBQ-RGVD].

⁵⁹ *Ibid.*

⁶⁰ *Supra* note 38.

de variables, la conception juridique de la médecine est bousculée. Des centaines de variables seraient utilisées par la formule mathématique complexe de l'outil BOADICEA. Ces variables incluent les résultats pour plus de 300 variants génétiques, la présence de cancer dans la famille élargie, l'histoire reproductive et l'histoire médicale personnelle.). Malgré la complexité du calcul, le résultat que l'outil BOADICEA fournirait à l'infirmière est simple : une probabilité de développer le cancer du sein, exprimée en pourcentage, ainsi que la catégorie de risque correspondante (voir Tableau 1).

Tableau 1. extrait du résultat fourni par l'outil de calcul boadicea (traduit de l'anglais)

Le risque de cette femme de développer le **cancer du sein durant les 10 prochaines années est de 8.1%**. En d'autres mots, environ 81 femmes sur 1000 avec ces facteurs de risque développeront le cancer durant cette période de 10 ans.

[...]

En se basant sur l'évaluation de son risque, cette femme est à **risque élevé**.

L'infirmière n'aurait pas à analyser un rapport provenant du laboratoire de génétique puisque ces données auraient déjà été intégrées au calcul par BOADICEA. L'objectif de ces nouvelles approches utilisant la génétique à l'échelle de dizaines de milliers de patients est justement de limiter la nécessité de recourir à des professionnels très spécialisés pour interpréter les résultats. Avec le modèle de l'Approche individualisée, des lignes directrices détaillées établiraient le suivi proposé pour chaque catégorie de risque.

L'infirmière devrait donc orienter la patiente vers un suivi correspondant à la catégorie de risque indiquée. Toutefois, l'infirmière devrait utiliser son jugement clinique pour évaluer si des facteurs non considérés par l'outil BOADICEA pourraient avoir un impact sur le risque (ex. une maladie préexistante non prise en compte) et déterminer si le suivi proposé par les lignes directrices est approprié. Ceci nécessiterait notamment de considérer les préférences, l'espérance de vie, les problèmes de santé et les limitations fonctionnelles de la patiente. Même dans un scénario où il existe des lignes directrices claires pour le suivi, les particularités de certaines patientes rendront leur adaptation nécessaire dans certaines circonstances. Or, cet exercice d'adaptation suivant une évaluation de l'état de santé global semble se situer hors du champ d'exercice de l'infirmière. En effet, l'infirmière est habilitée à « évaluer la condition physique et mentale d'une personne *symptomatique* [nos italiques] »⁶¹. Comme l'Approche individualisée est utilisée

⁶¹ *Ibid*, art 36(1).

seulement avant l'apparition des symptômes de cancer du sein, la clientèle à évaluer n'est pas symptomatique d'un cancer du sein. L'évaluation de tous les aspects liés à la santé (pas seulement d'un seul organe) se rapproche de l'établissement d'un diagnostic, lequel « peut requérir un examen complet de l'ensemble des organes, appareils et systèmes du corps humain [...] »⁶². Si l'infirmière ne peut évaluer la condition de santé globale à la suite de l'estimation du risque d'une patiente asymptomatique, il est difficile de concevoir comment elle pourrait recommander un suivi adapté aux particularités de la patiente. La recommandation que devrait formuler l'infirmière dans l'Approche individualisée nous semble plus étendue que celle que vise l'évaluation de la « condition physique et mentale » que peut effectuer l'infirmière. Évaluer la condition physique et mentale lui « permet de distinguer l'anormalité de la normalité, de détecter des complications, de déceler des problèmes de santé, de déterminer le degré de gravité ou d'urgence de la situation de santé de la personne et d'établir les priorités et les conditions d'intervention »⁶³. Cela a pour objectif « la formulation de constats permettant d'établir les priorités en matière de soins et de suivi »⁶⁴. Il ne s'agit pas d'une étape où il serait permis de poser un diagnostic. Pourtant, cela pourrait être nécessaire avec les patientes dont la situation si particulière les empêche d'être visées par les lignes directrices de suivi. Par ailleurs, la formulation de recommandations de suivi découlant de l'interprétation d'un test médical fait traditionnellement partie du champ d'exercice du médecin, peut-être parce que cela constitue la suite logique du test médical qu'il a prescrit. Considérant tous ces éléments, il faut donc conclure que la formulation de recommandations du suivi dans l'Approche individualisée serait hors du champ d'exercice de l'infirmière.

La troisième étape où l'infirmière jouerait un rôle élargi touche la mise en œuvre du suivi, soit la **prescription d'examen d'imagerie hors programme** (voir la Figure 2). Cette situation concernerait seulement les patientes à risque plus élevé que la population générale, car la prise en charge dont elles auraient besoin n'est pas offerte par le programme actuel de

⁶² Office des professions du Québec, «Loi modifiant le Code des professions et d'autres dispositions législatives dans le domaine de la santé mentale et des relations humaines - Guide explicatif» (2013) à la p 89, en ligne (pdf) : *Office des professions Québec* <www.opq.gouv.qc.ca/fileadmin/documents/Système_professionnel/Guide_explicatif_decembre_2013.pdf> [perma.cc/B44K-RUP2].

⁶³ *Le champ d'exercice*, supra note 37, à la p 29.

⁶⁴ *Ibid* à la p 33.

dépistage. Il faut préciser qu'il n'a jamais été proposé que l'infirmière interprète ces examens d'imagerie ni qu'elle ne prenne en charge les résultats d'imagerie incluant une suspicion de cancer: cela continuerait d'être du ressort des médecins. Le rôle élargi de l'infirmière se situerait uniquement dans la période précédant la détection d'un cancer.

Comme mentionné haut, l'infirmière n'est pas habilitée, de façon autonome, à initier ou prescrire des examens diagnostiques⁶⁵. Nous avons expliqué auparavant comment la notion d'examens diagnostiques est assez large pour inclure des examens de dépistage visant à identifier des indices de cancer. Ainsi, il faut conclure que la prescription d'examens d'imagerie médicale se situerait hors du champ d'exercice de l'infirmière.

Finalement, le rôle élargi que jouerait l'infirmière dans trois étapes de l'Approche individualisée se situerait effectivement en dehors de son champ d'activité professionnelle autonome. Devant ce constat, nous examinons maintenant quelles avenues juridiques pourraient être utilisées pour lui permettre de jouer ce rôle en respect du cadre juridique en vigueur.

III. Avenues juridiques pour élargir le rôle de l'infirmière

L'objectif est d'identifier comment le cadre juridique pourrait accommoder un rôle élargi de l'infirmière dans l'Approche individualisée. La faisabilité ou la pertinence des solutions juridiques proposées ne seront pas analysées puisque cela excéderait le mandat d'une analyse juridique et nécessiterait une évaluation de facteurs d'acceptabilité sociale et clinique. Nous avons identifié quatre voies juridiques dans lesquelles l'élargissement du rôle de l'infirmière pourrait s'inscrire : A) le Programme national de santé publique, B) le partage d'activités réservées aux médecins, C) l'ordonnance collective, et D) le recours aux IPS (voir Tableau 2). Chacun de ces moyens s'appuie sur des dispositions législatives différentes et, comme nous le verrons, seulement le dernier moyen (le recours aux IPS) couvrirait toutes les tâches de l'infirmière dans l'Approche individualisée.

⁶⁵ Voir *Loi sur les infirmières*, *supra* note 39 art 36(3).

**Tableau 2. moyens pour élargir le rôle de l'infirmière dans le
cadre juridique actuel**

	Programme national de santé publique	Partage d'activités réservées aux médecins	Ordonnance collective	Infirmières praticiennes spécialisées (IPS)
Action à prendre	☒ Modification du Programme	☒ Adoption d'un règlement par le Collège des médecins du Québec	☒ Rédaction d'une ordon- nance col- lective par un médecin	☒ Recours aux IPS en soins de première ligne
Rôles possibles de l'infirmière	☒ Prélèvement et demande d'analyse ☒ Prescription d'examen d'imagerie	☒ Prélèvement et demande d'analyse ☒ Prescription d'examen d'imagerie	☒ Prélèvement et demande d'analyse ☒ Prescription d'examen d'imagerie	☒ Prélèvement et demande d'analyse ☒ Prescription d'examen d'imagerie ☒ Recomman- dations de suivi

A. Le Programme national de santé publique

Pour l'Organisation mondiale de la Santé, la santé publique est une notion politique et sociale : elle « vise à améliorer la santé, à prolonger la vie et à donner une meilleure qualité de vie à des populations entières, par la promotion de la santé, la prévention de la maladie et d'autres types d'intervention sanitaire »⁶⁶. Les lois prévoient souvent des mesures hors du commun pour atteindre des objectifs de santé publique. Au Québec, par exemple, la *Loi sur la santé publique* prévoit la déclaration obligatoire de certaines maladies⁶⁷ et la vaccination obligatoire en état d'urgence sanitaire⁶⁸. À des fins de santé publique, le législateur québécois autorise l'infirmière à exercer certains actes de dépistage qui seraient autrement réservés aux médecins. La

⁶⁶ Organisation mondiale de la Santé, « Glossaire de la promotion de la santé » (1999) à la p 3, en ligne (pdf) : [World Health Organization <apps.who.int/iris/bitstream/handle/10665/67245/WHO_HPR_HEP_98.1_fre.pdf?sequence=1&isAllowed=y>](http://www.who.int/iris/bitstream/handle/10665/67245/WHO_HPR_HEP_98.1_fre.pdf?sequence=1&isAllowed=y) [perma.cc/7B4Q-9Z6Z].

⁶⁷ *Loi sur la santé publique*, *supra* note 57, arts 79–82.

⁶⁸ *Ibid*, art 123(10).

fréquence d'un problème de santé et l'ampleur de ses impacts sur la population servent parfois à justifier ce type d'exception. Augmenter le nombre de professionnels qui peuvent dépister et prendre en charge un problème de santé peut favoriser l'accès aux services ou même diminuer les coûts pour la société. Ainsi, dans la *Loi sur les infirmières et les infirmiers*, le législateur a prévu que l'infirmière peut « initier des mesures diagnostiques à des fins de dépistage dans le cadre d'une activité découlant de l'application de la *Loi sur la santé publique* »⁶⁹. Ces mesures diagnostiques peuvent notamment être établies dans le Programme national de santé publique que le Ministre de la Santé et des Services sociaux est tenu d'élaborer pour encadrer les activités de santé publique⁷⁰.

C'est par le truchement de ce mécanisme juridique – l'inclusion dans le Programme national de santé publique – que les infirmières peuvent notamment jouer un rôle élargi dans deux types de dépistage : le dépistage des infections transmissibles sexuellement et par le sang (« ITSS ») et le dépistage néonatal. Comme ce mécanisme juridique permet de conférer un rôle élargi à l'infirmière dans le domaine du dépistage, il est intéressant de s'y pencher.

L'actuel Programme national de santé publique prévoit le déploiement de services intégrés de dépistage et de prévention des ITSS offerts par les infirmières⁷¹. Il inclut aussi l'élaboration d'orientations nationales en matière de programme de dépistage ciblant les enfants, par exemple le dépistage sanguin des nouveau-nés par les infirmières⁷². Le cadre de référence d'un tel programme de dépistage des nouveau-nés a justement été officialisé en 2018⁷³.

⁶⁹ *Supra* note 38, art 36(4).

⁷⁰ Voir *Loi sur la santé publique*, *supra* note 57, art 7.

⁷¹ Voir Ministère de la Santé et des services sociaux, « Programme national de Santé publique 2015-2025 » (2015), à la p 52, en ligne (pdf) : [MSSS <publications.msss.gouv.qc.ca/msss/fichiers/2015/15-216-01W.pdf>](https://publications.msss.gouv.qc.ca/msss/fichiers/2015/15-216-01W.pdf) [perma.cc/L352-EHX6] [Programme national de Santé publique 2015-2025].

⁷² Voir *ibid*, à la p 41.

⁷³ Voir Ministère de la Santé et des Services sociaux « Programme québécois de dépistage néonatal sanguin et urinaire – Cadre de référence » (2018), en ligne (pdf) : [MSSS <publications.msss.gouv.qc.ca/msss/fichiers/2018/18-918-13W.pdf>](https://publications.msss.gouv.qc.ca/msss/fichiers/2018/18-918-13W.pdf) [perma.cc/8KHH-W92K] [Programme québécois de dépistage néonatal – Cadre de référence].

Ces orientations du Programme national de santé publique, soutenues par une habilitation de la *Loi sur les infirmières et infirmiers*, permettent donc à l'infirmière d'initier le dépistage des ITSS et le dépistage de certaines maladies chez les nouveau-nés sans l'ordonnance d'un médecin⁷⁴. L'infirmière qui initie des telles mesures doit se conformer à un guide de pratique, tant pour les ITSS⁷⁵ que pour le dépistage des nouveau-nés⁷⁶.

Selon le ministère de la Santé et des Services sociaux, l'initiation de mesures diagnostiques pour les ITSS comprend le prélèvement, la demande d'analyse de laboratoire et l'interprétation des résultats :

Initier des mesures diagnostiques à des fins de dépistage signifie qu'une infirmière peut, sans ordonnance et quel que soit son lieu d'exercice, et en se conformant au présent guide, décider de procéder à des prélèvements et demander des analyses ayant pour but le dépistage des ITSS chez des personnes asymptomatiques. Cette activité permet à l'infirmière de décider du type de prélèvement requis et d'interpréter les résultats des analyses demandées⁷⁷.

Le prélèvement peut notamment être du sang veineux (aiguille transperçant la peau)⁷⁸. Même si l'infirmière peut interpréter un résultat, elle ne peut pas amorcer le traitement pharmacologique en s'appuyant sur l'autorisation à « initier des mesures diagnostiques » prévues au Programme national

⁷⁴ *Loi sur les infirmières*, *supra* note 38, art 36(4).

⁷⁵ Voir Ministère de la Santé et des Services sociaux, « Guide québécois de dépistage des infections transmissibles sexuellement et par le sang » (2019), en ligne (pdf) : [MSSS <publications.msss.gouv.qc.ca/msss/fichiers/2019/19-308-13W.pdf>](https://publications.msss.gouv.qc.ca/msss/fichiers/2019/19-308-13W.pdf) [perma.cc/XD3L-ZL95] [Guide québécois de dépistage des ITSS].

⁷⁶ Voir Ministère de la Santé et des Services sociaux « Guide de pratique pour le dépistage néonatal sanguin et urinaire - Destiné aux infirmières en périnatalité et aux sages-femmes » (2018), en ligne (pdf) : [MSSS <publications.msss.gouv.qc.ca/msss/fichiers/2018/18-918-12W.pdf>](https://publications.msss.gouv.qc.ca/msss/fichiers/2018/18-918-12W.pdf) [perma.cc/27XN-LE9X] [Guide de pratique pour le dépistage néonatal].

⁷⁷ *Guide québécois de dépistage des ITSS*, *supra* note 76, à la p 5.

⁷⁸ Voir *ibid*, à la p 101.

de santé publique : ce sont d'autres dispositions qui peuvent permettre à l'infirmière d'amorcer un traitement⁷⁹.

Pour le dépistage sanguin des nouveau-nés, selon le Ministère de la Santé et des Services sociaux, l'initiation des mesures diagnostiques par l'infirmière inclut la prescription du test et le prélèvement sanguin⁸⁰. Il s'agit habituellement d'une ponction de sang capillaire (lancette transperçant la peau)⁸¹. L'infirmière ayant initié le test au nouveau-né n'est pas impliquée dans l'interprétation des résultats ni dans les recommandations de suivi : c'est plutôt le centre d'analyses provincial qui communique avec les parents et fait le lien avec une clinique de prise en charge⁸².

Le rôle élargi qui a été attribué à l'infirmière dans le Programme national de santé publique pour les ITSS et les nouveau-nés concerne spécifiquement le « dépistage », soit l'identification de la maladie chez une personne qui ne présente pas encore de symptôme⁸³. Le programme québécois de dépistage du cancer du sein vise aussi à identifier la maladie au stade asymptomatique⁸⁴, comme l'Approche individualisée.

Comment le rôle de l'infirmière dans l'Approche individualisée pourrait-il être élargi avec le modèle juridique utilisé en santé publique?

D'abord, il serait nécessaire que le cancer du sein soit identifié comme une préoccupation de santé publique et que l'Approche individualisée soit un moyen priorisé dans le Programme national de santé publique. Par exemple, l'inclusion de mesures spécifiques pour les ITSS dans le Programme

⁷⁹ Voir *ibid*, à la p 10.

⁸⁰ Voir *Programme québécois de dépistage néonatal – Cadre de référence*, *supra* note 74, à la p 8; *Guide de pratique pour le dépistage néonatal*, *supra* note 77, à la p 7.

⁸¹ Voir *ibid*, à la p 19.

⁸² Voir *Programme québécois de dépistage néonatal – Cadre de référence*, *supra* note 74, aux pp 12 et 14.

⁸³ Voir *Guide Québécois de Dépistage des ITSS*, *supra* note 76, à la p 5.

⁸⁴ Voir Ministère de la Santé et des Services sociaux « Programme québécois de dépistage du cancer du sein – Cadre de référence » (1999) à la p 9, en ligne (pdf) : [MSSS <publications.msss.gouv.qc.ca/msss/fichiers/1996/96_005.pdf>](http://publications.msss.gouv.qc.ca/msss/fichiers/1996/96_005.pdf) [perma.cc/E7UQ-FCH9].

national de santé publique a été justifiée par la préoccupation importante de santé publique que celles-ci représentent :

La progression soutenue des ITSS est préoccupante et exige que soient renforcées les actions à cet égard, le plus en amont possible. Personne n'est à l'abri de ces infections. Des approches intégrées, qu'elles soient globales ou ciblées, sont requises pour assurer une meilleure complémentarité des services de lutte aux ITSS⁸⁵.

Ensuite, il faudrait que le Programme national de santé publique indique que l'infirmière peut initier les mesures diagnostiques de l'Approche individualisée. Cela devrait permettre à l'infirmière, comme avec les ITSS, d'effectuer de façon autonome le prélèvement, la demande d'analyse et l'interprétation des résultats.

Pour permettre à l'infirmière d'exercer toutes les tâches du rôle élargi qu'on entend lui donner dans l'Approche individualisée, il faudrait en plus qu'elle soit en mesure de recommander un suivi à la suite du résultat et, si approprié, de prescrire des examens d'imagerie. Or, comme il a été expliqué plus haut, recommander un suivi nécessite de pouvoir évaluer l'état de santé global d'une patiente, voire même de poser un diagnostic. On pourrait argumenter que cela ne fait pas partie des activités professionnelles que l'infirmière est autorisée à effectuer, même avec une ordonnance. D'ailleurs, les infirmières qui initient le dépistage des ITSS ou des nouveau-nés ne formulent pas de recommandations de suivi de l'alinéa 4 de l'article 36 de la *Loi sur les infirmières et infirmiers*⁸⁶. Toutefois, la prescription d'examens d'imagerie en fonction de la catégorie de risque pourrait constituer, en soi, une initiation de mesures diagnostiques spécifiquement autorisée par le Programme national de santé publique⁸⁷. L'infirmière pourrait être spécifiquement autorisée à initier une deuxième série de mesures diagnostiques, soit les examens d'imagerie, en suivant les modalités précises d'un guide de pratique (comme les guides développés pour les ITSS et les nouveau-nés). Ainsi, l'infirmière pourrait avoir un questionnaire permettant d'identifier les situations où les lignes directrices permettent d'initier des examens d'imagerie et les situations plus complexes qui nécessitent une évaluation par un médecin. L'infirmière n'aurait donc pas à effectuer une évaluation

⁸⁵ *Programme national de Santé publique 2015-2025, supra* note 72 à la p 50.

⁸⁶ *Supra* note 38.

⁸⁷ Voir *ibid*, art 36(4).

globale de l'état de santé. Enfin, il serait nécessaire qu'un mécanisme soit mis en place afin qu'un médecin puisse prendre en charge le suivi des résultats anormaux des examens d'imagerie (suspicion de cancer) initiés par l'infirmière. En effet, à chaque fois qu'une infirmière prescrit un examen, elle a l'obligation déontologique de s'assurer qu'un professionnel habilité peut assurer le suivi requis si elle n'assure pas elle-même ce suivi⁸⁸.

B. Le partage d'activités réservées aux médecins

Le Collège des médecins peut autoriser, par règlement, des personnes qui ne sont pas médecins à exercer des activités professionnelles réservées aux médecins⁸⁹. Les activités professionnelles qui peuvent ainsi être visées incluent notamment de « prescrire les examens diagnostiques »⁹⁰. Avant d'adopter un tel règlement, le Collège des médecins du Québec procède à une analyse de l'activité professionnelle à partager selon un cadre prédéterminé⁹¹. Ce cadre s'appuie sur certains principes directeurs, comme le rôle intégrateur du médecin de famille, et la valeur ajoutée pour le patient et le système de santé⁹².

Par exemple, un règlement a été adopté pour autoriser l'infirmière à prescrire des analyses de laboratoire pour le soin des plaies⁹³, et à prescrire un médicament pour le traitement des nausées chez la femme enceinte⁹⁴. Pour pouvoir exercer ces activités professionnelles, l'infirmière doit tout-

⁸⁸ Voir *Code de déontologie des infirmières et des infirmiers*, c I-8, r 9, art 44.1, 2e.

⁸⁹ Voir *Loi médicale*, *supra* note 33, arts 19(b), 31(2).

⁹⁰ *Ibid*, art 31 (2).

⁹¹ Voir Collège des médecins du Québec, « Cadre d'analyse des demandes de partage d'activités médicales » (2018), en ligne (pdf) : *Collège des médecins du Québec* <<http://www.cmq.org/publications-pdf/p-1-2017-04-13-fr-cadre-analyse-partage-activites-medicales.pdf?t=1616105944615>> [perma.cc/X7WX-S8JF] [« Cadre d'analyse des demandes de partage d'activités médicales »].

⁹² Voir *ibid*, à la p 4.

⁹³ Voir *Règlement sur certaines activités professionnelles qui peuvent être exercées par une infirmière et un infirmier*, c M-9, r 12.001, art 2, al 1 [*Règlement sur certaines activités professionnelles - infirmières*].

⁹⁴ Voir *ibid*, art 5, al 1.

efois remplir certaines conditions. Il s'agit de son niveau de diplomation (habituellement universitaire⁹⁵) ainsi que de la réussite d'une courte formation⁹⁶.

Parfois, l'adoption d'un tel règlement par le Collège des médecins du Québec cherche à supporter l'application du Programme national de santé publique. Ainsi, un règlement permet à l'inhalothérapeute⁹⁷ et à l'infirmière⁹⁸ de prescrire des médicaments pour la cessation tabagique dans le cadre du Programme national de santé publique. Le rôle de l'infirmière pour la prise en charge pharmacologique des ITSS dans le cadre du Programme national de santé publique a été renforcé par un règlement du Collège des médecins du Québec : l'infirmière peut prescrire aux personnes ayant eu un résultat positif de dépistage des ITSS des médicaments pour soigner 2 types d'ITSS⁹⁹. Cette prescription doit toutefois s'effectuer selon un protocole national¹⁰⁰, lequel encadre la gestion globale des résultats positifs¹⁰¹. On y prévoit notamment les situations qui dépassent l'expertise de l'infirmière et nécessitent de référer le patient à un médecin. Ce protocole national est considéré comme une « norme de pratique » par l'Ordre des infirmières et infirmiers du Québec¹⁰². Le protocole national demande aux professionnels de la santé de se référer aussi au guide d'usage optimal du médicament en

⁹⁵ Voir *ibid*, art 7.

⁹⁶ Voir *ibid*, art 8.

⁹⁷ Voir *Règlement sur certaines activités professionnelles pouvant être exercées par un inhalothérapeute*, RLRQ c M-9, r 6, art 1.2.

⁹⁸ Voir *Règlement sur certaines activités professionnelles – infirmières*, *supra* note 84, art 4, 4o.

⁹⁹ Voir *ibid*, art 4, 5 et 6.

¹⁰⁰ Voir *ibid*.

¹⁰¹ Voir Institut national d'excellence en santé et services sociaux, « Protocole national pour le traitement d'une infection à *Chlamydia trachomatis* ou à *Neisseria gonorrhoeae* chez une personne asymptomatique » (2018), en ligne (pdf) : *Institut national d'excellence en santé et services sociaux* <www.inesss.qc.ca/fileadmin/doc/INESSS/Ordonnances_collectives/Chlam-Gono/INESSS_Protocole_national_ITSS.pdf> [perma.cc/XAA8-T6GG] [« Protocole national pour le traitement d'une infection à Chlamydia »].

¹⁰² Voir Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, « Guide explicatif conjoint- Prescription infirmière » (2015) à la p 28, en ligne (pdf) : *OIIQ* <oiiq.org/documents/20147/1457804/guide-

matière d'ITSS¹⁰³. Développé par l'Institut national d'excellence en santé et services sociaux, le guide d'usage optimal identifie précisément les médicaments à prescrire selon la situation ainsi que leur dosage¹⁰⁴.

Maintenant, il convient de regarder comment le rôle de l'infirmière dans l'Approche individualisée pourrait être élargi via l'adoption d'un règlement par le Collège des médecins du Québec. En premier lieu, il faudrait démontrer que ce partage d'activités médicales avec l'infirmière respecte les principes directeurs du cadre d'analyse du Collège des médecins du Québec, notamment en expliquant la valeur ajoutée pour la patiente et le système de santé¹⁰⁵.

Ensuite, il faudrait que le rôle élargi de l'infirmière fasse partie des activités réservées que le Collège des médecins du Québec peut partager par voie de règlement. Le Collège des médecins du Québec peut partager la prescription d'examens diagnostiques¹⁰⁶. L'initiation de mesures diagnostiques pour les ITSS devait être entendue comme incluant à la fois le prélèvement, la demande d'analyse au laboratoire et l'interprétation des résultats. Ainsi, dans l'Approche individualisée, l'infirmière pourrait être autorisée à prescrire les deux types d'examens diagnostiques en cause : ceux servant à l'estimation du risque (prélèvement sanguin, analyse génétique) et ceux découlant du risque estimé (examens d'imagerie).

Il reste que l'infirmière ne serait pas autorisée à formuler des recommandations de suivi à la suite d'une évaluation globale de l'état de santé. La formulation de recommandations de suivi nécessite de prendre en compte

explicatif-prescription-infirmiere-final-web.pdf/bc37d864-663f-5047-5afa-c0f8ac382e39> [perma.cc/RWD4-UJEU].

¹⁰³ Voir « Protocole national pour le traitement d'une infection à Chlamydia », *supra* note 102 à la p 4.

¹⁰⁴ Voir Institut national d'excellence en santé et services sociaux, « Traitement pharmacologique ITSS- infection non compliquée à *Chlamydia trachomatis* et à *Neisseria gonorrhoeae* » (2018), en ligne (pdf) : *Institut national d'excellence en santé et services sociaux* <www.inesss.qc.ca/fileadmin/doc/INESSS/Outils/Guides_ITSS/Guide_ITSS-Chlamydia_gonorrhoeae.pdf> [perma.cc/9FTV-GCP4].

¹⁰⁵ Voir « Cadre d'analyse des demandes de partage d'activités médicales », *supra* note 92 à la p 4.

¹⁰⁶ Voir *Loi médicale*, *supra* note 33 art 31(2).

de nombreux facteurs afin d'évaluer si le suivi proposé par les lignes directrices est approprié pour une patiente ou si une autre option devrait être envisagée. Or, l'infirmière n'est pas la professionnelle de la santé qui effectue habituellement ce type d'analyse clinique. Toutefois, l'infirmière pourrait être autorisée à prescrire des examens d'imagerie en présence de conditions précises qui ne nécessitent pas d'effectuer une évaluation globale de l'état de santé. De façon similaire au modèle des ITSS, la prescription d'examens d'imagerie dans l'Approche individualisée pourrait être encadrée par un protocole national ou un guide de pratique obligatoires qui définiraient les situations où les examens d'imagerie peuvent être prescrits et celles où la patiente doit être renvoyée à un médecin pour une analyse globale de son état de santé. Par exemple, comme dans le protocole national concernant les ITSS, les situations qui exigent une consultation avec un médecin en raison de leur complexité pourraient être définies.

En dernier lieu, pour élargir le rôle de l'infirmière, le règlement du Collège des médecins du Québec devrait autoriser l'infirmière à prescrire les deux types d'examens diagnostiques prévus dans l'Approche individualisée : les examens visant à calculer le risque (dont l'analyse génétique) et les examens d'imagerie.

C. L'ordonnance collective

L'ordonnance individuelle est rédigée pour un patient spécifique, alors que l'ordonnance collective est rédigée pour un groupe de patients qui ont des caractéristiques communes. L'ordonnance collective est :

Une prescription donnée par un médecin ou un groupe de médecins à un professionnel ou à une personne habilitée, ayant notamment pour objet les médicaments, les traitements, les examens ou les soins à donner à un groupe de personnes ou pour les situations cliniques déterminées dans cette ordonnance, les circonstances dans lesquelles ils peuvent l'être de même que les contre-indications possibles¹⁰⁷.

Avec une ordonnance collective, un médecin indique à quelles conditions spécifiques un professionnel de la santé peut effectuer des examens ou

¹⁰⁷ *Règlement sur les normes relatives aux ordonnances faites par un médecin*, RLRQ, c M-9, r 25.1, art 2(2). Voir aussi *Code des professions*, *supra* note 34, art 39.3.

prodiguer des soins à un groupe de personnes. Le médecin n'a pas besoin d'avoir préalablement examiné le groupe de personnes visé¹⁰⁸. Mais quand le patient n'a pas été préalablement examiné par un médecin, l'ordonnance collective « ne peut viser des situations cliniques qui nécessitent la pose d'un diagnostic ou une évaluation médicale préalable pour établir un plan de traitement en vertu des bonnes pratiques reconnues »¹⁰⁹.

L'ordonnance collective ne peut viser n'importe quel type d'activité. L'activité visée doit déjà faire partie du champ d'exercice professionnel de la personne qui l'appliquera¹¹⁰. Autrement dit, la loi doit déjà autoriser ce professionnel à exercer l'activité visée quand il se base sur une ordonnance. Par exemple, il serait impossible d'utiliser une ordonnance collective pour habilitier une infirmière à poser un diagnostic puisque la loi ne lui permet pas de poser un diagnostic à partir d'une ordonnance. Cependant, une ordonnance collective pourrait permettre à une infirmière d'effectuer des « tests diagnostiques invasifs » puisque la loi l'autorise à le faire lorsqu'une ordonnance existe¹¹¹.

Quand un médecin rédige une ordonnance collective, il peut la rendre applicable à petite échelle dans son milieu de pratique (par ex. aux infirmières travaillant dans sa clinique¹¹²) ou plus largement aux infirmières de sa région (par ex. aux infirmières du territoire d'un établissement de santé¹¹³).

¹⁰⁸ Voir Collège des médecins du Québec, « Les ordonnances collectives – Guide d'exercice, Montréal » (2017) à la p 6, en ligne (pdf) : <www.cmq.org/publications-pdf/p-1-2017-05-01-fr-ordonnances-collectives.pdf?t=1539281177942> [perma.cc/H4AX-QVPT].

¹⁰⁹ *Ibid* à la p 10.

¹¹⁰ Voir *ibid* à la p 11.

¹¹¹ *Loi sur les infirmières*, *supra* note 38, art 36(5).

¹¹² Voir Centre de santé et de services sociaux de Lanaudière, « Ordonnance collective : Initier un examen radiologique et de consultation en clinique de santé du sein » (2012) en ligne (pdf) : <https://www.cisss-lanaudiere.gouv.qc.ca/fileadmin/internet/cisss_lanaudiere/Professionnels/Ordonnances_collectives_Soins_infirmiers/Ordonnances_collectives_Soins_infirmiers_Sud/1ere_ligne_soins_ambulatoires_adultes_/SUD_OC_7.22_Examen_radiologique_et_consultation_sein.pdf> [perma.cc/38A2-AVTW].

¹¹³ Voir Centre intégré universitaire de santé et de services sociaux de l'Estrie, « Ordonnance Collective : Faire une demande de stratification ou de consultation en cardiologie dans le cadre du programme Agir sur sa santé » (2016) à

L'ordonnance collective doit toujours identifier le groupe de personnes visé ou la situation clinique visée¹¹⁴. Elle doit obligatoirement inclure un « protocole médical »¹¹⁵, c'est-à-dire « une description des procédures, méthodes, limites, contre-indications ou normes applicables pour une condition clinique particulière »¹¹⁶.

Il est essentiel de saisir que la mise en œuvre d'une ordonnance collective par une infirmière ne se déroule pas en vase clos. Il s'agit plutôt d'une façon d'organiser la synergie entre le médecin et l'infirmière. À ce titre, l'ordonnance collective implique la collaboration d'un médecin qui supporte, au besoin, l'infirmière qui applique l'ordonnance¹¹⁷. Aussi, l'ordonnance collective doit indiquer les renseignements que l'infirmière doit transmettre au médecin traitant du patient pour qu'il assure le suivi¹¹⁸. Ainsi, si l'ordonnance collective était utilisée pour faire jouer un rôle élargi à l'infirmière dans l'Approche individualisée, l'implication d'un médecin serait toujours possible devant une situation particulière dépassant les compétences de l'infirmière.

L'ordonnance collective est considérée comme « un levier qui permet d'améliorer l'accessibilité des services de santé à la population québécoise et de favoriser une meilleure utilisation des compétences professionnelles »¹¹⁹. Les objectifs de l'ordonnance collective semblent compatibles avec son utilisation dans l'Approche individualisée considérant qu'elle :

la p 1, en ligne (pdf) : *Centre hospitalier universitaire de Sherbrooke* <www.santeestrie.qc.ca/clients/SanteEstrie/Professionnels/Ordonnances_collectives/Ordonnances-collectives-regionales/OC-MC-004_Demande_de_stratification_ASSSE.pdf> [perma.cc/4FK4-XHY4].

¹¹⁴ Voir *Règlement sur les normes relatives aux ordonnances faites par un médecin*, *supra* note 108, art 24(4).

¹¹⁵ *Ibid*, art 24 (8).

¹¹⁶ *Les ordonnances collectives – Guide d'exercice*, *supra* note 109, à la p 7.

¹¹⁷ Voir *Règlement sur les normes relatives aux ordonnances faites par un médecin*, *supra* note 108, art 24(17); *Les ordonnances collectives – Guide d'exercice*, *supra* note 109, à la p 9.

¹¹⁸ Voir *Règlement sur les normes relatives aux ordonnances faites par un médecin*, *supra* note 108, art 24(16).

¹¹⁹ *Le champ d'exercice*, *supra* note 37, à la p 7.

[...] permet d'optimiser la prestation de soins par un déploiement complémentaire et plus efficace des compétences des différents professionnels de la santé. [...] Le médecin peut donc se concentrer sur les activités qu'il est le seul à pouvoir exercer¹²⁰.

Comment le rôle de l'infirmière dans l'Approche individualisée pourrait-il être élargi par le levier qu'est l'ordonnance collective?

Comme on l'a vu, en respect de son champ d'exercice professionnel, l'infirmière peut « initier des mesures diagnostiques selon une ordonnance »¹²¹. Il peut s'agir autant d'une ordonnance individuelle que d'une ordonnance collective¹²². Pour utiliser l'ordonnance collective dans l'Approche individualisée, un médecin devrait rédiger une telle ordonnance autorisant des infirmières à mettre en œuvre cette approche, soit : à effectuer le prélèvement sanguin, à demander l'analyse du risque et l'analyse génétique, et à demander des examens d'imagerie. D'ailleurs, des ordonnances collectives autorisant des infirmières à initier un prélèvement sanguin et leur analyse en laboratoire sont en vigueur dans le système de santé, par exemple lors de saignements chez la femme enceinte¹²³ ou lors d'une exposition accidentelle à un liquide biologique¹²⁴. D'autres milieux utilisent des ordonnances collectives qui permettent aux infirmières d'initier un examen radiologique des seins, comme lors d'une consultation en clinique du sein

¹²⁰ *Les ordonnances collectives – Guide d'exercice*, supra note 109, à la p 10.

¹²¹ *Loi sur les infirmières*, supra note 38, arts 36(3), (5), (8).

¹²² Voir *Code des professions*, supra note 34, art 39.3(1).

¹²³ Voir généralement Centre de santé et services sociaux de Québec-Nord, « Initier les prélèvements sanguins lors de saignement vaginal chez l'usagère enceinte » (2015), en ligne (pdf) : <www.ciuss-s-capitalnationale.gouv.qc.ca/sites/default/files/oc-44-initier-prelevements-sanguins-femme-enceinte.pdf> [perma.cc/7938-FFBB].

¹²⁴ Voir généralement Centre de santé et services sociaux, « Procéder à un bilan sanguin dans le cadre de l'application du protocole post exposition au sang et aux liquides biologiques (PPE) du CSSS-IUGS » (2011), en ligne (pdf) : *Institut universitaire de gériatrie de Sherbrooke* <www.csss-iugs.ca/c3s/data/files/Ordonnances%20collectives/ORD_CMDP_16_web.pdf> [perma.cc/3ZRW-Z7WW].

avec une patiente symptomatique¹²⁵, ou lors d'un suivi de résultat anormal de mammographie¹²⁶.

L'initiation de mesures diagnostiques par l'infirmière inclut aussi l'interprétation des résultats qui en découlent, mais non la formulation de recommandations de suivi basées sur une évaluation globale de l'état de santé. Pour cette raison, il faudrait envisager un mécanisme qui assurerait que l'initiation d'examen d'imagerie par l'infirmière se fasse en fonction de critères préétablis (et non à la suite d'une évaluation globale de l'état de santé). Ces conditions pourraient notamment être définies dans le « protocole médical » qui doit obligatoirement accompagner toute ordonnance collective¹²⁷. Ce protocole médical devrait préciser les situations où il est approprié que l'infirmière initie un examen d'imagerie et celles, plus complexes, où il est nécessaire de consulter un médecin.

D. Le recours aux IPS

La pratique de l'IPS combine la pratique infirmière courante et la pratique de certaines activités habituellement réservées au médecin, appelées « activités médicales ». Lorsque l'IPS exerce des activités médicales, elle le fait en respectant un ensemble de conditions déterminées par règlements qui sont adoptés par le Collège des médecins du Québec¹²⁸. Par exemple, l'IPS peut « prescrire des examens diagnostiques », « prescrire des médi-

¹²⁵ Voir Centre de santé et de services sociaux du Sud de Lanaudière, « Ordonnance collective : Initier un examen radiologique et de consultation en clinique de santé du sein » (2012), en ligne (pdf) : <https://www.cisss-lanaudiere.gouv.qc.ca/fileadmin/internet/cisss_lanaudiere/Professionnels/Ordonnances_collectives_Soins_infirmiers/Ordonnances_collectives_Soins_infirmiers_Sud/1ere_ligne_soins_ambulatoires_adultes_/SUD_OC_7.22_Examen_radiologique_et_consultation_sein.pdf> [perma.cc/G22F-94QV].

¹²⁶ Voir Centre de santé et de services sociaux, « Assurer le suivi des résultats des mammographies de dépistage dans le cadre du Programme québécois de dépistage du cancer du sein et procéder aux examens complémentaires requis » (2015), en ligne (pdf) : *Institut universitaire de gériatrie de Sherbrooke* <www.ccss-iugs.ca/c3s/data/files/Ordonnances%20collectives/ORD-CMDP-67-Web.pdf> [perma.cc/5Q98-A7MW].

¹²⁷ Voir *Règlement sur les normes relatives aux ordonnances faites par un médecin*, *supra* note 108, art 24 (8).

¹²⁸ Voir *Loi médicale*, *supra* note 33, art 19(b).

caments et d'autres substances » et « utiliser des techniques ou appliquer des traitements médicaux, invasifs ou présentant des risques de préjudice » aux conditions prévues dans le *Règlement sur les infirmières praticiennes spécialisées*¹²⁹. En 2018, on comptait 562 IPS au Québec, ce qui représente seulement 0,7% de l'effectif infirmier¹³⁰. L'IPS est une infirmière qui a complété une formation universitaire de deuxième cycle et qui a réussi un examen de spécialité qui lui permet d'exercer auprès d'une clientèle particulière¹³¹. Lorsque l'IPS exerce des activités médicales, elle doit les accomplir dans le cadre d'un « partenariat » formel avec un ou plusieurs médecins¹³². Malgré cette exigence de partenariat, le Collège des médecins du Québec et l'Ordre des infirmières et infirmiers du Québec considèrent que l'IPS n'est pas subordonnée à un médecin partenaire¹³³ et qu'elle agit en toute autonomie¹³⁴. Le médecin partenaire exerce plutôt « une surveillance générale de la qualité et de la pertinence des activités médicales » qui sont effectuées par l'IPS¹³⁵, sans que cela constitue de la subordination¹³⁶.

L'IPS doit respecter les conditions particulières applicables à l'un des 5 champs de spécialité lorsqu'elle exerce des activités médicales¹³⁷. Pour pou-

¹²⁹ RLRQ, c M-9, r 23.1, art 4 [*Règlement sur les IPS*].

¹³⁰ Voir OIIQ, « Rapport statistique », *supra* note 19, à la p 15.

¹³¹ Voir Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, « Pratique clinique de l'infirmière praticienne spécialisée en soins de première ligne : Lignes directrices » (2019) à la p 7, en ligne (pdf) : <www.cmq.org/publications-pdf/p-1-2019-07-23-fr-lignes-dir-ips-premiere-ligne.pdf> [perma.cc/Z3V8-JQ3C] [« Pratique clinique de l'IPS – Soins de première ligne (2019) »].

¹³² *Règlement sur les IPS*, *supra* note 130, art 12. Ce partenariat peut aussi être établi avec un département ou un service clinique d'un centre hospitalier.

¹³³ Voir « Pratique clinique de l'IPS – Soins de première ligne (2019) », *supra* note 132, à la p 32.

¹³⁴ Voir *ibid* à la p 34.

¹³⁵ *Règlement sur les IPS*, *supra* note 130, art 14.

¹³⁶ Voir Collège des médecins du Québec, « Pour un partenariat réussi MD-IPS. Guide à l'intention du médecin » (2019) à la p 12, en ligne (pdf) : <[www.cmq.org/publications-pdf/p-1-2019-02-18-fr-partenariat-reussi-md-ips.pdf](http://www.cmq.org/publications-pdf/p-1-2019-02-18-fr-partenariat-reussi-md-ips.pdf?t=1616119009319)?t=1616119009319> [perma.cc/YHJ4-FEBA].

¹³⁷ Voir *Règlement sur les IPS*, *supra* note 130, arts 5-9 (il s'agit de la néonata-

voir exercer des activités médicales dans l'un de ces champs de spécialité, l'IPS doit détenir un certificat approprié de spécialiste décerné par l'Ordre des infirmières et infirmiers du Québec¹³⁸. L'IPS en soins de première ligne (« IPS-SPL ») est la classe de spécialité qui pourrait être considérée pour exercer les activités de l'Approche individualisée¹³⁹. Selon la loi, l'IPS-SPL exerce ses activités médicales auprès d'une clientèle de tout âge qui requiert des soins de première ligne¹⁴⁰.

Comment le recours à l'IPS-SPL pourrait ouvrir la voie à un rôle élargi de l'infirmière dans l'Approche individualisée? D'abord, il faut préciser que l'IPS-SPL peut exercer des activités médicales (ex. prescrire des examens diagnostiques) seulement auprès de la clientèle de première ligne qui se trouve dans certaines situations définies par la loi¹⁴¹. La situation qui semble la plus compatible avec l'Approche individualisée est celle où la clientèle « présente un problème de santé courant »¹⁴². Cette exigence fait-elle en sorte d'exclure l'exercice d'activités médicales liées au dépistage du cancer

logie, des soins pédiatriques, des soins aux adultes, de la santé mentale et des soins de première ligne).

¹³⁸ Voir *ibid*, arts 1, 3, 26.

¹³⁹ L'IPS en soins aux adultes doit exercer ses activités médicales seulement auprès de personnes qui requièrent des soins de deuxième ou de troisième ligne. On retrouve l'IPS en soins aux adultes avec des clientèles déjà aux prises avec des problèmes de santé importants, comme en cardiologie ou en néphrologie. Il semble clair que l'Approche individualisée n'est pas appropriée pour ce type de pratique, car les activités systémiques de prévention et de dépistage sont habituellement initiées par les intervenants de première ligne (*Règlement sur les IPS, supra* note 130, arts 2, 7; Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, « Pratique clinique de l'infirmière praticienne spécialisée en soins aux adultes : Lignes directrices », (2019) aux pp 9–11, en ligne (pdf) : <www.oiiq.org/documents/20147/237836/2507-lignes-directrices-IPSSA-web.pdf/2cf994f4-4258-136f-8744-a6268c5561e3?version=1.0> [perma.cc/WJK7-P552]).

¹⁴⁰ *Règlement sur les IPS, supra* note 130, art 9.

¹⁴¹ Voir *ibid*.

¹⁴² *Ibid*. Des balises établissent les caractéristiques d'un problème de santé courant : ce dernier a une incidence élevée dans la communauté, les symptômes affectent habituellement un seul système, l'état général de la personne ne s'est pas détérioré et l'évolution est habituellement rapide et favorable (*ibid*, art 2 au para 3).

du sein par l'IPS-SPL auprès de la clientèle de l'Approche individualisée? Non seulement cette clientèle est asymptomatique de cancer du sein, mais elle peut aussi être asymptomatique de toute autre maladie au moment de rencontrer une IPS-SPL¹⁴³.

Si on regardait les dispositions légales dénuées d'un contexte factuel, on pourrait exiger que la clientèle desservie « présente un problème de santé courant » sous sa forme classique pour que l'IPS-SPL se qualifie pour exercer des activités médicales auprès de cette clientèle. Cette optique semblerait s'arrimer avec le principe voulant que les lois qui établissent les champs d'exercice professionnel doivent être interprétées restrictivement puisqu'elles visent à protéger le public¹⁴⁴. Toutefois, comme l'a rappelé la Cour supérieure, ce principe d'interprétation s'est toujours accompagné « du souci des tribunaux de ne pas restreindre indûment la liberté de travail » et de considérer le risque de préjudice au patient¹⁴⁵.

Ainsi, une lecture contextuelle et libérale des dispositions, qui prend en compte l'évolution du rôle de l'IPS-SPL dans la pratique et sur le plan

¹⁴³ En matière de dépistage des maladies, deux modèles principaux existent : le dépistage opportuniste et le dépistage systématique. Le dépistage opportuniste est offert aux patients à l'occasion d'une rencontre avec leur professionnel de la santé et la raison de la rencontre n'est pas forcément le dépistage. L'utilisation de ce modèle avec les IPS-SPL ne réglerait pas le problème d'accès aux professionnels de la santé soulevé au début de ce texte. En effet, ce modèle reproduirait un système où seulement les patientes qui ont la chance d'avoir un médecin de famille (ou une IPS-SPL) pourraient avoir une porte d'accès au dépistage. À l'opposé, un modèle de dépistage systématique sollicite périodiquement des personnes asymptomatiques sur une très large échelle en leur fournissant massivement des examens. Dans ce modèle, le mandat de l'IPS-SPL serait essentiellement la mise en œuvre de l'Approche individualisée, habituellement dans le cadre d'un programme de dépistage. C'est ce modèle qui nous intéresse – et auquel nous référons dans notre analyse – puisqu'il permettrait de répondre à la problématique de l'accès aux professionnels de la santé (Institut national de santé publique du Québec, « Pertinence et faisabilité d'un programme de dépistage du cancer colorectal au Québec » (2008) à la p 3, en ligne (pdf) : [INS PQ <www.inspq.qc.ca/pdf/publications/882_PertinFaisPrograCcColo.pdf](http://www.inspq.qc.ca/pdf/publications/882_PertinFaisPrograCcColo.pdf) > [<https://perma.cc/P3SP-36V7>]).

¹⁴⁴ Voir *Pauzé c Gauvin*, [1954] RCS 15 à la p 18; *Laporte c Collège des pharmaciens de la province de Québec*, [1976] 1 RCS 101 à la p 102.

¹⁴⁵ Voir *Collège des médecins du Québec c Galipeau*, 2008 QCCS 2983 aux para 14–15 [*Collège des médecins du Québec*].

juridique, nous laisse plutôt penser que l'IPS-SPL serait autorisée à exercer des activités médicales auprès de la clientèle de l'Approche individualisée. Avec cette interprétation libérale, le « problème de santé courant » que présente cette clientèle prendrait la forme d'un besoin de connaître son risque de développer un cancer du sein, d'obtenir davantage d'information sur les options offertes et d'avoir accès aux moyens de dépistage permettant d'identifier précocement une potentielle tumeur.

L'ancêtre de l'IPS est entrée dans le cadre juridique du système de santé du Québec en 2002 lorsque l'infirmière a obtenu le droit d'exercer certaines activités réservées au médecin, à des conditions précises¹⁴⁶. Plusieurs changements étaient apportés à la loi afin d'établir un « nouveau part-age des champs d'exercice professionnels dans le domaine de la santé »¹⁴⁷. À l'époque, les espoirs qui accompagnaient la reconnaissance de l'ancêtre de l'IPS se comprennent facilement lorsqu'on sait qu'elle était alors appelée « super infirmière ». Ainsi, la super infirmière pouvait désormais, entre autres, prescrire des examens diagnostiques et des médicaments¹⁴⁸. La spécialité de soins de première ligne est créée en 2008. À ce moment, les médicaments et examens qu'une IPS-SPL peut prescrire sont déterminés par règlement et incluent du dépistage pour clientèle asymptomatique (ex. mammographie)¹⁴⁹.

Pour encadrer davantage la pratique des IPS-SPL qui arrivent dans le système de santé, l'Ordre des infirmières et infirmiers du Québec et le Collège des médecins du Québec adoptent en 2008 des lignes directrices qui font une large place à la clientèle asymptomatique en reconnaissant à l'IPS-

¹⁴⁶ Voir PL 90, *Loi modifiant le Code des professions et d'autres dispositions législatives dans le domaine de la santé*, 2e sess, 36e lég, Québec, 2002 (sanctionné le 14 juin 2002), LQ 2002, c.33, aux para 10–14.

¹⁴⁷ *Ibid*, notes explicatives, à la p 2.

¹⁴⁸ *Ibid*, art 12. Il est intéressant de noter qu'il s'agit des mêmes activités médicales que l'IPS peut aujourd'hui exercer : le législateur n'y changera pas un mot lorsqu'il adoptera un tout nouveau règlement pour encadrer les IPS 16 ans plus tard (*Règlement sur les IPS*, *supra* note 130, art 4).

¹⁴⁹ Voir *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*, RLRQ c M-9, r 13, art 8.4. [*Règlement sur les activités visées à l'article 31 de la Loi médicale*].

SPL un rôle important dans la prévention et l'examen périodique¹⁵⁰. Il est alors considéré que l'anamnèse, l'examen physique et l'examen périodique sont des activités réservées que le médecin et l'IPS-SPL peuvent exercer¹⁵¹.

En 2018, dix ans après l'introduction de la super infirmière dans la loi, le législateur adopte un nouveau règlement qui augmente l'autonomie de celle-ci. D'abord, les médicaments et examens diagnostiques que peut prescrire l'IPS ne sont plus limités à ceux inscrits dans une liste¹⁵². En plus, l'IPS-SPL peut désormais « amorcer » le traitement de six problèmes de santé chroniques qui n'ont pas encore été confirmés par un diagnostic¹⁵³. Il faut préciser que selon les lignes directrices communes des deux ordres professionnels concernés, l'IPS-SPL n'est pas sensée poser de diagnostic : elle amorce un traitement « sans qu'un diagnostic final n'ait été établi au préalable par le médecin »¹⁵⁴. Un médecin sera appelé par la suite à établir le diagnostic dans les 30 jours¹⁵⁵. Le rôle de l'IPS-SPL est toutefois très large : elle peut « procéder à une évaluation avancée de l'état de santé », « établir des hypothèses ainsi que des impressions cliniques » et « déterminer les interventions thérapeutiques appropriées »¹⁵⁶. En fait, la frontière

¹⁵⁰ Voir Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, « Étendue des activités médicales exercées par l'infirmière praticienne spécialisée en soins de première ligne » (2008) à la p 23, en ligne (pdf) : *OIIQ* <https://www.oiq.org/uploads/publications/autres_publications/IPS_soins_premiere_ligne.pdf> [perma.cc/Y5CK-GHUZ]. On indique que l'IPS-SPL « peut prescrire ou procéder aux examens diagnostiques nécessaires à l'évaluation et au suivi du patient afin : [...] de procéder aux divers dépistages » (à la p 38).

¹⁵¹ Voir *ibid.*, à la p 38.

¹⁵² Voir *Règlement sur les IPS*, *supra* note 130, art 4.

¹⁵³ *Ibid.*, art 10. Il s'agit de l'hypertension, l'hypercholestérolémie, l'asthme, les maladies obstructives pulmonaires chroniques, et l'hypothyroïdie.

¹⁵⁴ Voir Ordre des infirmières et infirmiers du Québec et Collège des médecins du Québec, *Pratique clinique de l'infirmière praticienne spécialisée en soins de première ligne : Lignes directrices*, (2018) aux pp 13–14, en ligne (pdf) : *BAnQ numérique* <numerique.banq.qc.ca/patrimoine/details/52327/2434529?docref=350J2GcZe6AmAqSGXCCdeA> [perma.cc/B4MV-33LZ].

¹⁵⁵ Voir *Ibid.*

¹⁵⁶ *Ibid.*, à la p 30; *Pour un partenariat réussi MD-IPS*, *supra* note 127, p 9.

devient très floue entre le rôle de l'IPS-SPL et du médecin à l'égard de ces six problèmes de santé.

En juillet 2019, le Collège des médecins du Québec et l'Ordre des infirmières et infirmiers du Québec publient une version révisée des lignes directrices applicables aux différentes classes d'IPS, incluant l'IPS-SPL¹⁵⁷. Il n'est maintenant plus nécessaire de faire voir le patient par un médecin dans les 30 jours de l'amorce du traitement d'un problème de santé chronique¹⁵⁸. Dans la pratique, l'amorce du traitement d'un problème de santé chronique par une IPS, sans obligation de voir un médecin par la suite, produit peut-être les mêmes effets que l'établissement d'un diagnostic.

En mars 2020, le législateur adopte une loi visant à accroître les activités exercées par les IPS¹⁵⁹. Lorsque cette loi sera en vigueur, l'IPS pourra, à certaines conditions prévues par règlement, « diagnostiquer des maladies » et « déterminer des traitements médicaux »¹⁶⁰. Il ressort clairement de cette loi une volonté d'accroître le rôle de l'IPS en matière d'évaluation globale de l'état de santé.

À la lumière de l'évolution de l'encadrement juridique des activités de l'IPS-SPL, il est clair que les décideurs impliqués ont longtemps compris son rôle comme incluant la prise en charge des activités de dépistage chez une clientèle asymptomatique, sans égard à la raison de la consultation. La volonté récente d'élargir le rôle de l'IPS-SPL au regard du diagnostic, tel que nous venons de le voir, nous oblige à conclure que les compétences de celles-ci concernant le dépistage auprès d'une clientèle asymptomatique n'ont jamais été remises en question.

¹⁵⁷ Voir « Pratique clinique de l'IPS – Soins de première ligne (2019) », *supra* note 132.

¹⁵⁸ *Ibid* aux pages 16, 30, 58. Les lignes directrices précisent toujours explicitement que seul le médecin est habilité à poser un diagnostic, qu'il soit provisoire, différentiel ou final ; Ordre des infirmières et infirmiers du Québec, « IPS : Mise à jour des lignes directrices » (1er août 2019), en ligne : <www.oiiq.org/en/ips-mise-a-jour-des-lignes-directrices> [perma.cc/4QV7-846H].

¹⁵⁹ PL 43, *Loi modifiant la Loi sur les infirmières et les infirmiers et d'autres dispositions afin de favoriser l'accès aux services de santé*, 1^e sess, 42^e lég, Québec, 2020 (sanctionné le 17 mars 2020), LQ 2020, c.6.

¹⁶⁰ *Ibid.*, art. 3 par 1 et 4 (il faut noter que le projet de loi 43 limitait le diagnostic aux maladies qualifiées de « courantes »).

Ayant conclu que l'IPS-SPL est autorisée à exercer des activités médicales dans le cadre d'un dépistage auprès de la clientèle de l'Approche individualisée, il faut voir quelles activités du rôle élargi de l'infirmière dans l'Approche individualisée elle pourrait exercer (voir la Figure 2). D'abord, au moment de décider si l'IPS-SPL peut exercer une activité médicale, il est recommandé de considérer plusieurs paramètres, incluant la complexité clinique, le type de prise en charge requis, les risques de préjudice et la gravité des complications¹⁶¹. Procéder à une analyse approfondie de ces critères dépasserait le cadre de l'analyse juridique puisque cela nécessiterait une analyse conjuguant des données cliniques et contextuelles. Sans procéder à une telle analyse approfondie, il est utile de remarquer que les examens d'imagerie pour le dépistage du cancer du sein ont déjà été reconnus par le législateur parmi les examens que l'IPS-SPL peut prescrire¹⁶². De plus, les lignes directrices des ordres professionnels concernés ont déjà établi que l'IPS-SPL « peut prescrire ou procéder aux examens diagnostiques nécessaires à l'évaluation et au suivi du patient afin : [...] de procéder aux divers dépistages »¹⁶³.

Dans l'Approche individualisée, comme la loi autorise l'IPS-SPL à utiliser des techniques invasives sans ordonnance¹⁶⁴, elle serait habilitée à effectuer le prélèvement sanguin sans ordonnance. Ensuite, puisque l'IPS-SPL est habilitée à prescrire des examens diagnostiques (non limités par une liste)¹⁶⁵, elle pourrait requérir l'analyse de laboratoire aux fins d'évaluer le risque. Avec l'ampleur du rôle que l'IPS-SPL est maintenant autorisée à exercer à l'égard de la prise en charge des patients, il semble raisonnable de conclure qu'elle serait aussi autorisée à recommander et prescrire des examens de dépistage à la suite d'une évaluation globale de l'état de santé de la patiente.

La prise en compte de l'état de santé global fait nécessairement partie du mandat de l'IPS-SPL au moment de prescrire des médicaments ou des

¹⁶¹ Voir « Pratique clinique de l'IPS – Soins de première ligne (2019) », *supra* note 132, à la p 19.

¹⁶² Voir *Règlement sur les activités visées à l'article 31 de la Loi médicale, c M-9, r 1.3* *supra* note 150, Annexe 1.

¹⁶³ Voir *Étendue des activités médicales exercées par l'infirmières praticienne spécialisée en soins de première ligne*, à la p 23.

¹⁶⁴ *Règlement sur les IPS*, *supra* note 130, art 4.

¹⁶⁵ *Ibid.*

examens, ou d'initier le traitement de problèmes de santé chronique avant le diagnostic du médecin. Par exemple, bien qu'elle ne puisse diagnostiquer la maladie de Parkinson, l'IPS-SPL devrait prendre en compte les impacts de cette maladie (ex. médication, autonomie, espérance de vie) au moment de diagnostiquer et traiter n'importe quel problème de santé courant à une personne atteinte de Parkinson. Cette marge de manœuvre consentie à l'IPS-SPL est balisée par l'obligation qui lui est donnée de respecter les limites de ses habiletés et connaissances¹⁶⁶, et même de demander l'intervention d'un médecin partenaire lorsque « les soins requis par le patient dépassent ses compétences »¹⁶⁷. Aussi, tel que vu plus haut, le Collège des médecins du Québec a indiqué en 2019 son intention d'autoriser l'IPS à poser un diagnostic¹⁶⁸ pour un problème de santé courant ou pour l'un des six problèmes de santé identifiés. Et le législateur a adopté en 2020 une loi dont la mise en vigueur permettra aux IPS de diagnostiquer des maladies, en respect d'une réglementation¹⁶⁹. Dans ce contexte, il faut conclure que l'IPS-SPL pourrait effectuer, de façon autonome, toutes les tâches du rôle élargi que l'on souhaite faire jouer à l'infirmière dans l'Approche individualisée.

Conclusion

La personnalisation des mesures de prévention et de dépistage du cancer du sein, comme le fait l'Approche individualisée, s'apprête à prendre de l'expansion dans les systèmes de santé, ici et ailleurs dans le monde. Comme les programmes de dépistage actuels de cancer du sein concentrent leur interaction avec le patient dans la période suivant un résultat anormal de mammographie, implanter l'Approche individualisée impliquera un changement majeur de leur organisation, notamment quant au personnel qui évaluera le risque et fournira les conseils avant même d'arriver à la

¹⁶⁶ *Code de déontologie des infirmières et des infirmiers*, *supra* note 89, art 17.

¹⁶⁷ *Règlement sur les IPS*, *supra* note 130, art 15.

¹⁶⁸ Voir généralement Collège des médecins du Québec, « Infirmières praticiennes spécialisées : le Collège des médecins modifie sa position à l'égard du diagnostic pour améliorer l'accès aux soins », (23 février 2019), en ligne : *Collège des médecins du Québec* <www.cmq.org/nouvelle/fr/ips-le-college-modifie-sa-position-diagnostic.aspx> [perma.cc/M563-TRP5].

¹⁶⁹ Voir Loi modifiant la Loi sur les infirmières et les infirmiers et d'autres dispositions afin de favoriser l'accès aux services de santé, *supra* note 160, art 3 para1.

mammographie¹⁷⁰. Une réorganisation des rôles des professionnels de la santé impliqués dans le dépistage est à prévoir. Comme on l'a vu, le rôle de l'infirmière pourrait en faire partie.

Si l'élargissement du rôle de l'infirmière pourrait constituer une solution juridique à la difficulté d'accès aux médecins en contexte de dépistage, elle comporte tout de même des limites. Trois moyens juridiques pourraient être envisagées pour permettre à l'infirmière d'occuper un rôle élargi dans l'Approche individualisée sans toutefois pouvoir remplir toutes les tâches nécessaires : recourir au Programme national de santé publique, partager certains actes réservés aux médecins ou utiliser une ordonnance collective. Ces moyens ne permettraient pas à l'infirmière d'effectuer une évaluation de l'état de santé global de la patiente afin de formuler des recommandations personnalisées. Toutefois, cette étape devrait être nécessaire seulement dans les cas plus complexes qui ne peuvent être encadrés par des lignes directrices ou des guides de pratique.

Le recours à l'IPS-SPL serait une solution juridique à envisager pour permettre à l'infirmière de remplir toutes les tâches attendues, y incluant de formuler ces recommandations personnalisées. Il ne resterait que les situations dépassant les compétences de l'IPS-SPL qui nécessiteraient de référer la patiente vers un médecin. L'IPS-SPL pourrait assurer tout le continuum de soins de l'Approche individualisée, ou encore être impliquée seulement avec les patientes qui ont besoin d'une évaluation de l'état de santé global afin de leur formuler des recommandations personnalisées. Selon le contexte et les besoins, ces quatre moyens pourraient aussi bien être utilisés séparément qu'être combinés. Par exemple, une ordonnance collective pourrait être utilisée pour permettre à certaines infirmières d'accomplir la grande majorité des tâches, et des IPS-SPL pourraient arriver en renfort lorsqu'une évaluation de l'état de santé global et de recommandations personnalisées sont requises.

Notre analyse s'est attardée uniquement aux aspects juridiques de l'élargissement du rôle de l'infirmière, se limitant à l'analyse de son encadrement juridique et déontologique. La faisabilité et l'acceptabilité des quatre moyens théoriques que nous avons identifiés demeurent une question

¹⁷⁰ Voir Sowmiya Moorthie, Hilary Burton, Louise Gaynor, Tanya Brigden et Chantal Babb de Villiers, « Personalising Prevention for Breast Cancer - Workshop Report » (2019) aux pp 39, 46 et 47, en ligne (pdf) : *PHG Foundation* <<https://www.phgfoundation.org/documents/b-cast-workshop-2019.pdf>> [perma.cc/B9UL-99U8].

importante à laquelle notre analyse juridique ne peut répondre ici. Toutefois, d'autres membres de notre équipe de recherche étudient actuellement ces aspects en interrogeant des professionnels de la santé du Québec. Cela permettra de nous éclairer sur l'applicabilité de nos conclusions juridiques dans le contexte réel de la pratique clinique.

CASE COMMENT: MCKITTY v HAYANI: TIME FOR CANADA TO CLARIFY ITS LEGAL DEFINITION OF DEATH

*Erika Chamberlain, LLB, PhD**

This commentary analyzes the patchwork of Canadian legal provisions dealing with the definition of death, which largely accept the medical concept of brain death. However, as the Ontario Court of Appeal discussed in *McKitty v Hayani*, death is a complex phenomenon with important philosophical and spiritual dimensions. This complexity is especially prominent when a patient believes that a person whose heart is beating – even if only by mechanical means – is still alive. It is argued that greater transparency is needed regarding both the medical and legal concepts of brain death, such that organ donation or removal from life support are conducted with fully informed consent.

Ce commentaire analyse la mosaïque de dispositions juridiques canadiennes traitant de la définition de la mort, qui acceptent largement le concept médical de la mort cérébrale. Cependant, comme la Cour d'appel de l'Ontario l'a expliqué dans *McKitty c Hayani*, la mort est un phénomène complexe comportant d'importantes dimensions philosophiques et spirituelles. Cette complexité est particulièrement prononcée lorsqu'un patient croit qu'une personne dont le cœur bat – même si ce n'est que par des moyens mécaniques – est toujours en vie. Il est avancé qu'une plus grande transparence est nécessaire en ce qui concerne les concepts médicaux et juridiques de la mort cérébrale pour faire en sorte que le don d'organes ou le retrait de l'appareil de survie soient effectués avec un consentement pleinement éclairé.

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INTRODUCTION

In its recent decision in *McKitty v Hayani*,¹ the Ontario Court of Appeal confirmed that a person who experiences total brain death is legally dead, notwithstanding the fact that the person's heart, lungs and other organs may continue to function with mechanical assistance. Accordingly, at this point, a physician can complete a death certificate and withdraw life support. At the same time, the court of appeal stressed that the legal definition of death may be more complex than the one dictated by medical practice, involving profound questions of religion, culture, and philosophy. The court left an open opportunity for future litigants to challenge the accepted definition of death on the basis of a religious belief, for example, that a person is still alive as long as his or her heart continues to beat.

The *McKitty* decision thus brought renewed attention to the lack of a uniform legal definition of death in Canada.² Presently, there is a patchwork of definitions in the common law and in a range of provincial statutes that are used for purposes such as organ donation and vital statistics. Several of the statutes simply refer to the accepted medical criteria for death, which may shift over time and do not take into account the religious or cultural aspects emphasized by the court of appeal.³ Given the Court's thinly veiled invitation for a litigant to challenge the current law as a violation of the *Charter* right to freedom of religion,⁴ it is opportune to revisit the existing law and the complications it poses. This is especially true as provinces contemplate the introduction of opt-out (or "presumed consent") organ dona-

¹ 2019 ONCA 805 [*McKitty* ONCA], aff'g 2018 ONSC 4015 [*McKitty* ONSC].

² This would presumably need to include federal legislation as well, given the federal government's exclusive jurisdiction over criminal law. See *Constitution Act* (UK), 1867, 30 & 31 Vict, c 3, s 91(27).

³ See *McKitty* ONCA, *supra* note 1 at paras 76–78.

⁴ See *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, s 2(a) [*Charter*]; *McKitty* ONCA, *supra* note 1 (the court's comments at para 103).

tion frameworks.⁵ Such frameworks will potentially spawn additional challenges to the neurological determination of death, as some unsuspecting families may react negatively to efforts to remove organs from a loved one who has been declared brain-dead. In addition, as Parliament debates new amendments to the *Criminal Code* related to medical assistance in dying (MAID),⁶ it would help to develop consistent principles regarding dignity and autonomy in the dying process, and to provide clarity on the constitutional status of brain-dead patients.

The law discussed in this comment rests on the distinction between cardiopulmonary death and brain death – a distinction that oversimplifies what are complex, integrated processes. Cardiopulmonary death, which corresponds to traditional lay understandings of death, is demonstrated by the irreversible cessation of pulse and breathing.⁷ Hence, a person is typically considered dead by cardiopulmonary criteria if he or she has no pulse or breathing and the accepted period for spontaneous or medical resuscitation

⁵ In 2019, Nova Scotia became the first province to introduce opt-out legislation: see *Human Organ and Tissue Donation Act*, SNS 2019, c 6 (effective January 2021) [*NS 2019 Tissue Donation Act*]. A similar Bill has also been introduced in Alberta: See Bill 205, *Human Tissue and Organ Donation (Presumed Consent) Amendment Act*, 1st Sess, 30th Leg, Alberta, 2019. See also Carrie Tait, “Alberta’s tabled bill to opt-out of organ donation could backfire on health-care system, experts say” (29 November 2019), online: *The Globe and Mail* <the-globeandmail.com/canada/alberta/article-bill-could-make-alberta-the-second-province-with-an-opt-out-approach/> [perma.cc/X2QQ-PFSF].

⁶ See Bill C-7, *An Act to amend the Criminal Code (medical assistance in dying)*, 2nd Sess, 43rd Parl, 2020, especially in response to *Truchon c Procureur général du Canada*, 2019 QCCS 3792.

⁷ In this context, “irreversible” means that it is impossible to resuscitate the patient through CPR or other means. This is distinct from “permanent” cessation of cardiopulmonary function, which means that pulse and breathing have stopped and will not resume spontaneously or through medical intervention. Permanent cessation thus involves a human choice not to pursue resuscitative efforts, and will proceed to irreversible cessation. See James L Bernat, “On Noncongruence between the Concept and Determination of Death” (2013) November-December *Hastings Report* 25 at 27.

has passed.⁸ Once blood ceases to circulate through the body, organs (including the brain) will rapidly lose function and the decomposition process, sometimes referred to as biological death, will begin.⁹ The irreversible loss of cardiopulmonary function is uncontroversially accepted as a form of legal and moral death. Prior to the development of mechanical life support, it was the only means by which death was conclusively determined.

Brain death, sometimes known as “death by neurological criteria,” is a much more recent concept, first proposed in 1968 by the Ad Hoc Committee of the Harvard Medical School¹⁰ and then explained by the American President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in its 1981 report, *Defining Death*.¹¹ That report led to the development of the American *Uniform Determination of Death Act (UDDA)*, which defines brain death as “irreversible cessation of all functions of the entire brain, including the brain stem.”¹² The concept of brain death rests, in part, on the premise that the brain is critical in coordinating the body’s functions: once a person has lost “whole brain” function, the body is incapable of autonomously maintaining life. The person’s

⁸ Jurisdictions have different presumptions about how long this period lasts, as reflected in a “hands-off” period ranging from 2 to 20 minutes before organs can be retrieved. See Christopher James Doig & Graeme Rocker, “Retrieving Organs From Non-Heart-Beating Organ Donors: A Review of Medical and Ethical Issues” (2003) 50:10 *Neuroanesthesia and Intensive Care* 1069 at 1072.

⁹ See James L Bernat, Charles M Culver & Bernard Gert, “On the Definition and Criterion of Death” (1981) 94 *Annals of Internal Medicine* 389 at 389. Some processes of decomposition may begin before biological death, and the full decomposition of the body will take place over many years. For this reason, death is often described as a process rather than an event.

¹⁰ See “A Definition of Irreversible Coma: Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death” (1968) 205 *JAMA* 337 [Ad Hoc Committee].

¹¹ See United States, President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: A Report on the Medical, Legal, and Ethical Issues in the Determination of Death* (Washington: U.S. Government Printing Office, 1981) [*Defining Death*].

¹² *Uniform Determination of Death Act* § 1 (1980) [*UDDA*]. As discussed below, there are different schools of thought regarding *which* brain functions must have ceased in order for a person to be considered dead. However, on any definition, the loss of “whole brain” function is considered sufficient for brain death.

cardiopulmonary function will cease because the brain is no longer capable of directing it to operate.¹³

Legal and moral complications arise because the cardiopulmonary functions of a brain-dead patient can be maintained by means of a ventilator, which can “mask” the presence of death.¹⁴ Machines can keep oxygenated blood flowing through the body and enable vital functions like absorbing nutrients, excreting waste, and responding to infection to continue.¹⁵ The person’s “biological” death will not typically ensue until those mechanical supports have been removed.¹⁶ Nevertheless, as discussed in section II(a) below, the individual will already be considered dead in accordance with neurological criteria in some Canadian jurisdictions.

While brain death is well-accepted in medical circles, has been adopted in Canadian law, and is at least superficially understood by lay people, it is not universally accepted by the general population. As *McKitty* illustrates, some religions adhere to the belief that a person is not dead until his or her heart has stopped beating,¹⁷ and that removing a so-called brain-dead patient from life support – which brings about cardiopulmonary death – is a form of killing. The decisions in *McKitty* raise questions about whether that religious belief ought to be accommodated; indeed, they ask whether brain-dead patients are even protected by the *Charter*’s guarantee of freedom of religion or whether they have ceased to be “persons” capable

¹³ As discussed below, these integrative functions are sometimes described as “the functioning of the *organism as a whole*.” See Jocelyn Downie et al, “Eligibility for Organ Donation: A Medico-Legal Perspective on Defining and Determining Death” (2009) 56:11 Can J Anesth 851 at 859.

¹⁴ See *Defining Death*, *supra* note 11 at 33.

¹⁵ See e.g. Seema K Shah, “Piercing the Veil: The Limits of Brain Death as a Legal Fiction” (2015) 48:2 U Mich JL Ref 301 at 302; Mike Nair-Collins, “Death, Brain Death, and the Limits of Science: Why the Whole-Brain Concept of Death is a Flawed Public Policy” (2010) 38:3 J Law, Med & Ethics 667 at 671.

¹⁶ Some patients, like McKitty, may nevertheless suffer biological death due to some independent cardiac or respiratory event.

¹⁷ See also *Ouanounou v Humber River Hospital et al*, 2018 ONSC 6511, which arose around the same time as *McKitty* and involved a patient who was an Orthodox Jew. Since the patient had died and since Shaw J had already released her decision in *McKitty*, Hainey J found that the application was moot and declined to exercise judicial discretion to render a judgment.

of having *Charter* rights. In essence, cases like *McKitty* will force the law to come to grips with the moral and legal status of persons who have irreversibly lost essential brain functions, and to define what non-medical factors, if any, should be considered when determining that a life has ended.

I. THE DECISIONS

A. Facts

Taquissha McKitty was brought to the hospital in an unconscious state following a period of hypoxia, or oxygen deprivation, which caused significant brain damage.¹⁸ She suffered a second hypoxic event while in hospital and lost the ability to breathe without a ventilator. Dr. Hayani determined that she met the neurological criteria for death and completed a death certificate.¹⁹ However, McKitty's substitute decision makers obtained an interlocutory injunction preventing the doctor from removing her from the ventilator.²⁰ They brought an application against Dr. Hayani seeking, *inter alia*, the rescission of her death certificate and a declaration that her *Charter* rights had been infringed.²¹ No government party was involved in the litigation.

B. Superior Court of Justice

Justice Shaw began by reviewing the statutory and common law definitions of death in several provinces, the United Kingdom, and the United States. She concluded that the jurisprudence supported the conclusions that brain death should be accepted as legal death and that the criteria for determining brain death should be left to the medical community.²² She found no authority for the applicant's argument that a person who is brain dead could nevertheless be considered alive because the person's body continued to

¹⁸ See *McKitty* ONCA, *supra* note 1 at para 10.

¹⁹ See *ibid.*

²⁰ See *ibid* at para 11.

²¹ Namely, sections 2(a), 7, and 15, see *ibid.*

²² See *McKitty* ONSC, *supra* note 1 at para 93.

function biologically and physiologically.²³ Following the evolution of medical science, Justice Shaw concluded that the “[c]essation of *either* cardio-respiratory or brain function constitutes death.”²⁴ In doing so, she rejected the applicant’s suggestion that it is up to each individual to choose how their death would be determined based on their relevant values or beliefs.²⁵ In her view, death is a “finding of fact,” just like any other medical condition.

More controversially, Justice Shaw concluded that, because she was brain dead, McKitty was no longer a legal person and thus had no *Charter* rights.²⁶ Analogizing to the legal status of a fetus in Canada,²⁷ Justice Shaw explained, “[j]ust as the courts have not engaged in a theological debate on when life begins, so too should the court not become involved in a debate about when life ends.”²⁸ Such debate was best left to the legislature.²⁹ Justice Shaw supported this conclusion by noting that the rights ascribed to “everyone” in the *Charter* include things like freedom of religion and expression, the right to vote, security of the person, the right not to be arbitrarily detained, the right to be tried within a reasonable time, and language rights.³⁰ Presumably, Justice Shaw meant to underscore that these rights require some essential consciousness in order to be exercised. She explained that McKitty, with a “lack of capacity for consciousness, lack of capacity to breath[e] and no brain stem function, *is not able to exercise* any of these rights and freedoms.”³¹ This reasoning has the potential to lead to a drastic reduction in *Charter* protection: not only does it encompass someone who

²³ See *ibid.*

²⁴ *Ibid* at para 124.

²⁵ See *ibid.*

²⁶ See *ibid* at para 207.

²⁷ See *Tremblay v Daigle*, [1989] 2 SCR 530 at 552, 62 DLR (4th) 634.

²⁸ *McKitty* ONSC *supra* note 1 at para 205.

²⁹ See also *ibid* at paras 182–187 (Shaw J referred to cases where appellate courts had concluded that an estate did not have standing to assert *Charter* rights on behalf of the deceased, but found that they were not applicable in McKitty’s case: *Canada (Attorney General) v Hislop*, 2007 SCC 10 at para 73; *Giacomelli Estate v The Attorney General of Canada*, 2008 ONCA 346 at para 18; *Grant v Winnipeg Regional Health*, 2015 MBCA 44 at paras 54, 97).

³⁰ See *McKitty* ONSC, *supra* note 1 at para 203.

³¹ *Ibid* (emphasis added).

has suffered whole brain death, like McKitty, but it may also extend to those with conditions like persistent vegetative state, who lack consciousness and so may be unable to *exercise* certain rights, but who are nonetheless considered alive in our legal and social community.³²

Having found that the *Charter* did not formally apply to McKitty, Justice Shaw went on to analyze whether the common law definition of death is inconsistent with *Charter* values. Relying on *Ktunaxa Nation v Minister of Forests*,³³ she defined freedom of religion as the freedom to hold and manifest a particular religious belief.³⁴ Justice Shaw reasoned that the common law definition of death did not prevent people like McKitty from holding and manifesting their belief that a person is not dead until her heart has stopped beating and her soul has left her body.³⁵ However, Justice Shaw opined that freedom of religion does not extend to the “focal point” of her belief, in this case, to McKitty’s soul itself.³⁶ Finally, Justice Shaw stressed the importance of competing values like clarity and certainty in the determination of death, which could not accommodate *ad hoc* exceptions based on religious or other beliefs.³⁷ Moreover, keeping brain-dead patients on life support could impose significant costs on the medical system and interfere with organ donation schemes in Ontario.³⁸ Justice Shaw thus concluded that the current common law definition of death was consistent with *Charter* values,³⁹ and that McKitty’s death certificate was valid. Justice Shaw suspended the operation of her order to allow time for appeal.⁴⁰

³² See especially *Cuthbertson v Rasouli*, 2013 SCC 53 at paras 70, 78 [*Rasouli*] (the Court concluded that withdrawing life support from a patient in persistent vegetative state was “treatment” that required the consent of a substitute decision maker).

³³ 2017 SCC 54 [*Ktunaxa Nation*] (the Supreme Court of Canada held that freedom of religion does not protect “the spiritual focal point of worship” at para 71, in that case, the Grizzly Bear Spirit).

³⁴ See *McKitty* ONSC, *supra* note 1 at para 236.

³⁵ See *ibid* at para 239.

³⁶ See *ibid* at para 240.

³⁷ See *ibid* at para 241.

³⁸ See *ibid* at paras 248–49.

³⁹ See *ibid* at para 250.

⁴⁰ See *ibid* at para 292.

C. *Ontario Court of Appeal*

McKitty experienced cardiopulmonary death after her appeal was heard but before the decision was rendered, making the appeal moot. Nevertheless, both parties requested that the court proceed with its decision, and the court expressed its desire to clarify certain legal issues given that similar cases would likely arise in urgent circumstances.

The court of appeal affirmed Justice Shaw's conclusion that brain death constitutes legal death in Ontario. However, the court stressed that this was not because the law should defer to medical opinion, but because both cardiopulmonary death and brain death "have been judged by the common law to provide a sound answer to the question of how to determine whether a person has died."⁴¹ If medical practice developed some other criteria for determining death, the courts would not be obliged to accept them.

Moreover, the court of appeal disagreed with Justice Shaw's analysis of the *Charter* issues in the case. In particular, the court explained that analysis of whether the determination of death based on neurological criteria violated McKitty's freedom of religion has to occur prior to deciding whether she was legally dead.⁴² Otherwise, the analysis begs the very question that is in dispute.⁴³ While they acknowledged that Dr. Hayani was not an agent of the state, and thus did not owe *Charter* obligations to McKitty, they reasoned that *Charter* values could still be used to effect incremental changes to the common law in litigation between private parties.⁴⁴

The court of appeal found that Justice Shaw had made errors of both law and fact when assessing McKitty's *Charter* arguments. They disagreed with her comparison to *Ktunaxa Nation*; McKitty was not seeking to protect the "focal point" of her worship, but to observe a "divinely instituted and exceptionless moral norm that one must never intentionally kill a human person, including self-killing and acquiescing in one's own killing."⁴⁵ Withdrawing life support would fall afoul of this divine command. These beliefs,

⁴¹ *McKitty ONCA*, *supra* note 1 at para 28.

⁴² See *ibid* at para 39.

⁴³ See *ibid* at para 47.

⁴⁴ See *ibid* at para 56.

⁴⁵ *Ibid* at para 76.

if sincerely held, have a sufficient nexus with religion to be protected under section 2(a) of the *Charter*.

Ultimately, given the sparsity of the record, and the lack of any government participation in the litigation, the court of appeal concluded that it could not adequately address whether McKitty's freedom of religion was limited by statute or common law, or whether that limitation was justified under section 1 of the *Charter*.⁴⁶ The court of appeal suggested that such an analysis was best left to a case with a more robust record.⁴⁷

Perhaps the most striking aspect of the court of appeal's decision was its emphasis on the distinction between the medical and legal definitions of death. Courts should not simply delegate that determination to the medical profession, the court of appeal explained, nor are they obliged to accept medical opinion. Justice Miller wrote:

The determination of legal death is not simply, or even primarily, a medical or biological question. The question of who the law recognizes as a human being – entitled to all of the benefits and protections of the law – cannot be answered by medical knowledge alone. Facts about the physiology of the brain-dead patient are needed to determine what obligations are owed to the brain-dead patient, but the enquiry is not ultimately technical or scientific: it is evaluative. Who the common law ought to regard as a human being – a bearer of legal rights – is inescapably a question of justice, informed but not ultimately determined by current medical practice, bioethics, moral philosophy, and other disciplines.⁴⁸

This decision signals to future litigants that challenges to the common law or statutory definitions of death should be cognizant of the religious, cultural, and philosophical nuances that may be absent from purely medical assessments. Ultimately, the decision in a future case like *McKitty* will involve a fundamental assessment of what makes someone a “person” worthy of basic constitutional protection in our moral and political community.

⁴⁶ See *ibid* at para 58.

⁴⁷ See *ibid*.

⁴⁸ *Ibid* at para 29.

It is not obvious that the common law courts, which rely heavily on rules of evidence and adversarial argument, are best positioned to address these profound moral questions. Granted, in the post-*Charter* era, we have become accustomed to having the courts decide such weighty matters; our legislative scheme for MAID, for example, emerged from a Supreme Court decision.⁴⁹ Nevertheless, the courts' moral and philosophical discussions generally arise when an existing legislative scheme or government action is challenged as being unconstitutional, not in the context of incremental changes to common law. This system of constitutional dialogue gives the legislature primary authority to design the law, following consultation with experts and the public and allowing for open debate. A legislated approach has the added benefit of promoting relative consistency across situations and jurisdictions, which would assist both physicians and family members in understanding their obligations and rights. Finally, legislation would provide a clear basis on which to assess whether the legal definition of death violates the rights guaranteed by the *Charter*, especially under sections 2(a), 7, and 15. This would allow greater precision and enforceability than the more fluid application of *Charter* values in the common law.

The discussion below provides an overview of the current legal definitions of death in Canada, which emerged from a variety of situations and tend to be tailored to the specific objectives of different fields of law. These purposive approaches often focus on the needs of actors other than the patient – such as potential heirs, organ recipients, medical professionals, and the criminal justice system. Accordingly, jurisprudence that grapples with the legal standing of the brain-dead patient is scarce. The question of when legal death occurs cannot be adequately answered by science alone and has important implications not just for the withdrawal of life support, but also for patient autonomy, welfare, and dignity in the dying process.

II. CANADIAN LAW ON THE DEFINITION OF DEATH

Given the importance of death to a range of legal issues (for example, inheritance, homicide, organ donation, MAID), it is surprising that there is no uniform legal definition of death in Canada. While statutory definitions apply in some jurisdictions and in specific contexts, the definition of death is still frequently governed by common law and can sometimes be subject to *ad hoc* determination.

⁴⁹ See *Carter v Canada (AG)*, 2015 SCC 5.

A. *Statutory Provisions*

Only five jurisdictions (Manitoba, Newfoundland and Labrador, Nova Scotia, Prince Edward Island, and Northwest Territories) have a legislated definition of death. Notably, all of the statutory definitions make reference to some form of brain death. Manitoba, the only province whose legislative definition applies across all circumstances, stipulates: “For all purposes within the legislative competence of the Legislature of Manitoba the death of a person takes place at the time at which irreversible cessation of all that person’s brain function occurs.”⁵⁰

Three other jurisdictions provide definitions of death in their organ and tissue donation statutes, and it is not clear if these definitions would apply in other contexts. Prince Edward Island and the Northwest Territories have somewhat unhelpful provisions indicating that death “includes brain death.”⁵¹ Presumably, provisions like these were included to clarify that the procurement of organs or tissues from a brain-dead patient is not murder and does not run afoul of the so-called “Dead Donor Rule,” discussed in section IV below.

Nova Scotia’s statutory provision is perhaps the most complex, defining death as “the irreversible cessation of the functioning of the organism as a whole as determined by the irreversible loss of the brain’s ability to control and co-ordinate all of the organism’s critical functions.”⁵² Critical functions include spontaneous respiration, autonomic control of circulation, consciousness, and endocrine and homeostatic regulation.⁵³ This defini-

⁵⁰ *Vital Statistics Act*, CCSM c V60, s 2. Newfoundland and Labrador also use the definition, “irreversible cessation of all a person’s brain function”: *Vital Statistics Act*, SNL 2009, c V-6.01, s 2(h).

⁵¹ *Human Tissue Donation Act*, RSPEI 1988, c H-12.1, s 1(b) [*PEI Tissue Donation Act*]; *Human Tissue Donation Act*, SNWT 2014, c 30, s 1 [*NWT Tissue Donation Act*].

⁵² *Human Organ and Tissue Donation Act*, SNS 2010, c 36, s 2(j) [*NS 2010 Tissue Donation Act*]. The same definition is included in the new “opt-out” legislation (*NS 2019 Tissue Donation Act*, *supra* note 5, s 2(g)).

⁵³ See James L Bernat, “A Defense of the Whole-Brain Concept of Death” (1998) 28:2 *Hastings Center Report* 14 at 17.

ition, often known as “whole brain death,” is consistent with the American *UDDA*.⁵⁴

An important feature of the various legislative provisions on death (apart from Manitoba’s) is that they adopt the standard of “accepted medical practice” or “generally accepted medical criteria” to determine or demonstrate brain death.⁵⁵ As discussed below, this language acknowledges that the medical profession might develop new tests for confirming that brain death has occurred. In Prince Edward Island and the Northwest Territories (where only the broad term “brain death” is used), these provisions also leave open the possibility that the medical profession might come to a new conclusion about what constitutes brain death. For instance, some experts have argued that brain death should be determined by loss of consciousness and cognition (or “higher brain” function),⁵⁶ which would include patients in persistent vegetative states. Such deference to the medical profession is not possible in Manitoba or Newfoundland and Labrador, where the legislation requires “irreversible cessation of *all* that person’s brain function” (emphasis added).⁵⁷

Justice Shaw’s decision in *McKitty* similarly deferred to the medical profession, stating, “[i]t is important that the law keeps up with technological and medical advancements which, in turn, is consistent with permitting the medical community to establish the practice or guidelines to

⁵⁴ See *UDDA*, *supra* note 12 at § 1.

⁵⁵ See *PEI Tissue Donation Act*, *supra* note 51, s 11(1); *NWT Tissue Donation Act*, *supra* note 51, s 14(1); See *NS 2010 Tissue Donation Act*, *supra* note 52, s 15. The same standard is outlined in the new Nova Scotia “opt-out” legislation (*NS 2019 Tissue Donation Act*, *supra* note 5, s 16).

⁵⁶ This so-called “higher-brain formulation of death” postulates that consciousness and cognition are the functions that are essential to human nature. This formulation relies on death of the neocortex, rather than the whole brain/brain stem. See Robert M Veatch, “The Whole-Brain-Oriented Concept of Death: An Outmoded Philosophical Formulation” (1975) 3 *J Thanatology* 13; Robert M Veatch, “The Impending Collapse of the Whole-Brain Definition of Death” (1993) 23:4 *Hastings Center Report* 18. Others argue that a definition based on higher brain function could create a dangerous slippery slope. For example, this definition could raise the question of whether severely demented patients could be considered to be dead. See the critique by Bernat, *supra* note 53 at 17.

⁵⁷ *Vital Statistics Act*, *supra* note 50.

determine brain death.”⁵⁸ In this respect, it is important to distinguish the medical definition or concept of brain death from the diagnostic practices used by medical practitioners to determine and demonstrate if brain death has occurred. Physicians use a range of medical tests to assess whether there has been a cessation of the relevant brain functions (for example, apnea, gag reflex, ocular functions, response to pain). In Canada, these tests are set out in the CMAJ Guidelines⁵⁹ and are broadly endorsed.⁶⁰

Justice Shaw’s deference toward the medical profession seems to have been directed toward these CMAJ Guidelines; she wrote, “There is no evidentiary basis for this court to find that the CMAJ Guidelines are not the appropriate medical practice *by which death by neurologic criteria is to be determined by physicians* in Ontario.”⁶¹ However, her deference toward those Guidelines seems to have led her to reject the applicant’s argument that the very notion of brain death might be objectionable to some. Justice Shaw explained: “Physiological and biological functioning of a body are not criteria to consider in the determination of brain death. That does not result in medical guidelines that are arbitrary or overbroad in their application.”⁶² In other words, Justice Shaw conflated accepted medical practice regarding the tests to be used to *demonstrate* whether a patient has lost brain functioning with the legal conclusion that there can be no exceptions to the equation of brain death with legal death. In so doing, she prematurely foreclosed the plaintiff’s arguments.

Finally, neither the extant statutory definitions nor Justice Shaw’s decision in *McKitty* include any reference to non-medical or non-scientific criteria in the legal definition of death. While we would not expect physicians to include religious or philosophical criteria in their determinations of death, the Ontario Court of Appeal and others have argued that the legal definition of death should incorporate broader concepts of death. As discussed below, an unqualified acceptance of the medical profession’s definition of death risks denying or at least obscuring the complex moral questions involved

⁵⁸ *McKitty* ONSC, *supra* note 1 at para 132.

⁵⁹ See Sam D Shemie et al, “Severe Brain Injury to Neurological Determination of Death: Canadian Forum Recommendations” (2006) 174:6 (Suppl) CMAJ 51 S1 at S2 [CMAJ Guidelines].

⁶⁰ See *McKitty* ONSC, *supra* note 1 at para 112.

⁶¹ *Ibid* at para 132 (emphasis added).

⁶² *Ibid*.

in deciding whether a patient who maintains cardiopulmonary function through mechanical assistance is entitled to *Charter* rights or other legal protections.

B. Common Law

The leading Canadian cases dealing with the common law definition of death have arisen in several contexts: criminal homicide, inheritance, organ and tissue donation, and the withdrawal of life support from a brain-dead patient. These contexts have distinct objectives that may lead the courts to define death in different ways. For instance, the law may be more likely to accept the concept of brain death in situations involving organ and tissue donation, where this concept of death facilitates donation goals and arguably enhances patient autonomy, than in a situation where an accused attempts to use the concept of brain death to avoid criminal conviction.

The historical common law definition of death relied on the cessation of pulse and breathing, which were also the historical medical means to determine death.⁶³ However, more recent cases have accepted a neurological determination of death.⁶⁴ In *R v Kitching and Adams*,⁶⁵ the two accused had dragged a severely intoxicated man from a bar and dropped him face-first on a concrete sidewalk.⁶⁶ He was taken to hospital and resuscitated. A short while later, he was put on a ventilator.⁶⁷ Two different physicians (an anaesthetist and a neurologist) found that he had no reflexes or responses to painful stimuli; they found no evidence of brain stem function

⁶³ See Bernat, *supra* note 53 at 16. Once any of a person's vital systems (respiration, circulation, brain function) ceased, the person's death would follow soon afterward.

⁶⁴ See e.g. *Kerr Estate v BC Motorist Insurance Co* (1972), 30 DLR (3d) 443, [1972] 6 WWR 400 (BCSC); *Johannisse v Johannisse Estate*, [1985] OJ No 1273 (QL) (H Ct J). But see *R v Green* (1988), 43 CCC (3d) 413, [1988] BCJ No 1807 (BCSC) [*Green* cited to CCC].

⁶⁵ (1976), 32 CCC (2d) 159, [1976] 6 WWR 697 (MBCA) [*Kitching* cited to CCC].

⁶⁶ See *ibid* at 163.

⁶⁷ See *ibid* at 164.

and concluded that he was brain dead.⁶⁸ Nevertheless, he was kept alive mechanically until his kidneys could be removed for transplant. Once the kidneys were removed, he was taken off life support and his heart stopped beating 13 minutes later.⁶⁹ The accused, who were charged with unlawful act manslaughter, argued that they had not caused the man's death; rather, his death had been caused by the physicians' act of removing his kidneys.⁷⁰ This argument did not persuade the jury or the Manitoba Court of Appeal, which reasoned that the man was brain dead, and thus legally dead, before the transplant surgery.⁷¹

Justice O'Sullivan's opinion in *Kitching and Adams* demonstrates both an imperfect scientific conception of brain death and a belief that death is more than just a medical phenomenon. He first discussed the variations in medical opinion at the time, including a view that, if a person is "as good as dead," then it will be ethically acceptable to harvest his or her organs.⁷² Justice O'Sullivan was troubled by the anaesthetist's view that death was a "process, not an event," describing this as "a most controversial statement at variance with centuries of religious tradition."⁷³ While Justice O'Sullivan went on to accept the concept of brain death, he stressed that medical practice was still uncertain about how and when brain death could be determined.⁷⁴ Moreover, his acceptance of brain death rested on grounds that had dubious scientific merit. He focused instead on concepts of moral agency or cognition: "[i]t is the activities operated through the brain which differentiate man from an animal. If the brain is dead, he is dead."⁷⁵ All of this had limited legal importance, however, since unlawful act manslaughter only required the accused's conduct to be an operative cause of death, not the sole

⁶⁸ See *ibid.*

⁶⁹ See *ibid.*

⁷⁰ See *ibid* at 172.

⁷¹ See *ibid* at 175.

⁷² See *ibid* at 173.

⁷³ See *ibid.* From a medical or scientific perspective, it is commonplace to view death as a process. See Sam David Shemie & Dale Gardiner, "Circulatory Arrest, Brain Arrest and Death Determination" (2018) 5:15 *Frontiers in Cardiovascular Medicine* 1.

⁷⁴ See *Kitching*, *supra* note 65 at 174–75.

⁷⁵ *Ibid* at 174.

cause of death. *Kitching and Adams* thus represents a rudimentary analysis of the legal significance of brain death.

In a subsequent criminal case, *R v Green*,⁷⁶ Justice Wood refused to apply brain death in the criminal law context, while acknowledging that it might be applicable in civil law or in situations where the interests of a patient were at stake (e.g., withdrawal of life-sustaining treatment or organ donation). In *Green*, the accused sought to avoid a murder conviction by arguing that another person had already shot the victim in the head before he did the same.⁷⁷ In other words, the first shot caused an irreversible cessation of brain function, so the victim was legally dead before the second shot took place. In making this argument, the accused cited medical experts and the 1981 Law Reform Commission report's recommendation that the concept of brain death be adopted in Canadian law.⁷⁸

Justice Wood rejected this argument, noting that the Law Reform Commission's work was prompted by the desire to increase the availability of organs for transplantation and that it had not been concerned with the administration of the criminal law.⁷⁹ He explained that it would be difficult for the Crown to prove beyond a reasonable doubt that the victim was still alive, that is, that his "brain function had not yet irreversibly ceased – when the [second] accused Green 'pumped' two bullets into him."⁸⁰ In rejecting the use of brain death in the criminal law context, Justice Wood reasoned that different legal definitions were justifiable, given the different objectives of criminal and civil law, for example:

⁷⁶ *Supra* note 64.

⁷⁷ See *ibid* at 414.

⁷⁸ See Law Reform Commission of Canada, *Report on the Criteria for the Determination of Death*, Report 15 (1981) at 25 [*Report on the Criteria for the Determination of Death*]. The recommendation was never adopted.

⁷⁹ See *Green*, *supra* note 64 at 415.

⁸⁰ *Ibid* at 415–416.

The criminal law seeks to deter the incidence of, *inter alia*, violent crime by holding accountable those whose conduct endangers the lives and safety of others. The civil law, in the context under discussion, seeks to ensure that societies' moral and personal values are not compromised in the pursuit of *bona fide* efforts to prolong or save meaningful life.⁸¹

Ultimately, Justice Wood applied the "traditional approach" that a person was alive as long as any of his vital organs continued to operate, including his heart.⁸²

While it did not apparently play a part in Justice Wood's decision, it is worth noting that brain death is not medically declared until multiple tests have been conducted, usually by different physicians and over a series of hours or days.⁸³ It would have been practically impossible to declare the victim in *Green* to be brain dead at the scene (and certainly not before the second shot occurred). Thus, *Green* could just as well have been decided without a statement about the legal validity of brain death as a form of death.

These limited and admittedly dated interpretations of brain death in the criminal law suggest that the Canadian courts will not permit an accused to take advantage of the concept of brain death – positively or negatively – to evade responsibility for criminal acts. However, both cases could have been decided without stating an opinion on the scientific or legal legitimacy of brain death and neither made an especially helpful contribution to the legal understanding of brain death.

A more sophisticated appreciation of brain death is evident in the more recent ruling, *Leclerc (Succession) v Turmel*.⁸⁴ In this case, the court had to determine whether a mother and her infant son had died at the same time in a motor vehicle crash, or whether she had died first. It was accepted that the

⁸¹ *Ibid* at 416.

⁸² For a bizarre application of this approach, see generally *Gray v Sawyer*, 247 SW (2d) 496 (1952) at 497 (The court found that a woman was still alive even though she had been decapitated, because her body was still gushing blood).

⁸³ But see CMAJ Guidelines, *supra* note 59 at S2 (recommends that there need not be a fixed examination interval for the determination of brain-death by a second medical practitioner).

⁸⁴ [2005] RJQ 1165 (SC).

mother was likely dead on the scene.⁸⁵ The infant, however, exhibited some vital signs and was breathing autonomously.⁸⁶ The petitioner, who stood to inherit the mother's estate if the deaths were simultaneous, argued that the infant was likely brain dead at the scene.⁸⁷ The court rejected this argument. While Justice Bureau agreed that brain death constituted death, he stressed that it must be "total brain death," not just the cessation of cerebral cortex activity (i.e., consciousness and cognition).⁸⁸ The fact that the infant was breathing autonomously indicated that he still had brain stem activity (i.e., his brain was still coordinating bodily functions). Moreover, Justice Bureau clarified that brain death cannot be adequately determined at the scene of an emergency, as it typically requires regular tests over many hours.⁸⁹ *Leclerc* thus reflects the accepted medical conception of brain death in Canada and an understanding that specific tests are required to demonstrate that brain death has occurred. Nevertheless, it does not, and did not need to, explore religious or moral questions of what makes a person dead.

The criminal law and inheritance cases dealing with brain death are relatively rare. A more common situation where the legal definition of death is implicated is the withdrawal of life support from a brain-dead patient. However, withdrawing life support when a patient is brain dead appears to be normal practice⁹⁰ and thus rarely appears in the jurisprudence. The more difficult legal cases arise when the patient does not exhibit all the indicia of brain death, but it is nevertheless considered impossible for the patient to recover. For instance, in *London Health Sciences Centre v RK*,⁹¹ the patient met the criteria for brain death, except that he still exhibited "agonal breathing" (i.e., gasping for air as a dying person would). The physicians applied to the court for a declaration that they would be immune from criminal and civil liability if they removed him from life support. Justice McDermid refused to make that declaration for several reasons, including that a declara-

⁸⁵ See *ibid* at para 66.

⁸⁶ See *ibid*.

⁸⁷ See *ibid* at paras 3–7.

⁸⁸ See *ibid* at para 52, or "higher brain function."

⁸⁹ See *ibid* at para 39, citing the opinions of experts.

⁹⁰ See John C Irvine, Philip H Osborne & Mary J Shariff, *Canadian Medical Law*, 4th ed (Scarborough: Carswell, 2013) at 437.

⁹¹ (1997), 152 DLR (4th) 724 at para 6.

tion of criminal immunity would interfere with prosecutorial discretion.⁹² As to any alleged “right” of the physicians to withdraw life support, Justice McDermid explained that this question involved “complex moral, ethical, religious and legal issues” that were best dealt with by the legislature.⁹³

The Canadian common law thus provides a range of opinions on the legal determination of death, with neurological death being accepted for only some purposes. Further, while the courts tend to be deferential toward the medical profession, they have been reluctant to completely delegate the determination of death. Even prior to the court of appeal’s decision in *McKitty*, courts had expressed unease with the argument that death was a purely scientific concept. Nevertheless, they have not been eager to engage with these issues themselves, and have suggested that the legal definition of death should be provided in legislation. In any event, it seems unhelpful to continue in a state of *ad hoc* decision making, particularly since the relevant cases can arise in time-sensitive circumstances where expert evidence tends to be more readily available from the health care professionals than from those representing the patient.

III. THE RELATIONSHIP BETWEEN THE LAW AND ACCEPTED MEDICAL PRACTICE

A key issue in the court of appeal’s decision in *McKitty* is the appropriate relationship between law and accepted medical practice. As noted above, the statutory definitions in Nova Scotia, Prince Edward Island, and Northwest Territories effectively defer to accepted medical practice or medical criteria to determine brain death. Similarly, Justice Shaw’s decision in *McKitty* referred to the CMAJ Guidelines as the authority for determining death,⁹⁴ and she expressly stated that “[t]he determination of death is made by physicians.”⁹⁵ Moreover, Justice Shaw refused to enter “a debate about when life ends” and explained that any such debate should be left to the legislature.⁹⁶

⁹² See *ibid* at para 16.

⁹³ See *ibid* at para 17.

⁹⁴ See *McKitty* ONSC, *supra* note 1 at para 132.

⁹⁵ *Ibid* at para 254.

⁹⁶ See *ibid* at para 205.

Indeed, the legislatures seem better positioned to debate the complex moral and philosophical questions regarding the legal definition of death. Legislators can engage with religious groups, ethicists, and medical experts, and can also consider more pragmatic (albeit highly sensitive) concerns about the prioritization of scarce health care resources and the desire for a robust organ donation system to prolong the lives of others. However, it is not surprising that legislators have been wary about entering these challenging debates. For instance, despite a Law Reform Commission of Canada⁹⁷ recommendation in 1981 that the *Interpretation Act*⁹⁸ include a definition of death, there is still no definition in federal law.

In this legislative vacuum, the legal determination of death has been largely left to the common law courts, which are required to make the determination in cases where considerations like criminal punishment or inheritance overshadow the moral status of the patient or victim. They may also have to deal with conflicts regarding end-of-life treatment, in which emotions may run high. As in *McKitty*, one of the parties will likely be a physician or hospital, which will be able to muster substantial evidence on the determination of death based on neurological criteria. Nevertheless, as discussed below, the concept of brain death was primarily developed in response to express health care needs and did not necessarily confront the moral issues involved. Over time, brain death has become a commonly accepted phenomenon among the general public, judges included; most of us tend to accept that brain death is equivalent to death, and may not ponder the deeper moral implications unless or until we are faced with such a diagnosis in a loved one.

In this vein, some scholars are critical of society's acceptance of brain death as equivalent to biological or legal death, arguing that we have effectively delegated the moral and philosophical debates to physicians, who have little incentive to engage with them.⁹⁹ These scholars typically explain that patients who are brain dead are nevertheless capable of supporting important biological functions, such as absorbing nutrients, excreting waste, maintaining body temperature, healing wounds, developing a fever in response to infections, and, in some cases, gestating a foetus and

⁹⁷ See *Report on the Criteria for the Determination of Death*, *supra* note 78.

⁹⁸ RSC 1985, c I-21.

⁹⁹ See e.g. Shah, *supra* note 15 at 302; Nair-Collins, *supra* note 15 at 671; Greg Yanke, Mohamed Y Rady & Joseph L Verheijde, "When Brain Death Belies Belief" (2016) 55 J Relig Health 2199.

giving birth.¹⁰⁰ Thus, they argue that it is misleading to equate brain death with biological death. In addition, they note that the act of “declaring” someone brain dead does not have the effect of changing their status from living to dead. As author Nair-Collins quipped, “I cannot be made dead because a legislator or physician has decreed it.”¹⁰¹ Biological death is a natural phenomenon – one which only occurs after a brain-dead patient has been taken off life support and cardiopulmonary functions cease.

Ultimately, these scholars suggest that, while the concept of brain death has practical utility in many circumstances, it should not be blindly accepted without wrestling with the moral assessments that it involves. Essentially, it involves an exploration of what biological functions are minimally necessary for a patient to be afforded basic legal and moral rights. Nair-Collins expresses this argument in terms of the “moral patient,” that is, someone who is a “member of the moral community” and is “afforded certain protections, such as the prohibition of autopsies, burial, or cremation.”¹⁰² Moral patients may not be conscious (in the case of comatose patients) and may not have moral agency (in the case of severely demented patients); nevertheless, they are worthy of moral consideration and are considered alive in all jurisdictions. He goes on to stress that the question,

whether brain dead individuals should be afforded the same or similar moral protections as non-brain-dead individuals, is not a scientific question. The answer to it depends on how much value gets assigned to biologically functioning individuals in the brain dead state. If little to none, then brain dead individuals are not members of the moral community, and it is morally acceptable to remove their vital organs (thus ending the biological life of the individual). . . . If, however, some level of biological functioning confers moral value on an individual, then . . . brain death is not the death of the moral patient.¹⁰³

¹⁰⁰ See Shah, *supra* note 15 at 302; Nair-Collins, *supra* note 15 at 682.

¹⁰¹ Nair-Collins, *supra* note 15 at 669.

¹⁰² See *ibid* at 668.

¹⁰³ *Ibid* at 674.

These value judgments are not for physicians alone, or even primarily, to make, but should be debated by the entire community.¹⁰⁴ The community may well conclude that it is morally acceptable to remove organs from brain-dead patients to save other lives, or to withdraw life support from them if the necessary medical equipment is more desperately needed by a patient who has a chance of recovering. Nevertheless, Nair-Collins argues that this public debate is obscured and even suppressed by an insistence on the purported “fact” that brain death is scientifically equivalent to biological death.¹⁰⁵

It was this type of debate that the Ontario Court of Appeal proposed in its decision in *McKitty*. The court indicated that there was no obligation for the courts to accept medical practice in the determination of death and that the question of “[w]ho the common law ought to regard as a human being – a bearer of legal rights – is inescapably a question of justice.”¹⁰⁶ While the court concluded that it did not have a sufficient record to answer this question, Justice Miller discussed at length how the *Charter* value of freedom of religion could inform the common law determination of death, and possibly allow for a religious exemption from the determination of death by neurological criteria.¹⁰⁷ It would require, for example, “an account... of the human goods served by protecting that right.” This analysis must be understood from the claimant’s perspective: how does a person’s religious belief about the end of life inform her understanding of humanity, the world, and the divine? Does the common law’s universal acceptance of brain death interfere with this religious freedom?

In raising these questions, the court of appeal seems to be opening the door for an accommodation akin to the statutory exemption that exists

¹⁰⁴ See *ibid* at 675.

¹⁰⁵ See *ibid*. See also Michael Shapiro, “Euthanasia by Organ Donation” (2018) 41:1 Dal LJ 153 at 156 (wherein the author notes that the “burden” that brain-dead patients may pose to their families or the health care system is not, in itself, a reason to change the definition of death).

¹⁰⁶ *McKitty* ONCA, *supra* note 1 at paras 28–29.

¹⁰⁷ See *ibid* at paras 84ff.

in New Jersey.¹⁰⁸ While New Jersey accepted the recommendations of the *UDDA*, its legislation indicates that death shall not be declared on the basis of neurological criteria:

when the licensed physician authorized to declare death, has reason to believe, on the basis of information in the individual's available medical records, or information provided by a member of the individual's family or any other person knowledgeable about the individual's personal religious beliefs that such a declaration would violate the personal religious beliefs of the individual.¹⁰⁹

Thus, individuals whose religious beliefs dictate that life does not end until one's heart has stopped beating can reject the neurological determination of their own deaths. It accommodates personal religious beliefs without rejecting brain death, thereby maintaining the utility of brain death for the health care and organ donation systems. Available evidence suggests that a small minority of the population would seek such accommodation.¹¹⁰ One can imagine that, if the current legal acceptance of the neurological determination of death is subject to *Charter* challenge,¹¹¹ allowing such an

¹⁰⁸ See generally Robert S Olick, "Brain Death, Religious Freedom, and Public Policy: New Jersey's Landmark Legislative Initiative" (1991) 1:4 *Kennedy Inst Ethics J* 275; Kristin Zeiler, "Deadly Pluralism? Why Death-Concept, Death-Definition, Death-Criterion and Death-Test Pluralism Should be Allowed, Even Though it Creates Some Problems" (2009) 23:8 *Bioethics* 450.

¹⁰⁹ *New Jersey Declaration of Death Act*, RSNJ 1991, c. 90, s 5.

¹¹⁰ Consider, for example, that a minority of all deaths occur in hospitals, that less than 1% of hospital deaths are declared by neurological criteria, and that religious objections tend to be limited to some Orthodox Jews, Muslims, Japanese Shinto, and Indigenous people. See Thaddeus Mason Pope, "Brain Death Rejected: Expanding Legal Duties to Accommodate Religious Objections" in Holly Fernandez Lynch, I Glenn Cohen & Elizabeth Sepper, eds, *Law, Religion, and Health in the United States* (New York: Cambridge University Press, 2017) 293 at 302–03.

¹¹¹ For a discussion of possible constitutional challenges to brain death in the United States, see Yanke et al, *supra* note 99 at 2201.

exemption could serve as a means of satisfying the “minimal impairment” aspect of the justification test under section 1.¹¹²

Before closing this section, it is worth noting that similar tensions between law and accepted medical practice arose in *Cuthbertson v Rasouli*.¹¹³ There, the patient was in a persistent vegetative state; physicians advised that maintaining him on life support was of no medical benefit and had the potential to cause him harm. His wife and substitute decision maker refused to consent to the withdrawal of life-sustaining treatment on various grounds, including that, as a devout Shia Muslim, the patient would want to be kept alive.

The Supreme Court of Canada treated the case primarily as a question of statutory interpretation, specifically, whether withdrawal of life-sustaining treatment amounted to “treatment” that required consent under the Ontario *Health Care Consent Act, 1996*.¹¹⁴ The Court thus did not engage with deeper philosophical issues of moral personhood. Nevertheless, the majority was clear that physicians, alone, could not dictate what should happen to patients like Rasouli. While the physicians’ opinions as to whether maintaining life-sustaining treatment is of “medical benefit” are an important consideration, they must be considered alongside other factors that comprise the patient’s best interests, including the patient’s prior expressed wishes, well-being and values. The majority stressed that the legislative scheme “aims at advancing the values that underpin the HCCA: enhancing patient autonomy and ensuring appropriate medical treatment.”¹¹⁵ Although mediated by a substitute decision maker (or in the event of dispute, the Consent and Capacity Board),

¹¹² See Abella J’s dissenting opinion in *Alberta v Hutterian Brethren of Wilson Colony*, 2009 SCC 37 at paras 143–146, where she stressed that the government’s chosen measure must be carefully tailored to impair freedom of religion as little as is reasonably necessary. Given the very personal nature of death, it may be difficult for the government to argue that an absolute insistence on the acceptance of death by neurological criteria is minimally impairing. Note also that other American states have more limited exemptions than New Jersey’s and are time-limited rather than indefinite .

¹¹³ *Supra* note 32 at para 78.

¹¹⁴ See *Health Care Consent Act*, SO 1996, c 2, Schedule A, s 20.

¹¹⁵ *Rasouli*, *supra* note 32 at para 87.

the patient's autonomy remains paramount; treatment can neither be administered nor withdrawn without consent.¹¹⁶

Thus, the Supreme Court of Canada has clearly indicated that patients in persistent vegetative state maintain autonomy and have "best interests" that must be considered, even if medical opinion indicates that they will never recover from that state. Cases like *McKitty* ask whether brain-dead patients might also possess a residuum of autonomy, such that removing them from life-sustaining treatment is, at least, a "decision" that must take into account their prior wishes and values, rather than being foreclosed by the medical determination of brain death.

IV. IMPLICATIONS FOR MEDICAL PRACTICE

While the definition of death has diverse legal implications, its implications for medical practice are likely more immediate and often more critical. Physicians need guidance and some sense of certainty, especially when dealing with patients who meet the current neurological criteria for death. Physicians are on the front lines in dealing with family members, who may be confused or in conflict when it comes to their loved ones' end-of-life treatment. This plays out most clearly in circumstances of potential organ donation and withdrawal of life-sustaining measures.

Canadian law currently operates on the concept of the "Dead Donor Rule," which stipulates that organs cannot be removed from a patient until the patient is dead.¹¹⁷ Otherwise, the act of removing a patient's vital organs would be murder. A patient may be declared dead by means of neurological or cardiopulmonary criteria. Some have argued that the very concept of brain death was developed to promote the objectives of organ donation. In a persuasive article,¹¹⁸ professor and bioethicist Seema Shah traces the evolution of the concept of brain death and argues that it is a legal fiction designed to resolve two practical problems: "the waste of resources spent

¹¹⁶ See *ibid* at paras 51, 78.

¹¹⁷ See Robert Veatch, "The Dead Donor Rule: True by Definition" (2003) 3:1 Am J Bioeth 10 at 10. See also Downie et al, *supra* note 13 at 852.

¹¹⁸ See Shah, *supra* note 15.

on people who will not recover consciousness and the need to have organs for transplantation.”¹¹⁹

By accepting brain death as equivalent to biological death, we are legally able to remove organs from a patient without violating the Dead Donor Rule. While their organs are typically kept viable by maintaining cardiopulmonary function by mechanical means, the patients are nevertheless considered “dead” by both medical and legal criteria. This is why brain death is expressly included as a form of death in organ and tissue donation statutes. Indeed, brain-dead patients have historically constituted the majority of organ donors, so the neurological definition of death is important to the modern organ donation system.¹²⁰ In *McKitty*, Justice Shaw noted that the “adverse consequences to the organ donation system” would need to be considered carefully by the legislature if there were a move toward “a recognition of biological functioning as life.”¹²¹

Those who question the equivalence of brain death with biological death acknowledge the possible consequences to organ donation, but argue that organ donation should not take priority over informed consent. Nair-Collins has suggested that, in portraying brain death as a form of death, the medical profession is not providing appropriate disclosure to substitute decision makers, leading them to provide consent for something that they do not fully understand.¹²² Many patients might consent to donation in any event. However, to respect autonomy in medical decision making, the consent of patients and their substitute decision makers should not be influenced by suggestions that a brain-dead individual is already dead, or by

¹¹⁹ *Ibid* at 320, referring to the pioneering work of the Ad Hoc Committee, *supra* note 10.

¹²⁰ See Andreas H Kramer et al, “Incidence of neurologic death among patients with brain injury: a cohort study in a Canadian health region” (2013) 185:18 CMAJ E838 at E842, which expresses concern that the decline in patients progressing to neurologic death has led to a decrease in organs available for donation.

¹²¹ *McKitty* ONSC, *supra* note 1 at para 127.

¹²² See Nair-Collins, *supra* note 15 at 680.

obscuring the moral dimensions of procuring organs from a patient who is not yet biologically dead.¹²³

Given decades of past practice and the importance of donations from brain-dead patients to the organ donation system, it seems unlikely that courts or legislators will seek to revisit the law allowing for the removal of organs from brain-dead patients. Moreover, donors and their loved ones are likely to continue consenting to this practice, as it helps to derive some meaning from what might otherwise be a tragic death.¹²⁴ Nevertheless, a religious exemption option, whether based on common law or statute, would not detract significantly from these laudable goals. Those who oppose the concept of brain-death on religious grounds would be unlikely to consent to donation under these circumstances anyway since they do not believe that their loved one is dead. They would be even less likely to consent if their religious belief led to disagreement or conflict with health care practitioners, as it would generate a sense of mistrust. Further, to the extent that there is conflict among family members about whether to accept the patient's brain death as death, the prospects of obtaining consent for organ donation are not obviously worse, from the physician's perspective, if some kind of religious exemption is recognized.

A legal definition of death that takes into account the plaintiff's religious beliefs would also be broadly consistent with the reasoning in *Rasouli*¹²⁵ and the legislative framework of the Ontario *Health Care Consent Act, 1996*¹²⁶ that it discussed. The majority in *Rasouli* found that the withdrawal of life-sustaining treatment requires consent; the substitute decision maker is governed by the patient's prior expressed wish or, in the absence of such a wish, the well-being, values and beliefs of the patient.¹²⁷ The majority also stressed the importance of patient autonomy and, while it did not engage in

¹²³ It has also been suggested that the removal of organs from brain-dead patients be considered a form of medical assistance in dying, which may be a more transparent way of conceiving the circumstances. See Shapiro, *supra* note 105 at 167.

¹²⁴ See e.g. Shaila J Merchant et al, "Exploring the psychological effects of deceased organ donation on the families of the organ donors" (2008) 22:3 Clin Transplant 341 at 344, 346.

¹²⁵ *Supra* note 32.

¹²⁶ *Supra* note 114.

¹²⁷ See *Rasouli*, *supra* note 32 at paras 87, 89. See also paras 196, 199.

a philosophical discussion of the value of life, it did not express doubt about the relevance of the patient's religious beliefs to the determination of his best interests.¹²⁸

It is beyond the scope of this case comment to determine whether there is a sufficient moral difference between patients in a persistent vegetative state and patients who are considered brain-dead to afford freedom of religion to only the former. Still, the Ontario Court of Appeal in *McKitty* seems correct in its suggestion that the legal and moral personhood of brain-dead patients cannot simply be assumed away or dictated by the medical profession alone.

Of course, the legal definition of death is not only relevant to situations involving brain death. Situations where the patient's heart has stopped beating also present some challenges in terms of the precise timing of the death declaration and the application of the Dead Donor Rule.¹²⁹ In those instances, organ donation typically follows the controlled withdrawal of life-sustaining measures, which allows transplant teams to prepare for surgery.¹³⁰ In Canada, the cessation of cardiopulmonary function in these circumstances is followed by a five-minute "hands-off" period to rule out the possibility of spontaneous auto-resuscitation.¹³¹ Only after this time can surgery be performed to remove the patient's organs. In some circumstances, the dying process can take so long that organs can no longer be transplanted or may not function properly post-transplantation. When this happens, the patient's wishes for organ donation are not fulfilled and families can sometimes feel that a "second loss" has occurred.¹³²

The hands-off period also operates on the assumption that when cardiopulmonary function has ceased (and the brain is thus deprived of

¹²⁸ See *ibid* at para 89.

¹²⁹ See Doig & Rocker, *supra* note 8 at 1071.

¹³⁰ See generally Sam D Shemie et al, "Donation after cardiocirculatory death in Canada" (2006) 175:8 CMAJ S1.

¹³¹ See *ibid* at S6. See also Sonny Dhanani et al, "Resumption of Cardiac Activity after Withdrawal of Life-Sustaining Measures" (2021) 384 New Eng J Med 345 at 351, which affirmed the appropriateness of five minutes as a hands-off period.

¹³² See Lauren Taylor et al, "Harms of Unsuccessful Donation After Circulatory Death: An Exploratory Study" (2017) 18:2 Am J Transplant 402 at 407.

oxygen), the person's critical brain function will irreversibly cease shortly thereafter¹³³ and they will not experience suffering through the removal of organs. To date, the temporal relationship between the cessation of cardiopulmonary and critical brain function has not been accurately measured, though some preliminary studies are underway.¹³⁴ If new evidence emerged that brain function ceases more rapidly than presently understood, then the hands-off period could possibly be reduced, and thus more organs would be available for successful transplant. A better understanding of the relationship between the cessation of cardiopulmonary and brain functions could help inform the definition of death, which would correspondingly promote patient autonomy and minimize suffering in the organ donation process.

A legislated definition of death is arguably less critical when it comes to the general withdrawal of life sustaining treatment, which is the "most common event preceding death in [intensive care unit] practice worldwide."¹³⁵ Whether the decision to withdraw life support is based on a patient's brain death or on weaknesses in their cardiopulmonary system, such that recovery of autonomous function is unlikely, it is a decision that families regularly make based on their perceptions of what is in the patient's best interests. The same can be said for the family of Taquisha McKitty, who believed that she would not have agreed to what amounted to, on her religious beliefs, ending her own life. Her case should cause us to critically evaluate whether brain-dead patients might also have some essential best interests to consider before they are legally and morally considered dead.

CONCLUSION

Death is a complex phenomenon, which has profound implications well beyond the simple decay of the body. In some instances, it also has critical legal implications. Yet, to a large extent, Canadian courts and some provincial legislatures have effectively delegated the definition of death to the medical profession. While physicians undoubtedly have important expertise

¹³³ See Sam D Shemie, "Clarifying the paradigm for the ethics of donation and transplantation: was 'dead' really so clear before organ donation?" (2007) 2:18 *Philos Ethics Humanit Med* 1 at 3.

¹³⁴ See DDePiCt Research Program, "The Neurologic Physiology after Removal of Therapy Study (The NeuPaRT Study)" (last modified 20 January 2021), online: *DDePiCt Research Program* <www.ddepict.com/neupart.html> (accessed 2 May 2021) [perma.cc/P3AN-WCLB].

¹³⁵ Shemie, *supra* note 133 at 3.

as to the functioning of the body's vital systems and the tests by which that functioning may be measured, they are not the ultimate authorities on the value of life or on the moral and legal rights that should be afforded to those who have limited brain function.

In *McKitty*, the Ontario Court of Appeal invited broader and deeper debate about the many dimensions of death. Given the recent adoption of an opt-out organ donation system in Nova Scotia, the acknowledged importance of dignity and autonomy in the dying process, and our increasingly pluralist society, this seems an opportune time for Parliament and provincial legislatures to engage in meaningful debate about the legal determination of death and whether it can accommodate a religious or other objection to declaring death based on neurological criteria.¹³⁶ In any event, it seems imprudent, and possibly cruel, to continue avoiding this important debate and subjecting patients, families, and physicians to distressing litigation in what are already traumatic circumstances.

¹³⁶ The details of how such a proposal would be implemented are beyond the scope of this case comment, and would require consideration of federalism issues, dispute resolution procedures, resource implications, etc.