REGULATION AND GOVERNANCE OF ACCESS TO UNPROVEN MEDICAL INTERVENTIONS IN CANADA;

A CASE STUDY ANALYSIS

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ABSTRACT

This research used case studies to identify and explore lessons from past regulation and governance of access to unproven medical interventions provided by physicians in Canada, with the goal of informing and strengthening future strategies. The examples selected were chelation therapy for applications other than treating heavy metal toxicity, liberation therapy for multiple sclerosis, and unproven stem cell interventions. For each case study, a systematic data collection strategy was used that included academic literature from relevant disciplines, legislation, government documents, records of legislative and parliamentary debates, jurisprudence, professional regulatory decisions and guidance, news media, and patient advocacy activity. The role of law helped set boundaries for the data collection and analysis, which focused primarily on regulatory and governance tools and strategies that use or are empowered or constrained by law.

A second objective of this research was to develop theoretical insights regarding the use of regulation and governance as frameworks for understanding complex policy issues. Drawing on the fields of regulation and governance, a conceptual framework was developed to guide the case study analyses. This conceptual framework was revised iteratively throughout the work. The key features of regulation and governance that were identified and explored through each case study were actors, instruments, purposes, legitimacy, and responsiveness and adaptability.

Following the individual case study analyses, which developed a deep understanding of each case, a cross-case analysis was conducted to identify features of the Canadian context that future regulation and governance of access to unproven medical interventions will likely need to account for to be successful. These features include our decentralized healthcare system, the importance of medical professional regulation, and our independent judicial processes. There are also several areas of focus that the findings from this research suggest may strengthen future regulation and governance of access to unproven medical interventions provided by physicians in Canada. These priorities include maximizing the potential of collaborative distributed governance, emphasizing protection of the public interest in renewal of medical professional regulation, prioritizing fairness and transparency in stakeholder engagement practices, promoting the need for clarity and nuance in discussions about evidence, and supporting strong science and health communication practices.

The conceptual framework developed in this work provided a systematic approach for identifying and analyzing the field of influence over the complex issues at the heart of this research and it may prove useful for future study in other fields. Bridging the fields of regulation and governance in this way also added richness and nuance to key concepts in each domain. In so doing, this research responded to calls for work that uses regulation and governance theory to inform and strengthen practice, and vice versa.

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DEDICATION

To my extended family and friends, whose confidence in my abilities so often exceeds my own. I appreciate your encouragement, patient support, and unwavering faith that I would succeed in this project more than I can express.

To my grandparents, whose examples of resilience, strong work ethic, and commitment to family and community were so influential in shaping who I am.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AHS	Alberta Health Services
ALS	Amyotrophic Lateral Sclerosis
CADTH	Canadian Agency for Drugs and Technologies in Health
CAM	Complementary and alternative medicine
CCSVI	Chronic Cerebrospinal Venous Insufficiency
CIHI	Canadian Institutes of Health Information
CIHR	Canadian Institutes of Health Research
CMA	Canadian Medical Association
CTSG	Cell Therapy Stakeholder Group
EDTA	Ethylenediaminetetraacetic Acid
FDA	Food and Drugs Administration
IPF	Idiopathic Pulmonary Fibrosis
INESSS	Quebec Institut national d'excellence en santé et en services sociaux
IRGC	International Risk Governance Centre
ISSCR	International Society for Stem Cell Research
MLA	Member of the Legislative Assembly
MP	Member of Parliament
MS	Multiple Sclerosis

OHIP	Ontario Health Insurance Plan
OHTAC	Ontario Health Technology Advisory Committee
ONHPARB	Ontario Health Professions Appeal and Review Board
ONHSARB	Ontario Health Services Appeal and Review Board
PRP	Platelet-rich plasma
REB	Research Ethics Board
RRMS	Relapsing-remitting multiple sclerosis
SCC	Supreme Court of Canada
TACT	Trial to Assess Chelation Therapy
TCPS2	Tri-Council Policy Statement

CHAPTER 1: FOUNDATIONS

1.1 Introduction

These are promising times in biomedical research and clinical innovation, with research across various fields signalling new and improved treatment options for a wide range of conditions in the not-too-distant future. However, the clinical translation process is challenging. It can take a significant amount of time and multiple phases of research and exploration before a new treatment, whether a drug, medical device, or other intervention, is sufficiently well understood to be used in routine clinical practice for the benefit of patients. In many contexts, the safety and effectiveness of an intervention are of paramount importance to decisions about access to that intervention, as are considerations regarding potential risks and how they compare to those of existing treatment options. Other times, medical interventions are offered to the public without demonstrated safety, effectiveness, or a favourable risk-benefit profile.

As will be discussed in more detail in the ensuing chapters, there can be different access pathways for medical interventions, ranging from institutionalized systems of oversight and approvals to private market options that may operate with limited accountability. There are multiple actors who have influence over when and under what circumstances people can access a given medical intervention, and many different priorities that affect those decisions. Access to medical interventions that lack evidence of their safety and efficacy can raise complex legal tensions and policy issues. In this thesis, I explore lessons to be drawn from previous regulation and governance of access to unproven medical interventions provided by physicians in Canada. The overall objective of this work is to inform and strengthen future strategies that support responsible development of potentially valuable health technologies while limiting provision of ineffective and possibly dangerous medical interventions by regulated healthcare professionals.[1]

1.2 Research questions

I developed the following research questions to guide my work in this doctoral project.

Primary research question: What can we learn from current and past practices to inform and improve future strategies for regulation and governance of access to unproven medical interventions in Canada?

Sub-questions:

(1) How can we characterize different examples (past and present) of regulation and governance of access to unproven medical interventions provided by physicians in Canada, and what lessons or principles can we draw from these examples?
(2) What is the role of law in setting the parameters within which regulation and governance of access to medical interventions take place, and as an instrument of regulation and governance?
(3) What features of regulation and governance of access to unproven medical interventions are particularly important for effective oversight in the Canadian context?

[1] For an argument regarding the need for this kind of work, see e.g. Gregory Mandel, "Regulating Emerging Technologies" (2009) 1:1 L, Innovation & Technology 75 at 92.

As will be described in Chapter 3 where I present my research strategy, I explore these research questions using three select case studies, each of which focuses on a different unproven medical intervention as defined below.

1.3 Terminology tensions and key concepts

As is reflected in the above research questions, "unproven medical interventions" are a central focus of this research and access is a key related concept. Accordingly, it is necessary to start this thesis by addressing important terminology tensions and explaining the foundational concepts for the work. To do so, I will first contextualize unproven medical interventions within broader classifications of medical interventions, including the sometimes complex and nuanced distinctions between clinical innovation and research. I will then outline my working definition of unproven medical interventions and explain my rationale for taking this approach. Following these definitional discussions, I will characterize the kinds of access that are most relevant for this research.

1.3.1 Distinctions between clinical innovation and research

Medical interventions, including medical and surgical innovations, are perhaps best viewed on a spectrum, with well-established clinical treatments falling within routine standards of care located on one end, interventions lacking any reasonable scientific or clinical rationale located on the other extreme, and a large area in-between where there is room for reasonable debate regarding the state of evidence about a particular intervention and the appropriateness of its use in different contexts.

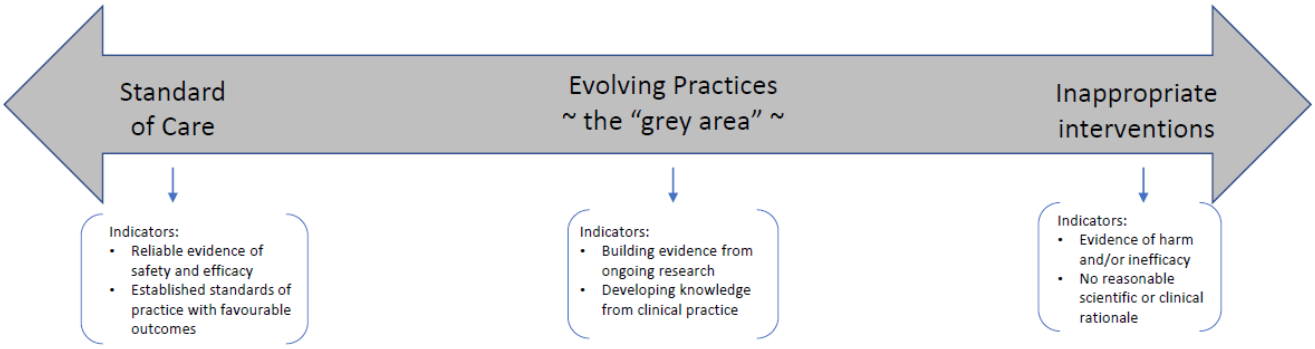

Figure 1.1: A Classification Spectrum for Medical Interventions

On this spectrum, categories are not static. They often shift as circumstances and knowledge evolve. For example, an intervention that initially begins as an early clinical innovation lacking substantiating evidence might ultimately be adopted as standard of care, once there is sufficient evidence of safety and efficacy from research or evolving practices. Similarly, another intervention might be regularly employed in clinical practice, but ultimately be invalidated as evidence demonstrates it is not effective or causes greater harm than benefit.

This admittedly simplistic portrayal should not be taken to suggest that the processes involved with clinical innovation and practice evolutions are always clear, transparent, or self-

reflective. It is an unfortunate historical reality that some medical interventions have continued to be provided for a long period of time even when they are of low value and sometimes contradicted by subsequent evidence.[2] Research exploring human behaviour may provide some insight into this pattern. For example, the results of one systematic review suggest that clinicians may not accurately estimate either the benefits or harms of treatments; rather, they tend to overestimate benefits and underestimate harms.[3] These findings mirror the results of a similar review of patients' expectations, which found that patients also tend to overestimate benefits while underestimating the potential harms of medical interventions.[4] These potential biases or errors in decision-making on the part of individual healthcare providers, many of whom may have the best of professional intentions, and of patients, who may be influenced by the power of hope or similar forces, illustrate the importance of robust and ongoing oversight of medical interventions and their outcomes.

Determining the appropriate locus of responsibility for oversight of a specific medical intervention, and identifying what policies and standards apply, depends to a large extent on whether it is characterized as research or as a clinical treatment provided as part of the practice of medicine. At its core, this characterization generally depends on the objective of the activity. Treatment provided as part of the practice of medicine is intended to benefit the individual patient, while research is primarily meant to advance knowledge.[5] The Belmont Report, a leading historical research ethics document, used the following distinctions:

> For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

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[2] Vinay Prasad et al, "A Decade of Reversal: An Analysis of 146 Contradicted Medical Practices" (2013) 88:8 Mayo Clinic Proceedings 790; Adam Elshaug et al, "Over 150 Potentially Low-Value Health Care Practices: An Australian Study" (2012) 197:10 Medical J Australia 556.

[3] Tammy Hoffmann & Chris Del Mar, "Clinicians' Expectations of the Benefits and Harms of Treatments, Screening and Tests; A Systematic Review" (2017) 177:3 J American Medical Assoc 407 at 415.

[4] Tammy Hoffmann & Chris Del Mar, "Patients' Expectations of the Benefits and Harms of Treatments, Screening and Tests; A Systematic Review" (2015) 175:2 J American Medical Assoc Internal Medicine 274. See also Don Swekoski & Deborah Barnbaum, "The Gambler's Fallacy, the Therapeutic Misconception, and Unrealistic Optimism" (2013) 35(2) IRB: Ethics & Human Research 1. Swekoski and Barnbaum define the gambler's fallacy as a misunderstanding about the statistical odds at play and unrealistic optimism as unwarranted optimism regarding expected benefit, notwithstanding information about risk. Although their focus is on the research context, I suggest the gambler's fallacy and unrealistic optimism are also relevant to patients' perceptions of risk and benefit in a treatment context. See also Neil Levy, "Forced to be free? Increasing patient autonomy by constraining it" (2012) 40 J Med Ethics 293 at 296-298. Levy defines motivated reasoning as the tendency to overemphasize evidence that supports our views and discount that which does not, and affective forecasting and recall as the tendency to unreliably predict or remember how events make us feel.

[5] Barbara von Tigerstrom, "Product Regulation and the Clinical Translation of Stem Cell Research" (2009) 5 Stem Cell Rev & Reports 135 at 137. See also Tracey Evans Chan, "Legal and regulatory responses to innovative treatment" (2013) 21 Med L Rev 92 at 101. Chan points to definitional challenges between research and innovative treatment.

> Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.[6]

As will be discussed in Chapter 4, if a medical intervention is provided by a physician in a research context, it will generally be subject to research ethics oversight, and potentially oversight by Health Canada if it is part of a clinical trial. If that medical intervention is provided for therapeutic purposes to benefit the individual patient, the physician's conduct will fall under the regulatory responsibility of the relevant college of physicians and surgeons. In both contexts, the courts may ultimately play a role in responding to harms suffered, via medical negligence litigation.[7]

Categorizing medical interventions and drawing lines between research and treatment can be far from simple or straightforward, even for experts. For example, one study suggests that surgeons have different views about what distinguishes surgical innovation from routine variations in practice, and from research activities.[8] Other research into the perspectives of pediatric physician researchers in Canada suggests a similar disconnect between how theoretical models conceptualize distinctions between medical practice and clinical research, and the lived experiences of those in the field.[9] There is also evidence indicating that research ethics boards vary substantially in how they assess innovation in clinical care, including regarding whether or not it is considered research.[10] How these distinctions are made is important for this thesis because the kinds of unproven medical interventions (as defined below) studied here could potentially be considered forms of medical or surgical innovation, depending on the context in which they are provided.

There can also be debate about whether a particular intervention should be characterized as a drug or product, versus as a practice or procedure.[11] As will be addressed in Chapter 4, these distinctions have important implications for regulatory responsibility and jurisdiction given that Health Canada has authority to regulate drugs and medical devices under the *Food and Drugs Act*[12], while responsibility for medical practice falls under provincial jurisdiction and has been delegated to medical regulatory bodies. Accordingly, it is worthwhile to briefly consider how medical or surgical innovation is conceptualized, to ground the discussion that will follow in

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[6] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report; Ethical Principles and Guidelines for the Protection of Human Subjects Research" (1979), online: <www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html> at A.A.

[7] See Chan, *supra* note 5 at 120.

[8] Wendy Rogers et al, "Identifying surgical innovation: a qualitative study of surgeon's views" (2014) 259:2 Annals Surgery 273.

[9] Christine Czoli et al, "Accountability and pediatric physician-researchers: are theoretical models compatible with Canadian lived experience?" (2011) 6 Philosophy, Ethics, & Humanities in Medicine 15.

[10] Johane Patenaude et al, "Evaluation of Clinical Innovation: A Gray Zone in the Ethics of Modern Clinical Practice?" (2007) 23:Supp1 J General Internal Medicine 27.

[11] For example, as discussed in Chapter 7, *below*, a Canadian provider of stem cell based interventions reportedly responded to Health Canada's enforcement efforts by taking the position that the stem cell therapies he was providing were surgical procedures as opposed to drugs, and thus not under the regulatory purview of Health Canada. See Mia Jensen, "City doctor, Health Canada at odds; 'Stem cells are safe. We've done over 150 treatments and we've never had an adverse event'", *Sudbury Star* (12 July 2019) A.1., online: <www.thesudburystar.com/news/local-news/sudbury-doctor-health-canada-at-odds-over-stem-cell-treatments>.

[12] RSC 1985, c F-27.

subsequent chapters of the oversight mechanisms that apply to the interventions in this case study research.

Mastroianni defines surgical innovation as "a novel procedure, a significant modification of a standard technique, a new application of or new indication for an established technique, or an alternative combination of an established technique with another therapeutic modality that was developed and tested for the first time".[13] For example, Riskin et al point to vascular anastomosis (a surgical procedure that connects vessels, such as arteries and veins, to one another) as one of many examples of surgical innovations that evolved outside traditional research contexts, and which enabled subsequence advances in surgery, such as organ transplantation.[14] Viewed as falling within the bounds of medical practice, surgical innovation has generally been subject to little to no oversight or accountability, apart from professional discipline and civil suits for negligence when harms are suffered.

However, the uncertainties associated with medical and surgical innovation share many commonalities with the research enterprise and call into question the logic of bright-line distinctions between these two domains. In his seminal work on research ethics, Fried used the terms therapeutic and non-therapeutic to distinguish between experimentation intended to treat an individual's illness versus that which is done "solely to obtain information of use to others" but also notes "large numbers of gradations in between".[15] Margot uses the term "informal research" to describe the practice where a surgeon has a hypothesis that they test on their own patient population, often using terms such as "new", "innovative", "breakthrough" to describe the treatment, and potentially tracking the outcomes in some manner.[16] However, he suggests that the practice of informal research, which bears many similarities to patterns observed in the interventions studied in my research, is a "flawed process" and that safeguards for good science and human subject protection can be improved.[17]

Perhaps most importantly, insufficient oversight of medical or surgical innovation raises concerns regarding patient safety, particularly where innovations are significant and potentially harmful.[18] A lack of clarity between research, innovative treatment, and the boundaries between

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[13] Anna Mastroianni, "Liability, regulation and policy in surgical innovation: the cutting edge of research and therapy" (2006) 16 Health Matrix 351 at 356.

[14] Daniel Riskin et al, "Innovation in surgery: a historical perspective" (2006) 244 Annals Surgery 686 at 687. See also Jeffrey Barkun et al, "Evaluation and stages of surgical innovations" (2009) 373 Lancet 1089.

[15] Charles Fried, *Medical Experimentation: Personal Integrity and Social Policy*, new ed by Franklin G. Miller & Alan Wertheimer (New York: Oxford University Press, 2016) at 31-32. Fried suggests that randomized clinical trials mix the goals of therapeutic and non-therapeutic research and thus raise significant legal and ethical issues. Fried's classic work (published in 1974) and the revised version (published in 2016) explore important questions and tensions related to physicians engaging in clinical research and the limitations of informed consent. Although current research ethics frameworks have provided a procedural answer to what is technically required such as, for example, in clinical trial research, the broader normative questions about what 'ought' and 'ought not' to occur remain relevant and important to revisit over time.

[16] Curtis Margot, "When is surgery research? Towards an operational definition of human research" (2001) 27 J Medical Ethics 40.

[17] *Ibid* at 42-43.

[18] Steven Strasberg & Philip Ludbrook, "Who oversees innovative practice? Is there a structure that meets the monitoring needs of new techniques?" (2003) 196 J American College Surgeons 938 at 939. The authors point to the example of laparoscopic cholecystectomy, which was a surgical technique that was introduced on a widespread basis without sufficient training or evaluation and was later determined to have caused widespread harm because of fundamental flaws in the procedure.

them, also raises concerns regarding the potential for "therapeutic misconception" on the part of patients. Henderson et al. define therapeutic misconception as "when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial".[19] In so doing, they also note widespread confusion about the purpose of research, which can be left unchecked in the absence of appropriate oversight.[20] In considering legal and regulatory responses to innovative treatment, Chan notes that innovative treatments often rely heavily on professional judgment and informed consent, and suggests that patients may not be well placed to evaluate medical complexities and uncertain risks, and may be vulnerable to false hopes.[21]

Notwithstanding these concerns, there is notable disagreement regarding whether it is appropriate to subject surgical innovation to oversight and, if so, to what form of oversight. This lack of consensus flows in part from the perspective that innovation has a different orientation from research in that it is intended to benefit the individual patient involved, and accordingly should not be subject to the same restrictions.[22] The IDEAL model is one example of an approach to providing oversight of medical innovation that offers considerable appeal.[23] It identifies different stages of surgical innovation including: innovation (i.e. the first attempt at a new approach); development (i.e. focus on technique); exploration (i.e. indications, risks, benefits); assessment (i.e. effectiveness, cost implications), and long-term study. The final stage of this model contemplates a role for ultimate validation of surgical innovation through trials, though the authors note that adopting standards of this nature would require widespread change in current practices.[24] Other recommendations flowing from concerns that current practices in surgical innovation do not involve sufficient oversight and patient protections include registries to track outcomes and accompanying educational programming for providers.[25]

As this brief discussion illustrates, there is much important work to be done in terms of clarifying distinctions between clinical research and responsible medical innovation, and in devising appropriate mechanisms of oversight that balance the benefits of innovation with attendant concerns regarding patient safety, therapeutic misconception, and potential conflicts of

[19] Gail Henderson et al, "Clinical trials and medical care: defining the therapeutic misconception" (2007) 4:11 Plos Medicine 1735 at 1736.

[20] Concerns regarding the therapeutic misconception have evolved over time and are not universally shared. See Debra Matthews, Joseph Fins & Eric Racine, "The Therapeutic 'Mis' Conception; An Examination of its Normative Assumptions and a Call for its Revision" (2018) 27 Cambridge Q Healthcare Ethics 154. Matthews et al argue that the traditional justifications underlying the therapeutic misconception are paternalistic.

[21] Chan, *supra* note 5 at 93.

[22] Haavi Morreim, Michael Mack & Robert Sade, "Surgical innovation: too risky to remain unregulated?" (2006) 82 Annals Thoracic Surgery 1957; see also George Agich, "Ethics and innovation in medicine" (2001) 27 J Medical Ethics 295 at 296. Agich argues that clinical innovation does not fit the parameters of scientific research because it thrives on intuition, experience, and uncertainty, and that there are better ways, including clinical, institutional, and professional mechanisms, to protect patients in the context of novel therapeutic applications than the use of regulatory ethics paradigms.

[23] Peter McCulloch et al, "No surgical innovation without evaluation: the IDEAL recommendations" (2009) 374: 9695 Lancet 1105 at 1106.

[24] *Ibid* at 1110.

[25] Mastroianni, *supra* note 13 at 434, 441-442.

interest for clinician-researchers, among others.[26] It is not my intent at this stage of my work to advocate for any one particular system (or constellation of systems) of oversight for different forms of clinical innovation. Rather, I present this general landscape as a backdrop to setting out the definitional approach I take in this research, outlined in the following section.

1.3.2 Defining "unproven" medical interventions

This research focuses on what I will refer to as unproven medical interventions. In this work, medical interventions are characterized as unproven when they have not been demonstrated to be safe and efficacious via current standards for clinical research in Canada and they are not widely accepted as a standard of care treatment, but are nonetheless provided under the auspices of treatment as opposed to research. In arriving at this definition, I draw on Srivastava et al.'s characteristics of unproven cell therapies, which include:

> Unclear scientific rationale to suggest potential efficacy; Lack of understanding on the mechanism of action and/or the biological function to support clinical use; Insufficient data from in vitro assays, animal models and clinical studies regarding the safety profile to support the use in patients; Lack of a standardized approach to confirm product quality and ensure consistency in cell manufacturing; Inadequate information disclosed to patients to enable proper informed consent; Use within non-standardized or non-validated administration methods; Uncontrolled experimental procedures in humans.[27]

Critically, I distinguish unproven medical interventions from experimental interventions, which I characterize as research that has been reviewed and approved by the appropriate bodies (e.g. research ethics boards, Health Canada) and which is conducted in accordance with current research ethics frameworks (e.g. the *Tri-Council Policy Statement*[28]*)*, as well as scientific and professional standards. This approach echoes that of leading ethics scholars, Beauchamp and Childress, who suggest that medical practices that have not been validated by research and which have not been approved for that particular use should be considered to be experimental practices that place patients in the position of research subjects, requiring the attendant protections.[29] I also distinguish unproven medical interventions from clinical innovation (discussed above), which in this work is best understood to require a scientific rationale and some evidence of efficacy without significant adverse effects (e.g. from animal models or carefully designed case studies) as well as, ideally, some form of scientific and ethical review or oversight.[30] Unproven medical interventions are often, but not necessarily, provided in a private for-profit context. In the interests of maintaining a feasible scope for this research, I focus on unproven medical

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[26] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics*, 7th ed (Oxford: Oxford University Press, 2012) at 332-333.

[27] Alok Srivastava et al, "Part 1: Defining unproven cellular therapies" (2016) 18:1 Cytotherapy 117 at 118.

[28] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (December 2014), online (pdf): <www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf> [TCPS2]. The TCPS2 will be discussed in Chapter 4, *below*.

[29] Beauchamp & Childress, *supra* note 26 at 332.

[30] Olle Lindvall & Insoo Hyun, "Medical Innovation Versus Stem Cell Tourism" (2009) 324:5935 Science 1664. For a discussion of the importance of limiting access to unproven interventions to contexts where they can be appropriately evaluated, see Matthew Stanbrook, "Access to treatment for multiple sclerosis must be based on science, not hope" (2010) 182:11 CMAJ 1151 at 1151.

interventions that are invasive (e.g. injections, insertion of medical devices, surgical procedures) as opposed to health-related products (e.g. compression stockings, lotions) or services (e.g. counselling, reiki). There can be exceptions, but in general invasive procedures tend to carry greater risk than non-invasive procedures and thus warrant focused consideration.

Although I have adopted the term unproven for the purpose of this research, there are other terms or sets of terms that could be used instead. For example, in considering questions of patient access, the Nuffield Council on Bioethics adopted the term "experimental treatments", while recognizing other similar terms include "innovative, novel, unproven, unvalidated, non-standard, and unlicensed treatments".[31] The authors also recognized that none of these terms are unproblematic and that all are value-laden and may have different meanings to different people.[32] Other potential options may include "unconventional", "unapproved", "alternative" and "unorthodox", though again none are uncomplicated in this context.

I have selected unproven from these varied alternatives for several reasons. "Experimental" is commonly associated with research and as discussed above, I distinguish my focus on unproven medical interventions from interventions that are provided in a research setting. The terms "novel" and "innovative" often carry positive normative and political undertones that I wish to avoid in this work.[33] "Unlicensed" and "unapproved" are too narrow for the purpose of this research, because there are many forms of medical interventions that are not subject to licensing or other approval regimes. In contrast, "non-standard" is too broad in that it may capture legitimate forms of clinical innovation (discussed above). "Unvalidated" would be another viable alternative, but "unproven" has a long history[34] and has been more widely adopted in relevant domains, including work related to unproven stem cell interventions (Chapter 7).[35]

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[31] Nuffield Council on Bioethics, "Bioethics Briefing Note: Patient access to experimental treatments" (2018), online: <nuffieldbioethics.org/project/briefing-notes/experimental-treatments>. See also Chan, *supra* note 5 at 94. Chan's definition of "innovative treatment" is very similar to the definition I adopt for unproven medical interventions. She suggests "this phrase refers to significant departures from standard medical therapy which has not been validated by reliable research methods, or where there is simply insufficient evidence to support the safety and efficacy of the innovative procedure, method, or device" (at 94).

[32] Nuffield Council, *supra* note 31 at footnote 2.

[33] "Innovation" is a particularly popular term in health-related contexts at present, including in government initiatives. See e.g. Health Canada, "Unleashing Innovation: Excellent Healthcare for Canada; Report on the Advisory Panel on Healthcare Innovation" (2015), online (pdf): <healthycanadians.gc.ca/publications/health-system-systeme-sante/report-healthcare-innovation-rapport-soins/alt/report-healthcare-innovation-rapport-soins-eng.pdf>. See also Wendy Lipworth & Renata Axler, "Towards a bioethics of innovation" (2016) 42 J Med Ethics 445. Lipworth and Axler discuss what they frame as the current drive to innovate in medicine and argue for the need for a bioethics framework based on the framework of responsible innovation, which includes considerations of anticipation, reflexivity, inclusiveness, and responsiveness.

[34] See e.g. Victor Herbert, "Unproven (Questionable) Dietary and Nutritional Methods in Cancer Prevention and Treatment" (1986) 58 Cancer 1930. Herbert suggested that "unproven" is a euphemism for questionable and refers to approaches that have not answered the "basic questions regarding safety and efficacy". He further argued that this approach, "gets away from semantics, such as the use of terms like 'orthodox,' 'unorthodox,' 'alternative' (i.e. alternative to what works), 'holistic,' 'nutritional and metabolic,' 'establishment,' and 'nonestablishment.' There is no such thing as 'orthodox versus alternative' therapy. There is simply responsible therapy (therapy that works), irresponsible therapy (therapy that does not work), and experimental therapy." (at 1931)

[35] See e.g. Geoffrey Lomax, Art Torres & Maria Millan, "Regulated, reliable, and reputable: Protect patients with uniform standards for stem cell treatments" (2020) 9:5 Stem Cells Translational Medicine 547. Lomax et al use "unproven" to describe cell and tissue-based products that are marketed directly to consumers, and which are

To summarize this section on terminology tensions, in order to be consistent and clear in framing my topic of study, I have selected the term unproven medical interventions as best capturing the phenomenon of interest in this research. This choice to adopt the label of "unproven" medical interventions may be criticized for different reasons, including its potential normative implications including a preference for particular methodological approaches, such as randomized controlled clinical trials, or practice orientations. Although they are important, I do not seek to resolve these complex terminology tensions with this work. I do however acknowledge them, and the associated contested boundaries between different kinds of medical interventions.[36] I will return to consider the implications of these tensions and contested boundaries, including different understandings and perspectives about how evidence is constructed and used in these contexts, when discussing the results of my case study analysis in Chapter 8.

1.3.3 Characterizing different types of access claims

This research focuses on unproven medical interventions that are provided by physicians licensed to practice medicine in Canada, as opposed to by laypersons, other regulated healthcare professionals (e.g. pharmacists, nurses, some complementary and alternative medicine providers), or unregulated providers of health-related services.[37] Physicians play a central gatekeeping function in Canadian healthcare systems and have well-developed legal and professional responsibilities, including those that follow the privilege of professional self-regulation.[38] Although much of this work will also be relevant to other regulated healthcare professionals, focusing on physicians will assist with maintaining a feasible scope for the research.

When considering healthcare interventions provided by physicians, there are two key aspects of access that are particularly relevant to this research.[39] By access, I refer here to an individual's ability to obtain a particular healthcare intervention. There are different ways access can be understood, but my focus in this research is on what I will characterize as availability. Availability in relation to access can have varied meanings in the healthcare context. For example, it can capture questions about wait times, challenges related to locality (e.g. differential

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considered by the FDA to be biological products under its regulatory authority, and/or "have not been evaluated to characterize product composition, safety, or efficacy for the intended indication" (at 547).

[36] This terminology challenge, which includes the difficulty of being broad enough to capture the phenomena of interest without losing meaning for vagueness, is shared with other study of traditional and alternative medicine. See Terry Kaan, "Traditional, complementary, and alternative medicine" in Yann Joly & Bartha M. Knoppers, eds, *Routledge Handbook of Medical Law and Ethics* (New York: Routledge, 2015) 419 at 419.

[37] The regulatory status of complementary and alternative medicine varies by profession and jurisdiction, and continues to generate debate about the merits of extending the privilege of professional self-regulation (e.g. protection of the public) and the attendant concerns (e.g. legitimization of practices that lack evidence of efficacy). See Erin Nelson & Ubaka Ogbogu, *Law for Healthcare Providers* (Toronto: LexisNexis, 2018) at 49-51; see also Sandy Welsh et al, "Moving Forward? Complementary and Alternative Practitioners Seeking Self-Regulation" (2004) 26:2 Sociology Health & Illness 216 at 234-237.

[38] Roger Collier, "Professionalism: the privilege and burden of self-regulation" (2012) 184:14 CMAJ 1559.

[39] There can also be important temporal aspects to questions of access (i.e. short, medium, or long-term), as well regarding the focus of the analysis (i.e. individual versus population). See e.g. Barbara von Tigerstrom, "New Regulatory Pathways for Stem Cell-Based Therapies: Comparison and Critique of Potential Models" in Phuc Van Pham & Achim, eds, *Safety, Ethics and Regulations; Stem Cells in Clinical Applications* (Springer, 2017) 173 at 191.

access to specialists in rural and remote regions as compared to urban areas), and issues related to health human resource planning (e.g. insufficient numbers of specialists, such as mental health providers).

For this work, the most relevant aspect of availability relates to whether a particular healthcare intervention can be legitimately provided. In one sense, the use of "legitimacy" here captures the legality of the intervention (i.e. that it is not prohibited by law, can lawfully be provided). Access claims related to this form of legitimacy, or the legality, of a healthcare intervention most often take the form of negative rights claims. Negative rights claims are discussed in more detail in Chapter 4, Section 4.2.4. In brief, negative rights claims refer to demands for government to stop interfering with or limiting individual rights.[40] Legitimacy, as defined for the purpose of this research, also includes professional obligations and legal duties that may require or prohibit certain practices. For instance, medical professional regulatory bodies often establish standards of practice that impact the care that a physician can or in some cases must, or must not, provide.[41]

The second noteworthy element of access for the purpose of this work is the matter of funding; in other words, whether the healthcare intervention is paid for using public funds or whether it is not publicly funded but legitimately available on the private market. It is important to reiterate that this work is situated in the Canadian context which includes the current medicare system where approximately 70%-75% of healthcare is publicly funded, primarily through provincial or territorial health insurance programs.[42] Some non-publicly funded healthcare interventions, such as many dentistry and optometry services, are covered by other forms of healthcare insurance (e.g. supplementary insurance provided as an employment benefit, or that which is obtained and paid for privately). Access claims tied to funding are often characterized as positive rights claims, which capture rights-based demands that government fund or otherwise facilitate access to a particular product or service.[43] These kinds of access claims will also be discussed in Chapter 4, Section 4.2.4.

1.4 Access claims and countervailing concerns

Unproven medical interventions have a long history, and patients have frequently sought healthcare options beyond what are available as standard of care treatments. Accordingly, in some ways the issues at the heart of this research agenda are not new. However, they are particularly pressing today. It is well established that the internet has had a dramatic impact on how people access information about a wide range of topics, including health products and

[40] Abortion and Medical Assistance in Dying serve as two examples of medical interventions that were criminally prohibited prior to court decisions that determined those prohibitions were unconstitutional. See *R v Morgentaler*, [1988] 1 SCR 30 [*Morgentaler*]; see also *Carter v Canada (Attorney General)*, 2015 SCC 5 [*Carter*].

[41] For example, the College of Physicians and Surgeons of Ontario prohibits physicians from performing any female genital cutting or mutilation procedures. See College of Physicians and Surgeons of Ontario, "Female Genital Cutting (Mutilation)" (February 2001), online: <www.cpso.on.ca/Physicians/Policies-Guidance/Policies/Female-Genital-Cutting-Mutilation>.

[42] See Canadian Institute for Health Information, "National Health Expenditure Trends, 1975-2019" (2021), online: <www.cihi.ca/en/who-is-paying-for-these-services>.

[43] See e.g. Matthew Voell, "PHS Community Services Society v. Canada (Attorney General): Positive Health Rights, Health Care Policy, and Section 7 of the Charter" (2012) 31 Windsor Rev Leg Soc Issues 41. For a discussion of access in terms of public funding for alternative medicine, see Richard A. Haigh, "Reconstructing Paradise: Canada's Health Care System, Alternative Medicine and the Charter of Rights" (1999) 7 Health LJ 141.

services.[44] The plethora of online information about medical interventions, established and otherwise, has fueled consumer health information-seeking on the internet and raised concerns regarding the quality and trustworthiness of different kinds of information that are now readily accessible.[45] Today's information environment is arguably more complex than ever, with the added challenges of social media, online marketing, and misinformation. It can be daunting for patients and their loved ones to navigate this environment when seeking information about their health and potential treatment options. Healthcare providers are now routinely approached by patients who have consulted "Dr. Google",[46] and are called upon to respond to reams of information patients have located online, including about interventions that fall outside the standard of care for their condition.[47]

The digital era in health has also been associated with "growing scepticism towards conventional scientific medicine".[48] Erikainen et al. use what they term as the "experimental stem cell therapy market"[49] as an example of how the online agency of both providers and patients is serving to challenge "orthodox" medicine and its governance.[50] Although the digital era in health and the proliferation of health information and health-related marketing via online sources, referred to by some as "Health 2.0", is sometimes characterized as empowerment via information, other work points to the complexity of health-related digital information gathering and sharing practices and notes that these practices carry both burdens and expectations for patients, providers, and regulators.[51]

As the breadth of health information and options available online have grown, so too has the global market for health products and services that are marketed largely online, directly to the

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[44] See e.g. Lee Rainie & Susannah Fox, "The Online Health Care Revolution; The Internet's powerful influence on 'health seekers'" (2001), online: *Pew Research Centre Information & Technology* <www.pewinternet.org/2000/11/26/the-online-health-care-revolution/>; Nancy Atkinson, Sandra Saperstein & John Pleis, "Using the Internet for Health-Related Activities: Findings From a National Probability Sample" (2009) 11:1 J Medical Internet Research e4. http://doi.org/10.2196/jmir.1035.

[45] R.J. Cline & K.M. Haynes, "Consumer health information seeking on the internet: the state of the art" (2001) 16:6 Health Education Research 671-692; see also Deborah Lupton, "The digitally engaged patient: Self-monitoring and self-care in the digital health era" (2013) 11:3 Soc Theory & Health 256.

[46] Kenneth Lee et al, "Dr Google and the Consumer: A Qualitative Study Exploring the Navigational Needs and Online Health Information-Seeking Behaviors of Consumers With Chronic Health Conditions" (2014) 16:12 J Medical Internet Research e262.

[47] Madison K. Kilbridge & Steven Joffe, "The New Age of Patient Autonomy Implications for the Patient-Physician Relationship" (2018) 320:19 J American Medical Assoc 1973; Allan Brett & Laurence McCullough, "Addressing Requests by Patients for Nonbeneficial Interventions" (2012) 307:2 J American Medical Assoc 149; Roger Ladouceur, "Online health; Is this the end of family medicine" (2013) 59 Canadian Family Physician 813.

[48] Sonja Erikainen, Anna Couturier & Sarah Chan, "Marketing Experimental Stem Cell Therapies in the UK: Biomedical Lifestyle Products and the Promise of Regenerative Medicine in the Digital Era" (2019) 29:2 Science as Culture 219 at 4. For a discussion about connections between growing mistrust in science, the emergence of online information sharing, and threats to the doctor-patient relationship, see Richard Baron & Adam Berinsky, "Mistrust in Science — A Threat to the Patient–Physician Relationship" (2019) 381 N Engl J Med 182.

[49] This market is the subject of the third case study, presented in Chapter 7, *below*.

[50] Erikainen, Couturier & Chan, *supra* note 48.

[51] Collette Sosnowy, "Practicing Patienthood Online: Social Media, Chronic Illness, and Lay Expertise" (2014) 4 Societies 316 at 326. See also Lewis A. Grossman, "FDA and the Rise of the Empowered Consumer" (2014) 66 Admin L Rev 627. Grossman focuses on the United States and discusses how the Food and Drugs Administration's regulatory role has evolved over time in relation to the rise of the "empowered consumer" and the dramateic expansion in access to information about medical options through the internet and the emergence of direct-to-consumer advertising.

public. Canadians have long been participants in medical tourism, where both routine and unproven medical interventions are sought out-of-country.[52] However, we also have Canadian markets for unproven medical interventions, some of which are provided by physicians and other regulated healthcare professionals, and many of which are marketed online in a direct-to-consumer approach.[53] In some cases, the greater accessibility of information about unproven medical interventions and the domestic availability of some of these alternatives to standard of care treatments have prompted demands for access. In the following sections, I will reflect on the nature and importance of autonomy in questions of access to unproven medical interventions. I will then identify important concerns with access to unproven medical interventions provided by physicians in Canada that may justify limiting autonomy. I will next discuss the merits of using the theoretical frameworks of regulation and governance to explore issues regarding access to unproven medical interventions, while also noting the potential for this work to contribute theoretical insights to these developing fields of scholarship. Finally, I will conclude this section by explaining how the role of law will assist with setting boundaries for this research.

1.4.1 Autonomy and access claims

Arguments in favour of access to unproven medical interventions often involve autonomy-based rationales, which are sometimes connected to the notion of patient or individual empowerment and rooted in rights-based discourse.[54] For example, patient autonomy has been highlighted in arguments underlying the related Right-to-Try movement, which involves access pathways for experimental pharmaceuticals.[55] Rothman explores how autonomy has become central in American healthcare and connects its evolution to the growth of the internet and direct-to-consumer pharmaceutical advertising, among other forces including rights movements. He suggests these shifts have changed patient-physician relationships and public expectations regarding the roles of healthcare providers and the state.[56] Although Rothman's work focuses on the United States, much the same could be said about the Canadian context, particularly if one

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[52] There is a large body of literature addressing medical tourism and its drivers and implications, including for patients, healthcare providers, and healthcare systems. See e.g. I. Glenn Cohen, *Patients with Passports*; *Medical Tourism, Law, and Ethics* (New York: Oxford University Press, 2016); see also Neil Lunt et al, "Medical Tourism: Treatments, Markets and Health System Implications: A scoping review" (last visited 23 May 2022), online (pdf): *OECD Directorate for Employment, Labour and Social Affairs* <www.oecd.org/els/health-systems/48723982.pdf>.; see also Valorie A. Crooks et al, "What is known about the patient's experience of medical tourism? A scoping review" (2010) 10 BMC Health Services 266; see also Jeremy Snyder et al, "'Do your homework … and then hope for the best': the challenges that medical tourism poses to Canadian family physicians' support of patients' informed decision-making" (2013) BMC Med Ethics doi: 10.1186/1472-6939-14-37.

[53] This approach differs from traditional care access routes in Canada's publicly funded healthcare systems, where family physicians or other primary care providers act as gatekeepers and access to specialists is generally only available by referral.

[54] As will be discussed in Chapter 6, *below*, there were strong autonomy-based undertones driving patients' demands for access to liberation therapy. See S. Michele Driedger et al, "Caught in a no-win situation: discussions about CCSVI between persons with multiple sclerosis and their neurologists – a qualitative study" (2017) 17: 176 BMC Neurology DOI 10.1186/s12883-017-0954-7 at 3. Driedger et al. reflected on the normative rights framing of access demands for this intervention; see also Tamra Lysaght, Bernadette Ricards & Anantharaman Muralidharan, "Exploring the boundaries of autonomy and the 'right' to access innovative stem cell therapies" (2017) 9 Asian Bioethics Rev 45.

[55] Jennifer Piel, "Informed Consent in Right-to-Try Cases" (2016) 44 J American Academy Psychiatry & L 290 at 293.

[56] David J. Rothman, "The Origins and Consequences of Patient Autonomy: A 25-Year Retrospective" (2001) 9 Health Care Analysis 255.

broadens the scope beyond pharmaceutical advertising to include other forms of medical interventions, including unproven medical interventions. Autonomy is a nuanced concept and the subject of rich bodies of literature from varied disciplines. In this section, I will briefly discuss the role of autonomy as it commonly features in the context of access demands for unproven medical interventions, with a focus on implications for their regulation and governance in Canada.

The concept of autonomy is ubiquitous in health law, bioethics, and medical ethics literature, as well as in clinical practice and research guidance. For example, autonomy is described as a principal cornerstone of clinical ethics,[57] and together with nonmaleficence, beneficence, and justice, is one of four key principles identified by Beauchamp and Childress in their seminal work on biomedical ethics.[58] Autonomy is often (though not universally or uncritically[59]) credited as underlying legal and ethical requirements for consent, which is a central element of the provision of healthcare in Canada.[60] Conceptualized as being part of respect for persons, respect for autonomy is also embedded in leading ethical guidance for both clinical practice and research in Canada including, respectively, the Canadian Medical Association's *Code of Ethics and Professionalism* and the *Tri-Council Policy Statement*, both of which are discussed in Chapter 4.[61] In addition, autonomy features prominently in Canadian jurisprudence regarding rights-based access claims to health-related interventions, where it has been framed as part of liberty and security of the person which are protected by s. 7 of the *Canadian Charter of Rights and Freedoms* (see Section 4.2.4).[62] Respect for autonomy is further found in professional regulatory guidance (see Section 4.3.1) such as, for example, the general expectations for conduct set out by the College of Physicians and Surgeons of Ontario.[63]

Despite the prominence of autonomy in these various contexts that underpin the regulation and governance of access to unproven medical interventions in Canada, there is no

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[57] Robert Wheeler, Paul Spargo & Anneke Lucassen, "The shifting sands of patient autonomy and public interest considerations in health care" (2011) 6 Clinical Ethics 203 at 203.
[58] Beauchamp & Childress, *supra* note 26 at 13.
[59] There are also many who critique consent as a vehicle for ensuring respect for autonomy. See e.g. Sheila McLean, *Autonomy, Consent and the Law* (New York: Routledge-Cavendish, 2010); see also Natalie Stoljar, "Informed Consent and Relational Conceptions of Autonomy" (2011) 36 J Medicine & Philosophy 375 at 375-376; see also James Stacey Taylor, "Autonomy and Informed Consent: A Much Misunderstood Relationship" (2004) 38 J Value Inquiry 383 at 389. Taylor looks to different values, such as concern for human well-being, as providing a more robust foundation for informed consent. See also Susan Dodds, "Choice and Control in Feminist Bioethics", in Catriona Mackenzie & Natalie Stoljar, eds, *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (Oxford: Oxford University Press, 2000) 213 at 216. Dodds is critical of limited conceptions of autonomy that are overly individualistic and focus on respecting "certain kind[s]" of choices; she argues in favour of approaches where respecting autonomy involves more than informed consent.
[60] Beauchamp & Childress, *supra* note 26 at 121-122; see also Wheeler, Spargo & Lucassen, *supra* note 57 at 203; see also Mary Donnelly, *Healthcare Decision-Making and the Law: Autonomy, Capacity and the Limits of Liberalism* (Cambridge: Cambridge University Press, 2010) at 52. As discussed in Chapter 4, *below*, healthcare provided without consent or without informed consent risks liability in battery or negligence, respectively.
[61] Canadian Medical Association, "CMA Code of Ethics and Professionalism" (2018), online (pdf): <policybase.cma.ca/documents/policypdf/PD19-03.pdf> at 2; TCPS2, *supra* note 28.
[62] Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11 [the *Charter*]; see *Carter*, *supra* note 40 at para 64; see also *Morgentaler*, *supra* note 40 at 587-588.
[63] College of Physicians and Surgeons of Ontario, "Policy on Complementary and Alternative Medicine" (last modified November 2011), online: <cpso.on.ca/Physicians/Policies-Guidance/Policies/Complementary-Alternative-Medicine>.

one definition or understanding of autonomy or of respect for autonomy that commands broad consensus, or that provides determinative guidance in these complex situations. To the contrary, there are multiple interpretations and conceptions flowing from different disciplines and varied perspectives, many of which are subject to criticism of one form or another. The purpose of this brief discussion is not to attempt to resolve long-standing debates about the meaning of autonomy or its implications for practice, nor does this thesis promote one conception of autonomy as superior to others. It is taken as a given that thinking on this issue is likely to continue to evolve over time. The goals here are merely to first, explicitly acknowledge the emphasis on autonomy that permeates many access claims for unproven medical interventions, second, discuss how autonomy tends to be characterized or approached in these contexts, and third, draw connections with how autonomy features in key elements of regulation and governance of access to unproven medical interventions.

Autonomy-based arguments that are used to support claims for access to unproven medical interventions often fall within what might be considered classic liberal conceptions of autonomy, which focus largely on self-sovereignty and non-interference.[64] Dworkin, a leading theorist on the subject of autonomy, referred to autonomy as the right of competent adults "to make important decisions defining their own lives",[65] and emphasized the importance of individuals being able to direct their lives according to their own values.[66] In their work on biomedical ethics, Beauchamp and Childress suggest that "personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice".[67] McLean similarly describes autonomy in contemporary bioethics as fundamentally being about self-determination and "freedom from external control".[68]

Conceptions of autonomy that focus on self-sovereignty and non-interference in decision-making are not without their critics. For example, some scholars argue that classic liberal views of autonomy are limited in their focus on the individual and do not adequately account for the impact of social context on decision-making.[69] Relational approaches are an alternative to classic liberal constructions of autonomy and take a more expansive approach to conceptualizing important features of decision-making in health-related contexts. Although there are varied perspectives under the relational autonomy "umbrella", in general relational approaches reject individually-focused conceptions of autonomy and instead emphasize the role of social

[64] These approaches are often traced to the work of John Stuart Mill, who argued that individuals must be sovereign over themselves. See John Stuart Mill, *On Liberty*, 2nd ed (London: Parker, 1859).
[65] Ronald Dworkin, "Life Past Reason" originally in Ronald Dworkin, *Life's Dominion: An Argument about Abortion, Euthanasia, and Individual Freedom* (New York: Knopf, 1993); here in Helga Kuhse et al, eds, *Bioethics: An Anthology* (John Wiley & Sons, Incorporated, ProQuest Ebook Central, 2015) ch. 35, at 335.
[66] Ronald Dworkin, "Autonomy and the Demented Self" (1986) 64:Supp 2 Millbank Q 4; see also *Ibid*.
[67] Beauchamp & Childress, *supra* note 26 at 101. Beauchamp & Childress identify liberty and agency as two essential conditions for autonomy, while noting that there can be different degrees of autonomy, depending on the amount of liberty and agency that an individual can claim.
[68] McLean, *supra* note 59 at 30.
[69] See e.g. Donnelly, *supra* note 60 at 33. See also Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002) at 37. O'Neill similarly critiques interpretations of autonomy that essentially limit it to informed consent and proposes instead a version of principled autonomy, drawn from the work of Immanuel Kant, whereby autonomy is framed in terms of obligations rather than rights and means acting in accordance with "principles that are fit to be laws for all".

connections, norms, and institutions in relation to both developing and exercising autonomy.[70] These broader conceptions of autonomy are important and offer considerable appeal in various areas of healthcare practice and policy[71]. However, the approaches to respect for autonomy that are reflected in key institutional features of regulation and governance relevant to unproven medical interventions, including professional regulation, research ethics, and jurisprudence (see Chapter 4), are generally more narrowly focused on the individual and their decision-making.

For example, the College of Physicians and Surgeons of Ontario states that members are to "Respect Patient Autonomy", explaining that: "Patients are entitled to make treatment decisions and to set health care goals that accord with their own wishes, values and beliefs. This includes decisions to pursue or to refuse treatment".[72] The *Tri-Council Policy Statement* defines autonomy as including "the ability to deliberate about a decision and to act based on that deliberation. Respecting autonomy means giving due deference to a person's judgment and ensuring that the person is free to choose without interference".[73] In *Blencoe v. British Columbia (Human Rights Commission)*[74], the Supreme Court of Canada (SCC) emphasized that the liberty interests protected by s. 7 of the *Charter* extend beyond criminal law contexts and protect individual autonomy which, according to the court, "[i]n our free and democratic society … [entitles individuals] to make decisions of fundamental importance free from state interference".[75] In *Carter v. Canada (Attorney General)*[76], the SCC confirmed that the personal autonomy encompassed by security of the person is "engaged by state interference with an individual's physical or psychological integrity, including any state action that causes physical or serious psychological suffering".[77]

Notwithstanding the latitude that these approaches to autonomy appear to provide to individual patients in their healthcare-related decisions, it is nonetheless important to stress that in Canada's current health law and policy context, respect for autonomy has not traditionally meant unfettered access to any medical intervention that an individual wishes to pursue.[78]

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[70] Catriona Mackenzie & Natalie Stoljar, eds, *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (Oxford: Oxford University Press, 2000) at 4. See e.g. Françoise Baylis, Nuala Kenny & Susan Sherwin, "A Relational Account of Public Health Ethics" (2008) 1:3 Public Health Ethics 196 at 202. See also Jennifer Nedelsky, *Law's Relations: A Relational Theory of Self, Autonomy and Law* (Oxford: Oxford University Press, 2013); see also Edward Dove et al, "Beyond individualism: Is there a place for relational autonomy in clinical practice and research?" (2017) 12:3 Clinical Ethics 150; see also Stoljar, *supra* note 59.

[71] See e.g. Jocelyn Downie & Jennifer Llewellyn, "Relational Theory & Health Law and Policy" (2008) Special Ed Health LJ 193. Downie and Llewellyn explore some implications of a relational conception of autonomy for consent to treatment.

[72] College of Physicians and Surgeons of Ontario, *supra* note 63.

[73] TCPS2, *supra* note X at B, 1.1, p. 6.

[74] *Blencoe v. British Columbia (Human Rights Commission)*, 2000 SCC 44.

[75] *Ibid* at 310.

[76] 2015 SCC 5.

[77] *Carter*, *supra* note 40 at para 64. In this same paragraph, the SCC also noted that concerns regarding protection of autonomy and dignity underpin rights to both liberty and security of the person.

[78] Chapter 4, *below*, includes a discussion of "positive" rights-based access claims under the *Charter*. See also Ubaka Ogbogu & Russell Brown, "Against Doctors' Orders: The Force and Limits of Personal Autonomy in the Health Care Setting" (2007) 15 Health LJ 515 at para 21. Ogbogu and Brown suggest that while patients' autonomy permits refusal of medically necessary treatment, it does not entitle them to demand treatment that is outside the standard of care. See also McLean, *supra* note 59 at 32. McLean suggests that 'rights' entitle patients to demand respect and facilitate legitimate claims but not absolute entitlement (she provides the example of scarce medical resources) or inappropriate demands. See also Brett & McCullough, *supra* note 47. Brett and McCullough argue that

Alongside their emphasis on autonomy, the frameworks and institutional contexts noted above also reflect other priorities that may justify limiting or restricting access to a medical intervention.[79] For example, government regulators such as Health Canada frequently limit or restrict access to medical interventions such as drugs and medical devices because their risk outweighs their benefit, or they lack sufficient evidence of safety or efficacy.[80] Regulatory and governance decisions that limit individual autonomy with the aim of benefiting or protecting the person are sometimes criticized for being paternalistic.[81]

Paternalism can be defined as: "the intentional overriding of one person's preferences or actions by another person, where the person who overrides justifies this action by appeal to the goal of benefiting or of preventing or mitigating harm to the person whose preferences or actions are overridden".[82] There are many examples of paternalistic policies related to health that while perhaps not universally supported, are largely accepted. Food safety regulations and mandatory seat belt and motorcycle helmet laws are just two examples.[83] Whether and to what degree paternalism can be justified in health policy, including regulation and governance of access to medical interventions, is a question that has spurred considerable debate.[84] Within this debate, there is a body of literature that focuses on the importance of balancing different priorities, including state goals and individuals' autonomy interests, and on considering the degree of intrusiveness on the latter.[85] In the following section, I will present an overview of some of the concerns about unproven medical interventions that are used to justify limiting or restricting access to them, whether for the good of individual patients or the public more broadly.

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patient autonomy does not mean an unqualified right to choose one's course of treatment. Rather, their view of autonomy incorporates the ability to understand and apply relevant information. See also Candace Gauthier, "The Virtue of Moral Responsibility in Healthcare Decisionmaking" (2002) 11 Cambridge Q Healthcare Ethics 273 at 278. Gauthier suggests that patients have a moral responsibility "not to request or demand inappropriate medical interventions" (at 279).

[79] See e.g. Richard Huxtable, "Autonomy, best interests and the public interest: treatment, non-treatment and the values of medical law" (2014) 22:4 Med L Rev 459. Matters of public health are another area where tensions between individual autonomy and the public interest or common good often come to the fore of regulation and governance decisions. See e.g. Lawrence O. Gostin, *Public Health Law; Power, Duty, Restraint* (California: University of California Press, 2008) at 33.

[80] See Chapter 4, Section 4.2.2, *below*, for discussion of Health Canada's role with respect to regulation and governance of access to unproven medical interventions.

[81] James Wilson, "Why it's time to stop worrying about paternalism in health policy" (2011) 4 Public Health Ethics 269 at 270.

[82] Beauchamp & Childress, *supra* note 26 at 215.

[83] See Nola Ries, "Legal Foundations of Public Health in Canada" in Nola Ries, Tracey Bailey & Timothy Caulfield, eds, *Public Health Law and Policy in Canada*, 3rd ed (Markham, ON: LexisNexis, 2013) 7 at 24.

[84] Similar questions have been debated in the context of research ethics requirements. See e.g. Lynn Jansen & Steven Wall, "Paternalism and Fairness in Clinical Research" (2009) 23:3 Bioethics 172. Jansen and Wall defend what could be considered paternalistic restrictions on particulation in clinical research on the grounds of fairness.

[85] See e.g. Beauchamp & Childress, *supra* note 26 at 221-222, 237; see also Wilson, *supra* note 81 at 276; see also Kai Möller, "Two Conceptions of Positive Liberty: Towards an Autonomy-based Theory of Constitutional Rights" (2009) 29:4 Oxford J Leg Stud 757 at 786. As will be discussed in Chapter 4, *below*, an emphasis on balance in this context echoes the approach taken by courts when responding to rights-based claims for access to medical interventions.

1.4.2 Concerns and evolving questions

Individuals commonly seek access to unproven medical interventions in the hope that they will provide them with some form of benefit. As Lysaght et al. observe, advocacy in favour of access to unproven (or innovative, in their framing) medical interventions often reflects the assumption that these interventions are "'new', and thus 'better' than existing treatment options".[86] However, the provision of unproven medical interventions raises several potential concerns, not the least of which is that patients may be harmed by unsafe interventions. Although healthcare is inherently risky, one of the issues with unproven medical interventions is that patients may face risks that have not been appropriately identified, weighed against potential benefits, and mitigated as much as possible. There are also potential opportunity cost-related concerns if patients forgo established treatments in favour of unproven interventions and experience reduced quality or duration of life as a result.[87] In the related context of first-in-human trials, Dresser notes the concern that seriously ill patients may be particularly susceptible to misleading or unduly positive messages about the treatment as well as media hype, which can fuel unrealistic expectations of benefit.[88] The same may be true outside the research context, in private market offerings of unproven medical interventions.

There are also public interest considerations engaged by the provision of unproven medical interventions. For example, public healthcare systems may bear the financial cost of providing follow-up care and addressing harms that follow unproven medical interventions.[89] There are also concerns that adverse events resulting from unproven medical interventions, or frustration regarding the ineffectiveness of an unproven medical intervention, may threaten the progress of research and legitimate clinical innovation by undermining public trust in these enterprises.[90] The attendant worry is that loss of public trust and support for research may damage or limit the long-term prospects of promising fields of medical innovation, to the detriment of the public and future patients who might otherwise benefit from eventual treatment advances. At the same time, unproven medical interventions can provide a sense of much-needed hope to individuals who may view their standard of care options as limited, unacceptable, or non-existent.[91] The rhetoric of hope can be a powerful and persuasive motivator on various levels, including informing policy decisions. Its influence can be seen through the internet and online tools such as social media, which now also function as advocacy vehicles for patients and

[86] Lysaght, Ricards & Muralidharan, *supra* note 54 at 51.
[87] *Ibid* at 50.
[88] Rebecca Dresser, "First-in-Human Trials Participants: Not a Vulnerable Population, but Vulnerable Nonetheless" (2009) J L Med & Ethics 38 at 46. For an example of physical harms caused by unproven stem cell-based interventions, see e.g. Gerhard Bauer, Magdi Elsallab & Mohamed Abou-El-Enein, "Concise Review: A Comprehensive Analysis of Reported Adverse Events in Patients Receiving Unproven Stem Cell-Based Interventions" (2018) 7:9 Stem Cells Translational Medicine 676.
[89] Similar concerns have been identified in relation to medical tourism more generally. See e.g. David Kim et al, "Financial costs and patients' perceptions of medical tourism in bariatric surgery" (2016) 59:1 Canadian J Surgery 59.
[90] James Wilson, "A History Lesson For Stem Cells" (2009) 324:5928 Science 727.
[91] For an analysis using the concept of a 'political economy of hope' see Alan Peterson et al, *Stem Cell Tourism and the Political Economy of Hope* (UK: Palgrave MacMillan, 2017).

supporters to exert pressure on decision-makers, for example when seeking funding or approval for particular medical interventions.[92]

Given the pervasiveness of the internet and the degree to which patients use it to access health information and as a vehicle to organize and advocate, it seems likely that patient demands for access to medical interventions, both within and outside the standard of care, will continue to grow. As noted above, these demands can have significant implications for the individual patients involved, their healthcare providers, healthcare systems, and society-at-large. Accordingly, the complex issues associated with domestic access to unproven medical interventions outside of Canada's publicly administered healthcare systems warrant in-depth study. In the following section, I will briefly identify some of the key tensions and questions that underpin this research and will introduce the theoretical frameworks and boundaries that helped shape my analysis.

1.5 Framing my approach to this thesis - regulation, governance, and the role of law

As is clear from the preceding discussion, access to unproven medical interventions in Canada raises important questions about oversight of medical interventions and about the balancing of different rights and interests. Demands for access to unproven medical interventions also engage debates about the appropriate role of regulation and about what kind of evidence of safety and efficacy should be required before access is permitted or perhaps even facilitated (e.g. through funding). There are varied perspectives about the meaning of evidence in the context of biomedical research, and cultural and historical factors, among other influences, can play a role.[93] Debates about how to manage unproven medical interventions also highlight challenges associated with balancing the different interests of key stakeholders including the state, patients and their families, medical professionals, providers, and industry. Further, considerations relating to implications for healthcare systems, including the costs of follow-up care, are particularly pressing from a public policy perspective in healthcare systems, like Canada's, that are primarily publicly funded.[94] Finally, decisions about whether and how to control access to unproven medical interventions also prompt policy questions about how to balance potentially competing priorities, such as the desire to encourage innovation while avoiding unacceptable risks.

Addressing these challenges and responding to the diverse interests engaged by questions of access to unproven medical interventions requires effective oversight. Regulation and governance provide a useful lens through which to understand how society responds to emerging issues in varied contexts, including new and unproven medical interventions. Using these concepts to ground my analysis facilitated a critical look at how the state and other actors

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[92] See e.g. Roger Chafe et al, "The rise of people power: calls in Canada for trials of a contentious treatment for multiple sclerosis illustrate how social media can affect research priorities" (2011) 472:7344 Nature 410; see also Arthur Caplan & Kenneth Moth, "Rescue Me: The Challenge of Compassionate Use in the Social Media Era" (2014) Health Affairs 10.1377/hblog20140827.041027; see also Fadhila Mazanderani, Braden O'Neil & John Powell, "'People power' or 'pester power'? YouTube as a forum for the generation of evidence and patient advocacy" (2013) 93 Public Education & Counselling 420.

[93] See e.g. Margaret Sleeboom-Faulkner et al, "Comparing national home-keeping and the regulation of translational stem cell applications: An international perspective" (2016) 153 Soc Science & Med 240.

[94] Rory Johnston et al, "Canadian family doctors' roles and responsibilities toward outbound medical tourists" (2013) 59:12 Canadian Family Physician 1314. For insight into costs of follow-up care related to one particular form of medical tourism, see Caroline Sheppard et al, "The cost of bariatric medical tourism on the Canadian healthcare system" (2014) 207 American J Surgery 743.

approach and address different elements of access to unproven medical interventions, including availability of information, products, services, providers, and funding. As will be discussed in Chapter 2, regulation and governance are theoretical frameworks with rich bodies of scholarship, but there is room in these fields for work that explores their relationship to one another and their collective strengths (and limitations) in supporting applied analyses of real-world phenomena. Providing insight on these issues is a theoretical contribution I hope to make with this research.

Regulation and governance frameworks can also enable normative analyses which are an important element of identifying potential lessons or principles that can be used to strengthen future oversight strategies. During my data collection, I located a recommendation from the CIHR Scientific Expert Working Group on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency that "a case study be conducted to discuss the lessons learned, and determine strategies to address similar unproven medical procedures or health research issues that may arise in the future".[95] My research answers this call, and is supported by its underlying premise, including the need to be better prepared to respond to similar issues around new unproven medical interventions that will likely emerge over time. This research project is also particularly timely in the current context of the federal government's regulatory modernization agenda, which is rooted in a recognition that Health Canada's regulatory environment must respond to new and emerging medicine, technologies, and globalization, among other forces.[96] Ideally, the work undertaken in this thesis may serve to inform these and future regulatory updates.

Research on legal and policy issues associated with the regulation and governance of unproven medical interventions in Canada is relatively limited in scope and yet the Canadian context is unique and warrants focused attention. Our current regulatory frameworks, constitutional division of powers, the structure of our publicly funded healthcare systems, the nature of medical self-regulation, and the role of the *Charter* all present both potential opportunities and constraints over regulatory and governance options in Canada. There is also a range of state and non-state actors (e.g. the Canadian Medical Association, the colleges of physicians and surgeons, and patient advocacy groups, among others) whose influence in this

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[95] Canadian Institutes of Health Research, "Highlights from the March 7, 2017 CIHR Scientific Expert Working Group on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency Meeting" (30 March 2017), online: *Government of Canada* <cihr-irsc.gc.ca/e/50159.html>. This is one of several instances where the value of exploring the liberation therapy phenomenon in Canada to understand the influence of different forces including social media and pressure on decision-makers, with the goal of strengthening responses (by health systems, decision-makers, and others) in future has been identified. See also Jeremy Snyder et al, "'I knew what was going to happen if I did nothing and so I was going to do something': Faith, hope, and trust in the decisions of Canadians with multiple sclerosis to seek unproven interventions abroad" (2014) 14:445 BMC Health Services Research http://www.biomedcentral.com/1472-6963/14/445 at 9; Ari Green, Hooman Kamel & Andrew Josephson, "Combating the Spread of Ineffective Medical Procedures A Lesson Learned From Multiple Sclerosis" (2018) 75:2 J American Medical Assoc Neurology 15 at 17; S. Michelle Driedger, Ebenezer Dassah & Ruth Ann Marrie, "Contesting Medical Miracles: A Collective Action Framing Analysis of CCSVI and Venous Angioplasty ("Liberation Therapy") for People With Multiple Sclerosis in News and Social Media" (2018) 40:4 Science Communication 469 at 492; Judy Illes, Anthony Traboulsee & Shelly Benjaminy, "Science and society must collaborate; Civic engagement vitally important", *The Vancouver Sun* (18 March 2017) G.4.

[96] Government of Canada, "Health Products and Food Regulatory Modernization - Health Canada" (6 May 2016), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/strategies-initiatives/health-products-food-regulatory-modernization.html>. Health Canada's Regulatory Roadmap is how it intends to protect the public from the sale and advertising of unsafe products, among other objectives.

space is under-explored.[97] Using a governance lens to identify key actors and explore how they exert influence over access decisions is a critical step in developing strategies for strengthening oversight of unproven medical interventions.

As will be discussed in Chapter 2, some constructions of governance take an expansive view of the relevant scope for analysis, potentially including wide-ranging social, political, and historical considerations. Although these factors and influences are important aspects of the context for this research, it is beyond the scope of this particular project to explore them in detail. Accordingly, for both practical and conceptual reasons, I have used the role of law to help set boundaries for this research. I have focused my analysis primarily on regulatory and governance tools and strategies that use or are empowered by law (e.g. legislation, delegated powers of professional self-regulation), or are potentially constrained by it (e.g. via successful negative rights claims), as opposed to evaluating broader social forces such as cultural norms and practices, or related philosophical debates.[98]

In the Canadian context, law can both empower and limit the exercise of authority while also serving as an instrument or a means for advancing particular objectives (e.g. via enforcement of regulations or pursuing litigation to achieve a particular outcome). Law can be defined in a narrow sense as "authoritative rules backed by coercive force, exercised at the national level by a legitimately constituted (democratic) nation-state, and constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law)".[99] For this project, I adopt a broader definition of law that also encompasses Canada's common law and administrative law traditions, along with our constitutional division of powers. This definition builds on work of scholars who consider the relationship between law and regulation. Brownsword observes that when law is used as a tool to control behaviour it is narrower than regulation, but also notes that law can also be broader than regulation when, for example, considering the role of constitutions; accordingly, he suggests that although law and regulation intersect, "they are not co-extensive".[100] Morgan and Yeung also describe law as having both facilitative and expressive roles; the former describes when law serves as an instrument to shape behaviour, and the latter for the way in which it can serve to institutionalize values.[101] Brownsword et al. propose that a multidisciplinary lens, including legal

[97] There are important questions regarding who regulates what, and how. See e.g. Barbara von Tigerstrom & Emily Harris, "Access to Experimental Treatments: Comparative Analysis of Three Special Access Regimes" (2016) 24 JL & Medicine 119 at 136. In the context of Special Access Regimes, von Tigerstrom and Harris identify and address questions about the roles and responsibilities of different regulatory bodies, including how they relate to oversight and control in this area.

[98] By way of concrete example, there are debates surrounding the *Charter of Rights and Freedoms*, including regarding what it has meant for policy, democracy, and human rights protection in Canada, and what its future should be. See e.g. James Kelly & Christopher Manfredi, eds, *Contested Constitutionalism; Reflections on the Canadian Charter of Rights and Freedoms* (Vancouver: UBC Vancouver Press, 2009). However, for this project I focused on the influence of the *Charter* in its current form, and specifically on its role with respect to rights-based access claims for medical interventions.

[99] Roger Brownsword, Eloise Scotford & Karen Yeung, "Law, Regulation and Technology: The Field, Frame and Focal Questions", in Roger Brownsword, Eloise Scotford & Karen Yeung, eds, *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) at 6.

[100] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 7.

[101] Bronwen Morgan & Karen Yeung, *An Introduction to Law and Regulation* (Cambridge: Cambridge University Press, 2007) at 6.

scholarship and regulatory governance studies (among other disciplines), is required when considering how society should respond to different challenges.[102] They argue that law is particularly important in these interdisciplinary and multidisciplinary efforts because it is the vehicle through which the state exercises its coercive powers and provides the constitutional bedrock for our "democratic pluralistic" society.[103] The conceptual framework I present in Chapter 2 creates space to account for the varied roles that laws plays in relation to regulation and governance of access to unproven medical interventions.

As reflected in the above comments, I have both explanatory and normative goals in this thesis. Using case studies, I explore current and past regulation and governance of access to three select examples of different unproven medical interventions in Canada. One of the goals of this work is to use the resulting insights to identify lessons or principles that could inform and strengthen future oversight strategies should similar issues arise.[104] Regulatory and governance scholarship lends itself well to this combined purpose. Brownsword has suggested that "the technologies of the 21st century, while presenting considerable challenges to regulators, also offer themselves as an opportunity for regulatory innovation".[105] I would build on this proposition by suggesting that this type of regulatory and governance innovation will require enhanced conceptual understanding grounded in real-world contexts, which this research provides.

This thesis is set out as follows:

> ***Chapter 1: Foundations*** – This introductory chapter sets the stage for this research by framing the topic and its core issues, outlining the research questions that guide this work, addressing terminology tensions and key concepts, and explaining how the thesis will unfold.
>
> ***Chapter 2: Theoretical constructs & their implications for this research –*** This chapter provides the theoretical foundation for this research by reviewing core literature on regulation and governance. It explores the connections between these bodies of work and proposes a conception of regulation, governance, and their relationship. It also presents the conceptual framework for this project.
>
> ***Chapter 3: Research Strategy –*** This chapter outlines the case study approach that I used in this research, including data collection strategies, inclusion criteria, and data management, and includes a discussion of how I applied the conceptual framework in my data analysis.

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[102] Brownsword, Scotford & Yeung, *supra* note 99 at 33.
[103] *Ibid*.
[104] John Braithwaite, Cary Coglianese & David Levi-Faur, "Can regulation and governance make a difference?" (2007) 1 Regulation & Governance 1 at 4-5; see also Cameron Holley & Clifford Shearing, "A nodal perspective on governance: Advances in nodal governance thinking" in Peter Drahos, ed, *Regulatory theory: foundations and applications* (Australia: ANU Press, 2017) 163 at 170; Jason Solomon, "New Governance, Preemptive Self-Regulation, and the Blurring of Boundaries in Regulatory Theory and Practice" (2010) 2 Wisconsin L Rev 591 at 593.
[105] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 28.

Chapter 4: Regulatory & governance mapping; key contextual considerations for oversight of access to unproven medical interventions in Canada – This chapter outlines and addresses key contextual considerations for oversight of access to unproven medical interventions in Canada including the constitutional division of powers, the role of the courts, research ethics oversight, and medical self-regulation.

Chapter 5: Case study 1 – chelation therapy – This chapter presents the findings from the case study on chelation therapy. It begins with a narrative account of chelation therapy in Canada, presents the corresponding regulatory and governance analysis, and concludes by addressing key lessons and identifying future priorities.

Chapter 6: Case study 2 – liberation therapy - This chapter presents the findings from the case study on liberation therapy. It begins with a narrative account of liberation therapy in Canada, presents the corresponding regulatory and governance analysis, and concludes by addressing key lessons and identifying future priorities.

Chapter 7: Case study 3 – unproven stem cell interventions - This chapter presents the findings from the case study on unproven stem cell interventions. It begins with a narrative account of unproven stem cell interventions in Canada, presents the corresponding regulatory and governance analysis, and concludes by addressing key lessons and identifying future priorities.

Chapter 8: Lesson drawing & looking forward – This last chapter presents the results of the cross-case synthesis and findings regarding strategies for strengthening future regulation and governance of access to unproven medical interventions in Canada. It includes reflections on the conceptual framework and its utility in supporting this research. This chapter also addresses notable limitations to this research and ends with concluding thoughts regarding future research opportunities.

CHAPTER 2: THEORETICAL CONSTRUCTS & THEIR IMPLICATIONS FOR THIS WORK

2.1 Regulation

2.1.1 Conceptions of regulation

Regulation is a critical construct and part of the theoretical framework for this work. It is also a concept with multiple meanings and interpretations. Later in this chapter I will focus on the approach that will guide my analysis. Before doing so, I will provide an overview of relevant conceptions of regulation found in the literature to situate my own interpretation within the broader field.

Definitions of regulation range from narrow formulations focused on the use of legal instruments, to intermediate descriptions of "deliberate state influence" in different forms, to broad constructions that capture "all forms of social control or influence".[1] Notwithstanding this wide potential range of interpretations, a review of how regulation was conceptualized in highly-cited articles across six disciplines including business, economics, law, political science, public administration, and sociology found that there is at least an abstract level of agreement across social science literatures "that regulation is about intervention in the behavior or activities of individual and/or corporate actors".[2] However, this review also identified varied preferred approaches to other key aspects of regulation including: the role intention plays; the types of interventions (including direct versus indirect) that can be used; the involvement and respective roles of state and non-state actors; the legitimacy of different regulatory targets, and whether regulators and actors need to be distinct from one another.[3] Koop and Lodge draw on the range of approaches found in this social science literature review to present the following, fairly narrow, definition of regulation "as intentional intervention in the activities of a target population, where the intervention is typically direct – involving binding standard-setting, monitoring, and sanctioning – and exercised by public-sector actors on the economic activities of private-sector actors".[4]

Intentionality and purpose are key to many definitions of regulation.[5] For example, regulatory scholar Julia Black defines regulation as "the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour-modification".[6] Braithwaite suggests regulation involves intervening "purposefully in any social world",[7] and Brownsword defines

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[1] Robert Baldwin & Martin Cave, *Understanding Regulation; Theory, Strategy, and Practice* (Oxford: Oxford University Press, 1999) at 2.
[2] Christel Koop & Martin Lodge, "What is regulation? An interdisciplinary concept analysis" (2017) 11 Regulation & Governance 95 at 97.
[3] *Ibid* at 97.
[4] *Ibid* at 105.
[5] *Ibid* at 102. The focus on economic activities is less widely adopted.
[6] Julia Black, "Critical Reflections on Regulation" (2002) 27 Australian J Leg Philosophy 1 at 20 [Black, "Critical Reflections".
[7] Valerie Braithwaite, "Closing the gap between regulation and the community" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 25 at 26.

regulation as "a sustained, focused and organised attempt to steer conduct".[8] Haines similarly characterizes regulation as "a technical, political and social project"[9] that is "'problem-focused' and goal-oriented".[10] Some work on regulation extends the focus beyond these steering types of activities to also capture strategies for monitoring and enforcement.[11] For instance, Scott suggests that an effective regulatory regime requires "a standard-setting element, and monitoring and enforcement" but argues that these elements can be located in more than one organization, whether public or private.[12]

The question of who or what holds regulatory power and responsibility is an important element of any definition of regulation. Much of the scholarship on regulation explicitly or implicitly presents the state as being in a position of central authority when it comes to setting and executing regulatory agendas. For example, Brownsword defines regulators as government agents authorized to exert control in a particular area (e.g. wearing seat belts) and defines regulation as the measures taken by such regulators (e.g. laws, public information campaigns). Although he characterizes this definition of regulation as broad, it is also narrow in that it does not consider activities of non-government actors to be regulation, even if they are influential in exerting control over the area or behaviour at issue.[13] Similarly, the Government of Canada provided the following definition of regulation as part of its Smart Regulation initiative: "Regulation, in its broadest sense, is a principle, rule, or condition that governs the behaviour of citizens and enterprises. Regulation is used by governments, in combination with other instruments, such as voluntary standards and taxation, to achieve public policy objectives".[14] Koop and Lodge's research on published academic literature also found that regulation is widely, though not exclusively, viewed as the responsibility of public-sector entities who have the authority to enforce binding standards.[15] In other words, in many interpretations of regulation, it is the state or an actor empowered by the state such as a regulatory agency, government department or tribunal,[16] that acts intentionally to achieve particular objectives or goals via regulation.[17]

In all but the narrowest constructions of regulation, it is common to find a range of potential mechanisms and approaches that are characterized as regulatory activity. These mechanisms typically include legal instruments as well as policy tools, procedures, and

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[8] Roger Brownsword, "Responsible Regulation: Prudence, Precaution and Stewardship" (2011) 62 N Ir Leg Q 573 at 576 [Brownsword, "Responsible Regulation"].
[9] Fiona Haines, *The paradox of regulation: what regulation can achieve and what it cannot* (Cheltenham, UK: Edward Elgar Pub, 2011) at 2 [Haines, "Paradox"].
[10] *Ibid* at 8.
[11] Baldwin & Cave, *supra* note 1 at 336.
[12] Colin Scott, "Private Regulation of the Public Sector: A Neglected Facet of Contemporary Governance" (2002) 29:1 JL & Soc'y 56 at 60. Scott specifically addresses the roles that private entities can play in monitoring and enforcing standards set by public agencies.
[13] Roger Brownsword, "Code, Control, and Choice: Why East is East and West is West" (2006) 25 LS 1 at 4-5 [Brownsword, "Code"].
[14] Government of Canada. "Smart Regulation; Report on Actions and Plans" (March 2005), online (pdf): <publications.gc.ca/collections/Collection/CP22-80-2005E.pdf> at 4 [Government of Canada, "Smart Regulation"].
[15] Koop & Lodge, *supra* note 2 at 103. Private sector bodies were recognized as regulators in 35% of the articles reviewed by Koop and Lodge.
[16] Baldwin & Cave, *supra* note 1 at 72.
[17] Koop & Lodge, *supra* note 2 at 103.

information-based strategies, among others.[18] One of the most influential approaches to conceptualizing the relationship between these varied regulatory strategies is the concept of responsive regulation, as represented by the regulatory pyramid. The pyramid presents various regulatory options, where the least coercive interventions (e.g. information, persuasion) are located at the lower levels of the pyramid, and increasingly coercive interventions (e.g. criminal sanction) are located at higher levels of the pyramid. The idea underlying the responsive regulation pyramid is that an effective regulator (typically the state, in the early uses of this concept) will take a dynamic approach to regulation, moving up and down the pyramid to increase or decrease the level of coercion used, as needed, depending on how the regulatory targets respond.[19] However, this concept tends to assume that the regulator has the knowledge, capacity and authority to engage in a reflexive and dynamic approach to regulation, which may not always be the case. It also does not necessarily account for the potential influence of other actors in the regulatory environment.

At least partly in response to these critiques, ideas about responsive regulation have evolved over time. For example, Black and Baldwin use the term "really responsive regulation" to describe an approach to regulation that is flexible in that it draws on various regulatory strategies and instruments so as to be responsive or sensitive to factors at play in the given context, including factors related to the regulated (e.g. the "behaviour, attitude and culture of the regulated firm or individual") and to the institutional environment (e.g. instrument interaction, regime performance, responsiveness to change).[20] There are now various types of responsiveness recognized including "networked" or "nodal" responsiveness, which account for the involvement of state and non-state actors as well as "horizontal, softer movements" to accompany the traditional vertical movements in the pyramid.[21] For example, Grabosky has suggested replacing the original responsive regulation pyramid with a 3D pyramid heuristic that incorporates greater complexity including direct and influential involvement of potentially diverse institutional actors.[22] This proposed pyramid still incorporates escalating levels of coerciveness on the vertical front, while also capturing more distributed involvement from state, self-regulatory, and third-party actors on a horizontal scale.[23]

Gunningham and Sinclair use "smart regulation" to describe another approach to regulatory pluralism.[24] Their approach also incorporates a broad range of actors including government and industry, as well as varied policy instruments. Under smart regulation, government is often viewed as the "catalyst or facilitator" that creates the conditions for other actors to carry more of the regulatory burden,[25] rather than being the primary actor in the regulatory enterprise. It should be noted that not all forms of smart regulation place non-state actors in positions of influence. For example, the Government of Canada has used smart

[18] Baldwin & Cave, *supra* note 1 at 336.
[19] John Braithwaite, "Types of responsiveness" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 117 at 117-118.
[20] Julia Black & Robert Baldwin, "Really Responsive Risk-Based Regulation" (2010) 32 Law & Pol'y 181.
[21] Braithwaite, *supra* note 19 at 123.
[22] Peter Grabosky, "Beyond Responsive Regulation: The expanding role of non-state actors in the regulatory process" (2013) 7 Regulation & Governance 114 at 120 [Grabosky, "Beyond Responsive Regulation"].
[23] *Ibid*.
[24] Neil Gunningham & Darren Sinclair, "Smart regulation" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 133.
[25] *Ibid* at 139.

regulation to describe a "whole-of-government" approach that encourages policy coherence and coordination between different departments,[26] but which does not directly account for the influence of non-governmental bodies such as professional associations or industry.

Conceptions of regulation that de-emphasize the role of the state are often referred to as "decentred". The concept of "decentred regulation" is generally used to describe systems that are complex, fragmented, interdependent, and without a clear distinction between public and private actors in terms of control.[27] Julia Black also uses the term "polycentricity" to describe regulation systems that involve "the dispersal and fragmentation of actors in the performance of regulation, including the definition of the problem/goals".[28] These systems typically involve "hybrid" regulatory strategies that combine both state and non-state actors, using multi-faceted and often indirect regulatory strategies.[29] One particularly prominent concept of regulation that is closely related to decentred perspectives is that of "meta-regulation", which recognizes the growing regulatory capacity and influence of non-state actors.[30] Sometimes described as regulation of the regulators, meta-regulation has been described as a "dynamic process-oriented regulatory institution", wherein meta-regulators set expectations for and monitor regulatee's internal compliance systems; it also often includes a significant focus on processes for regulatory learning.[31] The role of meta-regulation is potentially particularly important in situations of regulatory failure on the part of self-regulatory bodies. Grabosky points to several factors that have fueled meta-regulation and prompted the need for a broader approach, going beyond reliance on state authority; these factors include developments in the regulatory activity and potential of non-state actors, the weakening or withdrawal of the state's leadership in regulation, and advancements in digital technology.[32]

The foregoing approaches to conceptualizing what regulation is and how it operates can, in theory, apply across varied contexts. When looking at regulation in relation to health, the roles that patients play is a topic of growing interest. Patients (or "users of health services") could be viewed as regulatory actors in their own right, specifically insofar as they fill the roles of "informed patients, selective consumers, vocal complainants, entitled citizens, active partners and aggrieved litigants".[33] For example, Healy uses the concept of the regulatory pyramid,

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[26] Government of Canada, "Smart Regulation", *supra* note 14 at 7. The Government of Canada attributes the following benefits to its use of Smart Regulation: "better coordination across the federal government and with other jurisdictions to help meet national objectives; integration of social, economic and environmental considerations at all stages of policy and regulation making; improved transparency, efficiency and timeliness of regulatory decision-making processes; use of the best available knowledge, both within Canada and abroad; strengthened planning and priority setting; and enhanced ability to identify, manage and mitigate unintended impacts of regulation."

[27] Black, "Critical Reflections", *supra* note 6 at 3.

[28] Julia Black, "Constructing and contesting legitimacy and accountability in polycentric regulatory regimes" (2008) 2 Regulation & Governance 137 at 139 [Black, "Constructing and contesting"]. Black notes that polycentric and decentered are synonyms in this context, but then uses decentered regulation to focus on the involvement of non-state actors, and polycentric to focus on multiple sites of regulation (e.g. sub-national, national, and transnational).

[29] Black, "Critical Reflections", *supra* note 6 at 6.

[30] Peter Grabosky, "Meta-regulation" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 149 at 155 [Grabosky, "Meta-regulation"].

[31] Sharon Gilad, "It runs in the family: Meta-regulation and its siblings" (2010) 4 Regulation & Governance 485 at 488.

[32] Grabosky, "Meta-regulation", *supra* note 30 at 155.

[33] Judith Healy, "Patients as regulatory actors in their own health care" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 591 at 593.

introduced above, to describe escalating forms of influence on the part of patients. This influence ranges from voluntary forms such as information-seeking and consent practices at the base, to market strategies such as making a public complaint in the middle, to enforcement strategies such as rights-based claims at the top.[34] The roles of patients with respect to regulatory decisions seem likely to be particularly salient in relation to how risks are evaluated and approached.

2.1.2 Regulation, risk, and innovation

Managing, reducing, or controlling risks is often presented as one of the primary functions or purposes of regulation.[35] Brownsword argues that regulators have a responsibility to contain risks to "acceptable" levels.[36] Even the federal government's Strategic Risk Communication Framework identifies risk management as central to government's role as "regulator and a steward of the nation", noting that the rapid pace of scientific and technological development are quickly changing the nature of risk.[37] Risk governance and risk-based regulation are the subject of focused scholarship in their own right.[38] Although there are many nuances and interpretations, at a general level risk governance and risk-based regulation refer to approaches whereby risk is used, in one way or another, to inform decisions about whether and how to regulate.[39] Black and Baldwin suggest that in its ideal form, "risk-based regulation offers an evidence-based means of targeting the use of resources and of prioritising attention to the highest risks in accordance with a transparent, systematic and defensible framework".[40] Ansell and Baur adopt a "problem definition and control" approach to understanding trends in risk governance as being the result of how society defines risk, and how regulatory regimes try to control it.[41]

The varied risks associated with unproven medical interventions are one of the primary justifications supporting calls for oversight. Accordingly, it is worth engaging in a brief discussion of key narratives associated with the regulation of risk, particularly in relation to innovation and new technologies, as unproven medical interventions are often conceptualized – rightly or wrongly – as falling in these categories. Although the focus of this work is not specifically on technology regulation,[42] there is overlap insofar as unproven medical

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[34] *Ibid* at 593.
[35] Baldwin & Cave, *supra* note 1 at 138; see also Fiona Haines, "Regulation and Risk" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 181; see also Haines, "Paradox", *supra* note 9 at 229.
[36] Brownsword, "Responsible Regulation", *supra* note 8 at 573-574.
[37] Health Canada, "Strategic Risk Communications Framework; For Health Canada and the Public Health Agency of Canada" (2006), online (pdf): <www.canada.ca/content/dam/hc-sc/migration/hc-sc/ahc-asc/alt_formats/pacrb-dgapcr/pdf/pubs/ris/ris-comm-eng.pdf>.
[38] For a broad review, see Jeroen van der Heijden, "Risk governance and risk-based regulation; A review of the international academic literature" (June 2019) University of Wellington, Government Regulatory Initiative, State of the Art in Regulatory Governance Research Paper 2019.02, online: < papers.ssrn.com/sol3/papers.cfm?abstract_id=3406998>. See also OECD, "Risk and Regulatory Policy; Improving the Governance of Risk" (2010), online: *OECD Publishing* <doi.org/10.1787/9789264082939-en>.
[39] Terje Aven & Ortwin Renn, *Risk Management and Governance; Concepts, Guidelines and Applications* (Dordrecht: Springer, 2010).
[40] Black & Baldwin, *supra* note 20 at 181.
[41] Christopher Ansell & Patrick Baur, "Explaining Trends in Risk Governance: How Problem Definitions Underpin Risk Regimes" (2018) 9:4 Risk, Hazards & Crisis in Public Policy 397 at 399.
[42] Lyria Bennett Moses, "How to Think about Law, Regulation and Technology: Problems with 'Technology' as a Regulatory Target" (2013) 5:1 L Innovation & Technology 1 [Moses, "How to Think"]. Noting first its definitional

interventions are often (though certainly not always) related to, or viewed as being, new technologies. Perhaps more importantly, unproven medical interventions also embody the uncertainty about both risks and potential benefits that generally accompanies other forms of technological innovation.[43] Technology regulation and regulatory risk scholarship are thus used here for the limited purposes of identifying contextual considerations relevant to regulation of unproven medical interventions. Although assumptions about technology's implications for regulation, and vice versa, should not be made uncritically,[44] this body of work provides helpful insight into factors that may need to be accounted for when moving from theoretical conceptions of regulation to the applied contexts studied here.

Interpretations of the meaning of risk vary considerably and its features can be difficult to pinpoint with precision. It has been suggested that "[t]he notion of risk is like the notion of time or happiness: we all know perfectly well what it is, until we try to explain it to others (or to ourselves, for that matter)".[45] Risk has been defined both qualitatively and quantitatively, using considerations of probability and consequences.[46] For example, the International Risk Governance Council defines risk as:

> uncertainty about and the severity of the consequences of an activity or event with respect to something that humans value. Uncertainty can pertain to the type of consequences, the likelihood of these occurring (often expressed in probabilities), the severity of the consequences or the time or location where and when these consequences may occur. This definition accommodates both desirable (positive) and undesirable (negative) outcomes but most organisations focus on the negative outcomes.[47]

Some scholars including Fiona Haines frame risk by category, including actuarial (i.e. objective assessments of risk of harm), socio-cultural (i.e. impact on belonging, social order, identity), and political (i.e. related to political legitimacy and support), suggesting that reduction of political risk is often the central or primary issue pervading regulatory reform efforts, albeit not necessarily explicitly.[48] One consistent theme in literature that explores risk in relation to health and technology is that that there is a range of individual perspectives about, and reactions to, different types of risk.[49] Brownsword uses the term "prudential pluralism" to describe when

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challenges, Moses suggests that technology regulation "concerns regulation (defined broadly or narrowly) in a technological space, a socio-technical space, or possibly a 'new' technological space. Ultimately, technology regulation operates in practice as legal scholarship's answer to the call of sociologists and philosophers to think about how 'we' can influence the form that socio-technical complexes take" (at 6).

[43] See e.g. Brownsword, "Responsible Regulation", *supra* note 8 at 588.

[44] Moses, "How to Think", *supra* note 42 at 13.

[45] van der Heijden, *supra* note 38 at 3.

[46] Stanley Kaplan & B. John Garrick, "On the Quantitative Definition of Risk" (1981) 1:1 Risk Analysis 11.

[47] International Risk Governance Council, "Introduction to the IRGC Risk Governance Framework" (2017), online: *Lausanne: EPFL International Risk Governance Center* <irgc.org/publications/core-concepts-of-risk-governance/> at 5. The IRGC describes itself as an independent, non-profit foundation, and as a science-based think tank. See International Risk Governance Council, "About IRGC", (2019) online: <irgc.org/about/>.

[48] Haines, "Paradox", *supra* note 9 at 232. Baldwin and Cave make a similar argument in suggesting that choices in regulation are inevitably political. See Baldwin & Cave, *supra* note 1 at 335.

[49] See e.g. Roger Brownsword, Eloise Scotford & Karen Yeung, "Law, Regulation and Technology: The Field, Frame and Focal Questions" in Roger Brownsword, Eloise Scotford & Karen Yeung, eds, *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) 3 at 9. For a discussion of the

individuals hold different views about the acceptability of a particular risk (e.g. perhaps because of different risk thresholds or different priorities), and notes that it presents challenges for regulators.[50] It is reasonable to anticipate that prudential pluralism is particularly likely when considering patients' perceptions of risk in relation to new and unproven medical interventions, given other evidence that points to varied priorities and risk thresholds on the part of patients in different circumstances, such as clinical trials.[51]

Evaluating and responding to risk by way of regulation can be particularly challenging when dealing with new technologies,[52] including some unproven medical interventions, because of the uncertainty, rapid progress, and unpredictability that often surrounds them. These factors can trigger regulatory disconnection including gaps, ambiguities, over or under-inclusiveness, or obsolescence.[53] For example, stem cell research has been described as presenting a "moving target" for regulators, with the rapid pace with which its techniques and anticipated applications has evolved.[54] Moses uses the "pacing problem" to describe law and regulation's struggle to "keep up" with technological developments, including new risks and uncertainties.[55] Similarly, Brownsword, Scotford, and Yeung suggest that technological changes (defined to include products or processes) can generate legal and regulatory disruption by challenging existing forms, frameworks, and capacities.[56] Brownsword also suggests that regulating new technologies can trigger a challenge of regulatory connection, in other words, of ensuring that the regulation continues to fit the technology, remains clear, and achieves the original objectives.[57]

It is also not unusual for innovations and technological changes, perhaps particularly poignantly in the biomedical realm, to be associated with a strong rhetoric of hope and promise. These forces can, among other things, contribute to reflex regulation and its challenges.[58] Reflex

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relationship between risk and legal theory and, more specifically, a discussion about the association between risk and decision-making, see Jenny Steele, *Risks and Legal Theory* (Oxford and Portland Oregon: Hart Publishing, 2004).

[50] Brownsword, "Responsible Regulation", *supra* note 8 at 574.

[51] For e.g. see Brian Kwon et al, "Expectations of Benefit and Tolerance to Risk of Individuals with Spinal Cord Injury Regarding Potential Participation in Clinical Trials" (2012) 29:18 J Neurotrauma 2727.

[52] Brownsword defines new technologies by the speed of their development. See Roger Brownsword, "So What Does the World Need Now? Reflections on Regulating Technologies" in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 23 at 26 [Brownsword, "What Does the World Need"].

[53] Anna Butenko & Pierre Larouche, "Regulation for innovativeness or regulation of innovation?" (2015) 7:1 L Innovation & Technology 52 at 65-69; see also Shawn Harmon, Graeme Laurie & Gill Haddow, "Governing risk, engaging publics and engendering trust: New horizons for law and social science?" (2013) 40:1 Science & Public Policy 1 at 31. Harmon et al. focus on the biosciences, but the governance challenges they identify, including managing risk while coping with uncertainty, ambivalence, and trust issues, are relevant to many areas of innovation and technological change.

[54] Sarah Devaney, *Stem Cell Research and the Collaborative Regulation of Innovation* (London and New York: Routledge, 2014) at 29.

[55] Moses, "How to Think", *supra* note 42 at 7. See also Gary Marchant, Braden Allenby & Joseph Herkert, eds, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight; The Pacing Problem* (New York: Springer, 2011).

[56] Brownsword, Scotford & Yeung, *supra* note 49 at 6-8.

[57] Brownsword, "What Does the World Need", *supra* note 52 at 26.

[58] Nik Brown & Sianm Beynon-Jones, "Reflex regulation: an anatomy of promissory science governance" (2012) 14 Health Risk & Society 223. They draw on a comparative case study analysis of the regulation of xenotransplantation and trans-species embryo research. For a discussion of the concept of hope and its growing prominence in relation to

regulation is a term used to describe a default-type of response to an emerging issue, where habitual responses prevail over more critical and reflexive regulatory approaches. Brown and Beynon-Jones discuss two particularly influential reflexes: first, technocratic reflex, which is when scientific knowledge is privileged in decision-making, even in morally or culturally contested areas; and second, temporal reflex, which describes a disproportionate degree of focus on present and near future opportunities and consequences, rather than taking a longer-term perspective or acknowledging lessons of the past.[59] The latter is particularly relevant for the case study research presented in this thesis, given the goal of learning from previous experiences to inform future practices. By contrast, the use of "reflexive" in regulation and governance scholarship tends to refer to learning-based practices, where the actors involved deliberately assess and adjust their approaches based on past experience, as well as critically evaluate their respective positions.[60] One element of a reflexive approach to regulation and governance that is likely particularly important for new and unproven medical interventions relates to the timing of regulation and governance responses in relation to evolving information or evidence.

New technologies and emerging areas of medicine also often lack sufficient or robust evidence about harms and benefits, which can make regulatory efforts to maximize the benefits of innovation while minimizing its risks a challenging task.[61] These tensions are captured in what is sometimes described in regulatory scholarship as the "Collingridge dilemma". The Collingridge dilemma describes the dilemma regulators have regarding when to intervene and regulate a new technology or innovation. Intervening at early stages of its development, potentially with insufficient information about risks and benefits, can risk premature or unnecessary limitations of promising developments. However, waiting until more evidence of risk or harm is available before intervening creates the risk that the technology may already be entrenched at that point, which can make regulatory changes more difficult or expensive.[62]

Some scholars suggest that these challenges call for new regulatory and governance approaches such as legal foresighting,[63] or experimentalist models.[64] Legal foresighting is defined by Laurie, Harmon, and Arzuaga as "the identification and exploration of possible and desirable future legal or quasi-legal developments aimed at achieving valued social and technological ends".[65] It is an active process that adopts a "law in society" perspective that seeks to challenge assumptions about law's role in relation to "dynamic, complex and uncertain science".[66] Wansley's experimentalist approach envisions a regulatory environment that combines moratoriums on technologies that present emerging risks while also permitting limited

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health and healthcare, see Alan Petersen, *Hope in Health; The Socio-Politics of Optimism* (United Kingdom: Palgrave Macmillan, 2015).

[59] Brown & Beynon-Jones, *supra* note 58 at 224-225.

[60] See Devaney, *supra* note 54 at 67-68.

[61] Butenko & Larouche, *supra* note 53 at 64.

[62] *Ibid* at 70. The Collingridge dilemma is credited to David Collingridge, *The Social Control of Technology* (New York: St. Martin's Press, 1980).

[63] See Graeme Laurie, Shawn HE Harmon & Fabiana Arzuaga, "Foresighting Futures: Law, New Technologies, and the Challenges of Regulating for Uncertainty" (2012) 4:1 L Innovation & Technology 1. The authors propose a matrix method which they suggest can be applied to any new technology. It involves challenging assumptions, identifying possible legal responses, and constructing effective legal options.

[64] Matthew Wansley, "Regulation of Emerging Risks" (2016) 69 Vand L Rev 401.

[65] Laurie, Harmon & Arzuaga, *supra* note 63 at 3.

[66] *Ibid*.

use of the technology under particular regulatory conditions, using a randomized experiment design, so as to capture data about both potential risks and regulatory effectiveness.[67] The most persuasive benefits of an experimentalist approach are that it maximizes opportunities for regulatory learning while "preserving regulatory options".[68] However, the practical utility of either of these approaches remains generally untested on a large scale.

Precautionary approaches are another way regulators respond to situations of uncertainty about risk and evidentiary limitations, particularly in public health contexts.[69] The term "precautionary approach" can be used to describe different kinds of approaches, with the common feature of a proactive or preventative stance to limit, mitigate, or avoid risk in the face of scientific uncertainty regarding potential harms.[70] A recent analysis in the context of COVID-19 response measures provided the following definition:

> As traditionally understood, the precautionary principle is the idea that measures should be taken to protect against a risk even if there is uncertainty over the benefit of the measures or the level of risk; the burden of proof rests on those who argue against the measures. The principle reflects a recognition of the limitations of scientific models to accurately describe complex issues pertaining to environmental harm or health risks, and the need for policy-makers to act notwithstanding those limitations.[71]

Related guidance from the European Commission suggests that restrictive measures imposed under a precautionary approach should be reviewed as scientific evidence evolves.[72] Although there are different versions of the precautionary principle, many share the following key variables: "(i) a degree of scientific uncertainty; (ii) concerning some class, kind, or type of hazard or risk; (iii) where the damage associated with the perceived hazard or risk is of a certain degree or character; (iv) as a result of which some measure of precaution is advocated".[73] Uncertainty about risk is generally seen as a key element of precautionary approaches; where there are known risks, preventative approaches apply.[74] Some claim that precautionary approaches function to lower "the threshold for regulatory action",[75] while others suggest they elevate the evidentiary bar by using scientific uncertainty about risk to ground resistance to regulatory intervention.[76]

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[67] Wansley, *supra* note 64.
[68] *Ibid* at 405.
[69] Kumanan Wilson & Jennifer Keelan. "Risk, Causation and Precaution: Understanding Policy-Making Regarding Public Health Risks" in Tracey Bailey, C. Tess Sheldon & Jacob Shelley, eds, *Public Health Law and Policy in Canada* (Ontario: LexisNexis Canada, 2019) 59.
[70] David Kriebel & Joel Tickner, "Reenergizing Public Health Through Precaution" (2001) 91:9 American J Public Health 1351.
[71] Colleen M. Flood, Bryan Thomas & Kumanan Wilson, "Civil Liberties vs. Public Health" in Colleen Flood et al, eds, *Vulnerable; The Law, Policy, and Ethics of* COVID-*19* (Ontario: University of Ottawa Press, 2020) 249 at 253.
[72] *Ibid* at 254-255.
[73] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 106 [Brownsword, "Technological Revolution"].
[74] Jale Toson, *Risk Regulation in Europe Assessing the Application of the Precautionary Principle* (New York: Springer, 2013) at 39-41.
[75] *Ibid* at 42.
[76] George Taylor, "Understanding risk and regulatory reform" (2018) 39:5 Policy Studies 465 at 467.

Toson identifies four different types or categories of precautionary measures including; "non-preclusion measures, i.e., action that can be taken to control risk-generating activities….safety measures that establish certain cautious limits… prescription of criteria for activities or products, mainly the 'best available technology.' … [and] prohibitory measures, meaning that a presumably risky activity should not be undertaken unless there is no appreciable risk". [77] Precautionary approaches have been widely used in various spheres that are relevant to the topic of this thesis. For example, the Government of Canada developed a specific framework for the use of precaution in "science-based decision-making about risk".[78] Under this framework, there are three tenets underlying the use of precaution in the context of science-based risk management: "the need for a decision, a risk of serious or irreversible harm and a lack of full scientific certainty".[79] The framework also specifies that precautionary measures should be reconsidered as science evolves, that they should be proportional to the risk, non-discriminatory and cost-effective, and that the least restrictive approach should be adopted. Regardless of whether they are specifically identified as such, precautionary approaches are generally intended to be provisional in nature and to serve as guiding principles as opposed to specific directives about the shape regulation should take.

Despite their appeal in many circles, precautionary approaches are not immune from criticism. Common sources of critique include challenges relating to vagueness and ambiguity,[80] as well as to their reliance on "artificial" distinctions between certain and uncertain science regarding particular risks.[81] Beauchamp and Childress suggest that the strongest versions of precautionary principles can "be too abstract to give substantive, practical guidance", and can lead to paralysis, where decision-makers take a narrow view of the risks and fail to consider other risks, including those of inaction, as well as benefits.[82] It has been observed that slowing or halting progress on the basis of a precautionary approach can lead to different risks, including those related to missed opportunities.[83] Sunstein also observes that a strong precautionary approach can fail to provide any direction at all, because in the real world there are often risks associated with any regulatory choice. He distinguishes between the rational use of precaution in risk regulation and the Precautionary Principle as a determinative approach.[84] Wilson and Keelan argue that ultimately, "[a]pproaches that combine components of risk modelling, precaution and evidence-based decision-making are required to adequately address public health challenges pertaining to risk".[85]

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[77] Toson, *supra* note 74 at 43.
[78] Government of Canada, "A Framework for the Application of Precaution in Science-Based Decision Making About Risk" (2003), online (pdf): *National Library of Canada* <publications.gc.ca/collections/Collection/CP22-70-2003E.pdf>.
[79] *Ibid* at 2.
[80] Gregory Kaebnick et al, "Precaution and governance of emerging technologies" (2016) 354:6313 Science 710.
[81] Giandomenico Majone, "What Price Safety? The Precautionary Principle and its Policy Implications" (2002) 40:1 J Common Market Studies 89 at 104. It is worth noting that although Majone emphasizes various flaws of the precautionary principle, he still suggests that it has a legitimate (albeit limited) role in risk management.
[82] Tom Beauchamp & James Childress, *Principles of Biomedical Ethics*, 7th ed (Oxford: Oxford University Press, 2012) at 236.
[83] See e.g. Cass Sunstein, *Laws of Fear* (Cambridge: Cambridge University Press, 2005).
[84] Cass Sunstein, "The Paralyzing Principle" (2002) 25 Regulation 32 at 37.
[85] Wilson & Keelan, *supra* note 69 at 85.

Notwithstanding their close connection, as evidenced from the foregoing discussion, the relationship between regulation and risk is far from straightforward, including with respect to health-related technologies. Fiona Haines uses the term "paradox of regulation" to describe the conflicting imperatives we often see play out in the context of regulation.[86] The paradox of regulation is reflected when governments use regulation to respond to an undesirable situation or event in an effort to prevent its reoccurrence while also, sometimes simultaneously, seeking to limit or reduce regulatory complexity that seeks to control risk.[87] In other words, regulation is viewed as both the solution and the problem.[88] For this research, it is necessary to consider how we evaluate regulation with a view to concrete implications for practice.

2.1.3 Evaluating regulation

There is no discernable consensus regarding the features of "good" regulation. At a basic level, the success of regulation (or regulatory instruments) is sometimes evaluated based on whether the underlying policy goal was achieved.[89] For example, Brownsword defines regulatory effectiveness "in terms of whether, and how well, a regulatory intervention is serving its intended purpose".[90] At a more granular level, there are different conceptions about what good regulation looks like, and how it relates to governance (discussed below).[91] There are nonetheless some broad themes from the literature that provide a useful point of departure. According to Baldwin and Cave, evaluating regulation requires clear benchmarks.[92] They propose five considerations that they suggest are key to that evaluation, notwithstanding their acknowledged limitations. These considerations include legislative mandate, accountability, due process, expertise, and efficiency.[93] Haines suggests good regulation is that which is "clearly targeted, well designed, that draws on the good intentions of the regulated community and that is appropriately enforced".[94] Although a helpful starting point in terms of identifying priorities, Haines' approach requires greater clarity around its core elements including how quality of design is assessed, how intention is evaluated, and what constitutes appropriate enforcement.

Gunningham and Sinclair propose a number of design principles that they suggest should guide approaches to smart regulation.[95] These principles include a preference for complementary instrument mixes (e.g. command and control regulation, economic instruments, self-regulation, voluntarism, information strategies) as opposed to single instrument approaches, while avoiding "smorgasbordism", where many or all available instruments are used regardless of whether a smaller set would be sufficient to achieve the desired outcome.[96] They also prioritize regulatory responsiveness, captured by graduated responses that – unless dealing with high-risk scenarios -

[86] Haines, "Paradox", *supra* note 9 at 2.
[87] *Ibid*.
[88] *Ibid* at 3.
[89] Karen Yeung, "Towards an Understanding of Regulation by Design" in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 79 at 91.
[90] Brownsword, "Technological Revolution", *supra* note 73 at 11.
[91] Haines, "Paradox", *supra* note 9 at 8-9.
[92] Baldwin & Cave, *supra* note 1 at 76.
[93] *Ibid*.
[94] Haines, "Paradox", *supra* note 9 at 20-21.
[95] Gunningham & Sinclair, *supra* note 24 at 133.
[96] *Ibid* at 134, 140.

start with less intrusive approaches, and focus on empowering non-state entities to share the regulatory burden.[97] The benefits of an approach that is incremental, flexible, and cooperative have similarly been identified by scholars writing in the law and technology space, particularly in light of the above-noted challenges that innovation can pose to regulation.[98]

However, even if one accepts that these features are, at least generally speaking, desirable qualities in regulation, how they can be achieved in a practical sense is less clear. They also have potential downsides such as, for example, if flexibility leads to lack of certainty, if incrementalism does not respond quickly enough to contain evolving risks, or if cooperation without sufficient coordination leads to regulatory gaps or inconsistencies. There are also risks that cooperation with stakeholders who may have vested interests, such as industry, will lead to regulatory capture.[99] Regulatory capture can be broadly defined as "the process through which special interests affect state intervention in any of its forms, which can include areas as diverse as the setting of taxes, the choice of foreign or monetary policy, or the legislation affecting R&D".[100] In the context of pharmaceutical regulation, capture has been described as "administrative drift", whereby regulators drift away from their mandates to protect the public interest, towards the commercial interests of industry.[101] The potential for capture is also a central point of criticism of self-regulation, including of healthcare professionals, which is particularly relevant for this research and will be discussed in Chapter 4.[102]

There are a number of tensions inherent in regulatory design, including tensions "between independence and accountability, expertise and detachment, transparency and confidentiality, efficiency and due process, and predictability and flexibility".[103] There are also normative considerations involved in selecting regulatory approaches including the respective nuances of incentive-based strategies (which often, though not necessarily, seek to mobilize economic self-interest) as contrasted against command-and-control instruments.[104] Howse argues that "[t]he normative dimension cannot be captured by any kind of simple contrast between the purported ethical properties of incentive instruments in general, as against those of command-and-control instruments in general".[105] There accordingly seems a strong argument to be made that while good regulation may be characterized by the design features noted above, critical

[97] *Ibid* at 135, 138-139.
[98] Butenko & Larouche, *supra* note 53 at 77.
[99] Barbara von Tigerstrom, "The patient's voice: Patient involvement in medical product regulation" (2016) 16:1-2 Medical L Intl 27 [von Tigerstrom, "The patient's voice"].
[100] Ernesto Dal Bó, "Regulatory Capture: A Review" (2006) 22:2 Oxford Rev Economic Policy 203 at 203.
[101] John Abraham & Rachel Ballinger, "Science, politics, and health in the brave new world of pharmaceutical carcinogenic risk assessment: Technical progress or cycle of regulatory capture?" (2012) 75 Soc Science & Medicine 1433 at 1424. Pharmaceutical regulation is a comparable context to regulation of medical interventions because in both cases regulators generally seek to approve or permit new drugs and approaches while protecting the public from those that are unsafe or ineffective.
[102] See Chapter 4, Section 4.6, *below*, for a more in-depth discussion of this point.
[103] Brownsword, "What Does the World Need", *supra* note 52 at 37. In this discussion, Brownsword cites the foundational ideas of Michael Trebilcock and Edward Iacobucci, "Designing Competition Law Institutions" Cambridge Lectures (for the Canadian Bar), Queen's College, Cambridge, July 2001.
[104] Robert Howse, "Retrenchment, Reform or Revolution? The Shift to Incentives and the Future of the Regulatory State" (1993) 31 Alta L Rev 455.
[105] *Ibid* at 12 [cited to PDF, LexisNexis].

reflection that continually evaluates tensions, trade-offs, and normative considerations will also be an important element of any strong regulatory system.

Questions of timing are also important from a design perspective. As noted above, there are recognized challenges when it comes to the timing of regulatory action in the face of new technologies or emerging risks. The International Risk Governance Centre (IRGC) defines emerging risks as those that are either new risks or familiar risks in new conditions and "which may not be fully understood and assessed".[106] As already discussed, intervening too early with regulation can risk unnecessarily stifling potentially valuable innovation, while intervening too late may allow unacceptable harm to occur and permit entrenchment of the technology, which can make it difficult or even impossible to contain or restrict it later on.[107] Accordingly, appropriateness of the timing of regulatory intervention is likely an element of good regulation. In practice, the success of timing can only be evaluated with the benefit of hindsight and will always involve some degree of speculation, given that one cannot know for certain what would have happened if a different path had been taken in the same circumstances. This limitation does not negate the value of considering the timing of an intervention in evaluating the quality of a regulatory strategy. It simply requires transparent acknowledgment that it functions as a post-hoc mechanism for evaluation.

The role of intention and the extent to which (if at all) the stated goals or purpose of regulation should be factored into an assessment of regulatory strengths or merits is another complex question from both practical and principled perspectives. Practically, explicit regulatory goals may not capture the full story or set of influences on regulatory direction, and it may not always be possible to discern the implicit intention(s) underlying regulation in a particular area. From a principled perspective, there will almost undoubtedly always be varied opinions regarding what constitutes an acceptable or persuasive regulatory intention. For example, there is a body of literature exploring law and technology wherein the role of regulation in relation to innovation is said to "ensure compliance of innovation with fundamental rights, maximize the positive effects and minimize the negative effects."[108] Butenko and Larouche acknowledge the difficulty of doing so when dealing with innovations that are complex, evolving quickly, and where benefits and risks are unpredictable, all of which is true of many medical innovations generally, and unproven medical interventions in particular. Other scholars writing about regulation in the context of health, medicine, and biotechnology have discussed what they call regulatory "desirables" for the regulation of new health technologies.[109] These desirables include hybridity (i.e. mixed models where state and non-state actors are involved in regulation and governance), regulatory certainty and stability, moving beyond risk-based regulation, and participation and information provision (includes a focus on decision-making processes).[110] In reflecting on these desirables, Farrell et al. describe what they call the "messiness" of different value relationships at play, including collective interests and individual rights. Debates about the role of government in balancing individual rights and interests with broader public interest

[106] International Risk Governance Council, *supra* note 47 at 19.
[107] For example, Wansley identifies two types of entrenchment - interest group and social norm, the first of which is often used as a justification for early regulation, while the latter is, in his view, more normatively complex. Wansley, *supra* note 64 at 413.
[108] Butenko & Larouche, *supra* note 53 at 64.
[109] See Anne-Marie Farrell et al, "Regulatory 'desirables' for new health technologies" (2013) 21 Med L Rev 1.
[110] *Ibid* at 4.

considerations in the context of regulation and governance of unproven medical interventions, and the role of rights-based access claims, are relevant to questions of regulatory purpose but may not necessarily be reflected in regulatory activities. Some of these complexities are discussed in Chapter 4 and again in Chapter 8.

The importance of regulatory intention is not universally emphasized in evaluation of regulation. Some scholars focus less on intention and more on other processes underpinning regulatory decision-making. For example, Sunstein focuses on the role of empirical evidence in devising and shaping regulation. He suggests that in order for regulation to be empirically informed, there must be a clearly identified rationale accompanied by analysis of the relevant facts and attendant costs, benefits, and alternatives, all of which should be revised and reviewed with consideration also given to any intended side-effects.[111] Focusing on the existence of a clear rationale or intention that can be evaluated alongside other relevant factors, such as those identified by Sunstein, is a pragmatic approach to integrating intention into an evaluation of regulation.

Enforcement and compliance are other significant and closely linked concepts in the evaluation of regulation, and the subject of rich discussion within the field of regulatory scholarship.[112] Whether and to what degree compliance should be viewed as a marker of effective or "good" regulation remains an open question.[113] Compliance is itself is a concept with varied interpretations. Parker and Nielson present a multi-faceted view of compliance as being "a complex, ambiguous process in which the meaning of regulation is transformed as it is interpreted, implemented and negotiated in everyday life by those to whom it is addressed". [114] They suggest that compliance captures meanings, interpretations, habits, practices and communications.[115] Levels of compliance are likely connected not only to economic considerations but also to other contextual factors such as whether the regulated persons or entities believe the regulator to be exercising legitimate authority.[116]

Accountability and legitimacy are also important but complex and often highly debated concepts in regulatory scholarship. In the context of regulation (and governance) the concept of legitimacy is often used to capture the perception by "both those it seeks to govern and those on

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[111] Cass Sunstein, "Empirically Informed Regulation" (2012) 78 U Chi L Rev 1349 at 1387-1389.

[112] See e.g. Christine Parker & Vibeke Lehmann Nielson, eds, *Explaining Compliance; Business Responses to Regulation* (Cheltenham, UK: Edward Elgar Publishing Ltd, 2011). This edited collection presents a series of empirical papers that explore how regulatory targets respond to efforts to influence (i.e. regulate) their behaviour and, in so doing, highlight the complexities of regulation, implementation, and compliance. See also Neil Gunningham, "Compliance, Enforcement, and Regulatory Excellence" in Cary Coglianese & Jim Ellis, eds, *Achieving Regulatory Excellence* (Washington, DC: Brookings Institution Press, 2017) 188. Gunningham discusses intervention strategies for compliance and enforcement, which, he argues, are "core concerns for any regulator" (at 188).

[113] Although the subject is beyond the scope of this work, the idea of techno-regulation and the West Coast approach, wherein technological design (coding) precludes any option but compliance, is a branch of scholarship that removes the more human-focused considerations of compliance, including individual choice. See Brownsword, "Code", *supra* note 13 at 11-13, 20.

[114] Christine Parker & Vibeke Lehmann Nielsen, "Compliance: 14 Questions" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 217 at 218.

[115] *Ibid*.

[116] Haines, "Paradox", *supra* note 9 at 29.

behalf of whom it purports to govern" that an actor has the "right to govern".[117] It is closely connected to the credibility and acceptability of the actor and, importantly, goes beyond legal validity.[118] According to Black, four types of accountability and legitimacy challenges are particularly salient with respect to decentered or polycentric regulatory regimes.[119] Functional challenges relate to questions of coordination, particularly between actors who may not share a central authority. Systemic challenges involve debates about the role of law and of "soft law" in regulation and governance. Democratic challenges involve questions about who is involved in decision-making, and to whom the decision-makers are held to account. Finally, normative challenges flow from the goals or purposes driving regulatory activity and may relate to different perspectives regarding what is considered "good" in this context.

Having some degree of voice in the regulatory process may serve to enhance perceptions of regulatory legitimacy among regulatory targets.[120] With respect to regulation of medical interventions, whether unproven or otherwise, patients and healthcare providers are important stakeholders. As noted above, the role of patients (and the public more broadly) as actors in the regulatory process is a topic of growing interest. In addition to considering their role(s) regarding behaviour modification and compliance, some approaches to evaluating regulation consider the extent to which different stakeholders, including patients and other members of the public, are given voice in decision-making processes. Patient involvement in regulation of medical products and services, for example, is a complex topic with varying purposes, expectations, and challenges.[121]

Renn argues that different forms of stakeholder involvement can be appropriate and necessary depending on the complexity, uncertainty, and ambiguity of the risks at issue.[122] Brownsword suggests that an "appropriate regulatory response to prudential pluralism" (i.e. different perspectives about acceptable levels of risk) may involve some process of public engagement, though there are challenges associated with managing varied levels of understanding, different groups of the public, diverse stakeholders, and differing degrees of trust.[123] Sunstein similarly proposes that empirically informed regulation will involve, where feasible, opportunities for the public to review and comment on regulatory choices.[124] It has also been argued that an important "theoretical question is whether, in relation to a new technology, a regulatory decision may claim liberal egalitarian credentials that render it worthy of respect and compliance".[125] This consideration connects closely to matters of regulatory processes, including questions of jurisdiction and public mandate.

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[117] Black, "Constructing and contesting", *supra* note 28 at 144.
[118] *Ibid* at 144-145.
[119] *Ibid* at 140-141.
[120] Black frames some regulators' use of public consultation and reporting as a means of enhancing their normative legitimacy. See Black, "Constructing and contesting", *supra* note 28 at 147.
[121] von Tigerstrom, "The patient's voice", *supra* note 99.
[122] Ortwin Renn, "Stakeholder and Public Involvement in Risk Governance" (2015) 6 Intl J Disaster Risk Science 8 at 13.
[123] Brownsword, "Responsible Regulation", *supra* note 8.
[124] Sunstein, *supra* note 111 at 1389.
[125] John McMillan & Jeanne Snelling, "Equality: Old Debates, New Technologies" in Roger Brownsword, Eloise Scotford & Karen Yeung, eds, *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) 69 at 70.

I have drawn on these and the related principles discussed above to devise a strategy to evaluate regulation in this case study analysis. This strategy is presented in the conceptual framework found at the conclusion of this chapter.

2.2 Governance

2.2.1 Conceptions of governance

Like regulation, there is a large body of scholarship addressing governance, its varied interpretations, and diverse implications. Peters describes the body of work on governance as an "explosion of scholarly literature".[126] In addition to its sheer volume, the literature on governance[127] has other parallels with that on regulation, including varied approaches to key concepts and matters of definition. The Institute on Governance defines governance in terms of "who has power, who makes decisions, how other players make their voice heard and how account is rendered".[128] The IRGC defines governance as "the actions, processes, traditions and institutions by which authority is exercised and collective decisions are taken and implemented".[129] Bevir discusses governance as "theory, practice, and dilemma" and suggests that at its "most general level, governance refers to theories and issues of social coordination and the nature of all patterns of rule. More specifically, governance refers to various new theories and practices of governing and the dilemmas to which they give rise".[130] Kooiman adopts a similar definition, suggesting that while "[g]overning can be considered as the totality of interactions in which public as well as private actors participate, aimed at solving social problems…[g]overnance can be seen as the totality of theoretical conceptions on governing".[131]

Governance has been distinguished from power, with the suggestion that power is exercised within a particular system or framework of governance. Fairbairn, Fulton, and Pohler suggest that "[g]overnance is a cognitive construct consisting of rules, norms, behaviours, and practices that assign power".[132] Hurlbert presents the following similar conception of governance:

> Governance entails the interactions among formal and informal institutions, i.e. traditions, norms, rules, processes and structures that determine how people in societies make decisions and share power, exercise responsibility and ensure accountability (Lebel et al. 2006; Raik and Decker 2007; Fabricius and Cundill 2014). Governance refers to political, legal, social, economic and administrative institutions

[126] B. Guy Peters, "Is governance for everybody?" (2014) 33 Policy & Society 301 at 301.
[127] For the purpose of this discussion, the focus in on governance in a general sense. It is nonetheless worth noting the existence of a wide variety of more specific theories of different types of governance including network governance, rational choice, interpretive theory, organization theory, institutional theory, systems theory, and collaborative governance. For more information on these specific forms and interpretations of different theories of governance, see Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011).
[128] Brett Fairbairn, Murray Fulton & Dionne Pohler, "Governance of co-operative federations: Principles and a framework for research" (2015) CIA Research International Conference at 5, citing work from the Institute on Governance (2015).
[129] International Risk Governance Council, *supra* note 47 at 5.
[130] Mark Bevir, "Governance as Theory, Practice and Dilemma" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 1 at 1.
[131] Jan Kooiman, *Governing as Governance* (London: SAGE Publications Ltd, 2003) at 4.
[132] Fairbairn, Fulton & Pohler, *supra* note 128 at 5.

> that develop, manage, and distribute societal goods (such as water) (Rogers and Hall 2003) involving public, private and civil society organizations that practice and implement the norms, programmes, regulations, and laws relevant to this exercise.[133]

McDonald and Williams-Jones suggest that:

> governance involves the use of various forms of power (legal, bureaucratic, financial, rhetorical, etc.) to bring about results either within an organization or in relation to other organizations. Governance is not only about organizational and inter-organizational lines of authority and accountability; it is also about organizational culture and socialization. Hence, governance involves bottom-up as well as top-down considerations.[134]

Although early and more traditional governance scholarship focused on the state and its exercise of powers,[135] newer governance theories are less hierarchical and state-centered in their approach. They account for the greater involvement of a broader range of actors, operating in more complex contexts.[136] For example, descriptions of nodal and networked governance recognize the state as located within "a broader context of other auspices and providers of governance".[137] This shift away from a state-centric perspective to governance can be seen as reflecting a decline in the power of the state or, in a more positive light, as reflecting the state's ability to adapt to changing social realities including greater social complexity. From this perspective, understanding governance involves exploring the boundaries of state authority and the role of third-party actors including the voluntary sector, as well as what governance looks like when the state does not have control in a particular area.[138]

The roles of markets and networks often feature prominently in understandings of more modern conceptions of governance.[139] These types of approaches use governance as a framing concept to explore how a system influences or 'steers' (i.e. rather than directs) conduct, often via relationship-building and coordination among multiple stakeholders, noting that varied actors (state and non-state, including potentially the public),[140] may be involved in this steering or

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[133] Margot Hurlbert, *Adaptive Governance of Disaster; Drought and Flood in Rural Areas* (Switzerland: Springer International Publishing AG, 2018) at 23.
[134] Michael McDonald & Brynn Williams-Jones, "Governance and Stem Cell Research: Towards the Clinic" (2008) 18:2 Health L Rev 27 at para 4.
[135] For example, Fukuyama defines governance "as a government's ability to make and enforce rules, and to deliver services". Francis Fukuyama, "What is Governance?" (2013) 36:3 Governance: Intl J Policy, Administration & Institutions 347 at 350.
[136] Patrick Le Galès, "Policy Instruments and Governance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 142; see also Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) at 3.
[137] Cameron Holley & Clifford Shearing, "A nodal perspective on governance: Advances in nodal governance thinking" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 163 at 165. Nodes may include individuals, organizations, and states (in whole or in part); in short, nodes can be comprised of any formal or informal institution (at 168).
[138] Bevir, *supra* note 130.
[139] *Ibid* at 1.
[140] Lisa Bingham, "Collaborative Governance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 386.

governing.[141] For example, the concept of meta-governance reflects these developing trends in governance scholarship, which are moving from a focus on government (in its narrow conception) and its direct exercise of authority to broader constructions that capture the activities of relatively autonomous stakeholders whose conduct is steered in some way by the state. Informal steering strategies may include use of negotiation, diplomacy, or other tactics.[142] Meta-governance has been described as "the steering of self-steering",[143] and is particularly relevant when considering the relationship between the state and professional self-regulatory bodies.

Collaborative governance is another more recent line of governance scholarship that is particularly useful for this research. Although there are different definitions, Bingham suggests that "[c]ollaborative governance entails shared, negotiated, and deliberative consultation and decision-making".[144] Even where the term "collaborative" is not used, similar conceptions of governance can be employed to capture reciprocal relations of influence between the state and society, rather than one-way models that focus only on how the state acts on or towards society.[145] Models of governance in this category are characterized by their focus on mutual influence, coordination, and interactive processes of decision-making and implementation. Collaborative governance practices present valuable potential to maximize the respective strengths of different governance actors.

As this brief review demonstrates, the concept of governance can be used to explore both the "what" (the institutional features of a system that provide a framework for governing, such as laws), and the "how" (the techniques and strategies different actors use to exercise influence in society).[146] It is important to note that notwithstanding their differences, the leading constructions of governance reviewed here share a fairly contained approach, as opposed to more expansive conceptions that follow what has been described as a "third-wave" or a move to more extreme forms of decentred governance and the "stateless state".[147] The "stateless state" focuses on the ideas, values, and practices of individuals which together construct the social world and the state.[148] This line of work is valuable, particularly insofar as it encourages critical reflection about assumptions regarding the foundations of institutional power and authority and the role of institutional norms. However, the breadth of third-wave style approaches to governance makes them less constructive for this research. Exploring the roles, beliefs, and practices of individual actors and how they relate to governance of unproven medical interventions would be a valuable avenue for subsequent study, but is beyond the scope of this particular project.

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[141] Andrew Gamble, "Economic Governance" in Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) 110 at 110.
[142] Rod Rhodes & Mark Bevir, "The Stateless State" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 203.
[143] Bob Jessop, "Metagovernance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 106 at 106.
[144] Bingham, *supra* note 140 at 388.
[145] Jeff Sellers, "State-Society Relations" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 124.
[146] Gamble, *supra* note 40 at 110-111. Although Gamble's ideas are framed in the context of economic governance, they are relevant to and useful for other fields, including governance of health and science.
[147] Rhodes & Bevir, *supra* note 142.
[148] *Ibid* at 214.

2.2.2 Interpretations of "good" governance

The foregoing section introduced the concept of governance and how it can help deepen our understanding about the roles different actors can play to influence the course of events in a particular sector. However, as with regulation, there is a wide range of ideas regarding what constitutes "good" governance. There is also a body of work that explores different types of governance failures, some of which uses past failures to identify principles for good governance.[149] For example, Jessop suggests that analysis of past governance failures points to three resulting principles that could be interpreted as best practices for metagovernance. These principles include: (i) flexibility in the use of varied strategies and tactics to respond to complex policy contexts and changing risks; (ii) a reflexive orientation that allows for continual assessment of the extent to which the desired outcomes are being achieved, recognizing the potential for "incomplete success", and (iii) a "self-reflexive 'irony'" whereby participants proceed with the work of governance or, as here, metagovernance, even while acknowledging the likelihood of failure.[150] Although framed in the specific context of metagovernance, the value of flexibility and reflexivity resonate in varied governance constructs. They are likely particularly important in contexts characterized by uncertainty and unpredictability, such as is often the case with new forms of biomedicine including unproven medical interventions. Accordingly, for the purpose of this research I accept that the capacity to respond efficiently and effectively to emerging issues or changing information is an important aspect of good governance.

The literature on anticipatory governance is helpful for explaining one way in which this capacity can be exercised. Anticipatory governance describes an approach that addresses a variety of inputs in a proactive manner, to manage emerging technologies while it is still possible to do so.[151] With connections to work in public administration, anticipatory governance is interpreted by some scholars to mean "to govern with vision and foresight". [152] It uses a long-term and self-reflective perspective, and draws on the collective experiences of both lay and expert stakeholders.[153] Engaging in anticipatory governance can involve different strategies including foresighting using scenario development, engagement with lay publics and research leaders, and integration of research and training to build capacity.[154] Without going so far as to suggest a full anticipatory approach is required for good governance, the reflexivity, dialogue, and engagement practices that are embedded with anticipatory governance approaches[155] do offer advantages, particularly with respect to emerging areas of biomedicine.

Using an adaptive governance framework may be another helpful approach to understanding and evaluating the capacity of a governance system to deal with change and uncertainty. Hurlbert and Gupta use the term adaptive governance "as a theoretical framework of

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[149] Jessop, *supra* note 143 at 113.
[150] *Ibid* at 117.
[151] David Guston, "Understanding 'anticipatory governance'" (2014) 44:2 Soc Studies Science 218 at 219. Guston notes that the idea of anticipatory governance has emerged from two different literatures: public administration and management, and environmental studies.
[152] Yann Joly, "Clinical Translation of Stem Cell Therapies - Intellectual Property and Anticipatory Governance" (2010) 7:2 Scripted 265 at 270-271.
[153] *Ibid*.
[154] Guston, *supra* note 151 at 226.
[155] See *Ibid* at 232-234.

governance that best responds to the uncertain, systemic, complex and often contested problem of climate change".[156] Duit and Galaz suggest that a governance system's adaptive capacity results from a trade-off between exploration (i.e. flexibility, experimentation, innovation, etc.), and exploitation (i.e. choice, efficiency, implementation); more broadly, this trade-off is suggested to be rooted in the tension between the need for institutional stability and the demand to respond to change.[157] Adaptive governance is a concept that features most commonly in work on environmental governance.[158] However, because adaptive governance captures flexible approaches that are able to respond to complexity, uncertainty, and contested evidence, as well as those that navigate multifaceted systems with multiple interests,[159] it may prove useful as a way of evaluating efforts to govern new and unproven medical interventions. Although Mandel does not use the term adaptive governance, he nonetheless describes the value of "adaptability and flexibility … for emerging technology governance", particularly in the face of uncertainty regarding the technology and its risks and benefits.[160] Similarly, while she does not use the term "governance", Moses' work on technological neutrality is reminiscent of similar themes to those discussed under the umbrella of adaptive governance. Moses proposes that technological neutrality should be "reconceived as a property of systems of law, rather than as a characteristic of particular statutes"; she argues that administrative agencies, courts, and other entities such as law reform bodies, are crucial to creating legal systems that are able to respond effectively to technological advances.[161]

If we accept that adaptive or responsive capacity is a desirable feature of good governance, the next question is how it can be identified or put into practice. Dietz et al. propose several requirements for adaptive governance in complex systems including: providing information; dealing with conflict; inducing rule compliance; providing infrastructure; being prepared for change; facilitating analytic deliberation; nesting, and institutional variety.[162] While they situate their analysis in relation to the environmental 'commons', the core of their ideas resonates strongly with analogous demands of what could be termed the biotechnical 'commons' (or, in other words, fields of health innovation and medical interventions, both proven and unproven).

Other approaches to evaluating governance focus on assessing the strategies or mechanisms used to steer or influence conduct, such as choice of policy instruments. Policy instruments are not value neutral. They generally involve the exercise of some form of political power and can produce unintended results; thus, looking at which instruments are used in

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[156] Margot Hurlbert & Joyeeta Gupta, "An institutional analysis method for identifying policy instruments facilitating the adaptive governance of drought" (2019) 9 Environmental Science & Policy 221 at 222.
[157] Andreas Duit & Victor Galaz, "Governance and Complexity - Emerging Issues for Governance Theory" (2008) 21:3 Governance: An Intl J Policy, Administration & Institutions 311 at 319-320.
[158] See Brian Chaffin, Hannah Gosnell & Barbara Cosens, "A decade of adaptive governance scholarship: synthesis and future directions" (2014) 19:3 Ecology & Society 56.
[159] Frances Cleaver & Luke Whaley, "Understanding process, power, and meaning in adaptive governance: a critical institutional reading" (2018) 23:2 Ecology & Society 49 at 3.
[160] Gregory Mandel, "Regulating Emerging Technologies" (2009) 1:1 L Innovation & Technology 75 at 89. Mandel focuses here on biotechnologies.
[161] See Lyria Bennett Moses, "Recurring Dilemmas: The Law's Race to Keep Up with Technological Change" (2007) 7 University of Illinois JLTechnology & Policy 239 at 270.
[162] Thomas Dietz, Elinor Ostrom & Paul Stern, "The struggle to govern the commons" (2003) 302:5652 Science 1907.

different circumstances can help inform an understanding and assessment of different modes of governance.[163] For example, Howlett and Rayner provide an approach to characterizing new governance arrangements based on the extent to which their instrument mixes are consistent or inconsistent, and their policy goals are coherent or incoherent. They identify a range of possible outcomes including optimal, ineffective, misdirected, and failed, and suggest that this variety is explained at least in part by the reality that previous policy choices can become institutionalized and operate to constrain new policy development.[164] These authors point to layering (when new goals and instruments are merely added on top of old ones), drift (when policy goals are allowed to change without changing the instruments), and conversion (when policy change is blocked in one area and an attempt is made to change the policy instrument mix in a domain more amenable to updates) as major areas of challenge for optimal integrated design.[165] The role of different types of instruments will be an important consideration in my analysis of past and present governance of unproven medical interventions.

Evaluating the quality of governance approaches can also involve considerations of process, including whether and to what degree different stakeholders have input. Cappe argues that "[g]ood governance requires inclusive, informed, and accountable processes".[166] The quality and availability of the evidence upon which decisions are made is an important aspect of decision-making processes.[167] Another important consideration involves processes of engagement and decision-making independence for stakeholders and other expert voices. A critique of newer, non-state focused approaches to governance is that important decisions made outside the "sphere of representative control" can lack political legitimacy and be exclusionary in different ways, including through defective participatory processes whereby only select perspectives are accounted for.[168] Harmon, Laurie, and Haddow suggest that good governance frameworks are effective, efficient, responsive and proportionate.[169] They place public engagement at the core of governance frameworks that seek to account for uncertainty, including as related to risk, suggesting that appropriate public engagement can enhance the legitimacy of a governance framework and prompt trust in it.[170] Legitimacy may be particularly important for non-state actors when it comes to motivating compliance, particularly if they lack legal mechanisms of enforcement.[171]

The value of or need for public engagement is now a familiar refrain in many decision-making spheres including medicine, science, and public policy more broadly. However, practical

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[163] Le Galès, *supra* note 136 at 157.
[164] Michael Howlett & Jeremy Rayner, "Design Principles for Policy Mixes: Cohesion and Coherence in 'New Governance Arrangements'" (2007) 26:4 Policy & Society 1.
[165] *Ibid* at 8, 13-14.
[166] Mel Cappe, "Good Governance: Institutions, Processes, and People" in Colleen Flood et al, eds, *Vulnerable; The Law, Policy, and Ethics of* COVID-*19* (Ontario: University of Ottawa Press, 2020) 165 at 170.
[167] *Ibid* at 171.
[168] Albert Weale, "New Modes of Governance, Political Accountability and Public Reason" (2011) 46:1 Government & Opposition 58 at 62.
[169] Harmon, Laurie & Haddow, *supra* note 53 at 31.
[170] *Ibid* at 26. The authors use the example of biobanking to situate their analysis. For a more in-depth analysis of the importance of trust in medicine, science and biomedicine, and the role of appropriate regulation in promoting it, see Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002).
[171] This point is made by Julia Black in relation to polycentric regulatory regimes but seems equally applicable to governance actors as defined for the purpose of my research. See Black, "Constructing and contesting", *supra* note 28 at 148-149.

considerations such as how to acknowledge and account for varied publics, and what engagement really means and demands, are often less clear. In view of the varied possible forms of public participation in governance,[172] this lack of specificity risks reducing its potential value and importance in terms of guiding practice. Harmon, Laurie, and Haddow acknowledge some of these challenges and suggest engagement should be "an enduring dialogue between publics and policy-makers".[173] Forms of distributed governance, characterized by varied "non-hierarchical, interlaced state-society interactions" can raise both managerial and democratic or social justice dilemmas.[174] Without going so far as to suggest public engagement is always a necessary criterion for good governance, it nonetheless seems reasonable to suggest that good governance should, to at least some degree, emphasize accountability and mechanisms for addressing concerns related to "ethics, legitimacy, inclusion, and justice" in its engagement and decision-making processes.[175]

2.3 Exploring connections between regulation and governance scholarship

The foregoing sections reviewed key literature on both regulation and governance, largely in isolation from one another. Nonetheless, there are notable points of synergy and ideas in common to both these domains, even though they are typically not explicitly addressed in the relevant scholarship. The apparent overlap between broader conceptions of regulation and how governance is characterized may explain, at least in part, their ambiguous relationship. Extensions of responsive regulation, smart regulation, and some forms of meta-regulation could perhaps also logically be described as governance. By way of example, Solomon uses the term "new governance" in a manner that could be interpreted as a "third-way" form of regulation.[176] Similar to the more modern approaches to governance discussed above, these broader conceptions of regulation also account for the active involvement of non-state actors who exercise agency in terms of establishing and advancing goals or objectives related to oversight of a particular field or activity. They also contemplate the use of a potentially wide range of varied policy instruments which may or may not be rooted in the state's law-making authority. Similarly, although the language varies, questions of legitimacy (including roles, processes, public and stakeholder engagement, and enforcement or compliance) and capacity for responsiveness or adaptability are similarly often emphasized in evaluation of both regulation and governance.

Despite these common elements, much of the literature on these branches of regulation and governance appears to have developed largely in silos. With few exceptions, there is little to no explicit consideration given in the literature to how they relate to one another including

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[172] See e.g. Archon Fung, "Varieties of Participation in Complex Governance" (2006) 66 Public Administration Rev 66. Arnstein's ladder of participation is a widely cited approach to conceptualizing different degrees of public participation, ranging from manipulation to citizen control. See Sherry Arnstein, "A ladder of citizen participation" (1969) 35:4 J American Institute Planners 216 at 217.

[173] Harmon, Laurie & Haddow, *supra* note 53 at 28.

[174] Bevir, *supra* note 130 at 11-12.

[175] *Ibid*. There is a growing body of work exploring when and under what conditions public participation in policy making is important and likely to work. See e.g. Margot Hurlbert & Joyeeta Gupta, "The split ladder of participation: A diagnostic, strategic, and evaluation tool to assess when participation is necessary" (2015) 50 Environmental Science & Policy 100.

[176] Jason M Solomon, "New Governance, Preemptive Self-Regulation, and the Blurring of Boundaries in Regulatory Theory and Practice" (2010) 2 Wisconsin L Rev 591 at 593.

whether they are in fact different concepts, or merely different terminology that capture the same ideas. In some cases, this question is acknowledged but not answered. For example, in her piece exploring *Critical Reflections on Regulation,* Julia Black explicitly leaves the question of "whether or how 'regulation' differs or should differ from governance or management" as an issue to be explored another time.[177]

The distinction between regulation and governance is clearest with the use of narrow conceptions of regulation that focus on the state as the central actor, employing its law-making authority. For example, Laurie, Harmon and Arzuaga differentiate regulation, which they characterize as "a state-driven, vertically-oriented, top-down, command-and-control deployment of formal (hard law) instruments", from governance, which they suggest is more horizontal and "reliant on soft law options such as guidance or professional codes".[178] Similarly, Mandel frames regulation as implying command and control-type rules, and governance as referring to a more flexible, participatory, and responsive management system.[179] He goes on to suggest that governance is a more appropriate construct for emerging areas of biotechnology. Döhler cautions against "conceptual overstretch" with respect to ideas about regulation, and suggests that regulation involves the use of authoritative state action as a tool to change behavior.[180] She also proposes that regulation is but one "part of a complex web of transnational governance in which nation-states, international organizations, and private actors – ranging from multinational firms to non-governmental organizations (NGOs) – participate to set standards and enforce rules to regulate markets, as well as technical or product-related risks".[181] Haines highlights the potential fluidity between the concepts of regulation and governance, and proposes that "[r]egulation is argued to be better conceptualized as governance where control originates from various public and private actors and is given effect not only through law, but also by private agreements, the implementation of non-governmental standards, accreditation schemes and a multitude of other potential control mechanisms".[182]

Although using hard law as a defining element of regulation to differentiate it from governance has some appeal due its clarity, it also has its limitations. More specifically, this type of narrow focus on legal instruments as a defining characteristic of state-led regulatory activity does not adequately capture the breadth of ways in which the state can exert influence without drawing explicitly on its law-making authority. Law is also sometimes ill-suited as a mechanism to address risks and uncertainties, particularly in emerging areas of biomedicine that can offer important benefits such as improved treatment options.[183] Focusing regulatory analyses on the use of hard law alone seems to unnecessarily foreclose consideration of other instruments the state might employ to further its regulatory agenda(s). For example, Howse identifies alternative state-led strategies that do not depend on either market forces (i.e. incentive-based strategies) or

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[177] Black, "Critical Reflections", *supra* note 6 at 29.
[178] Laurie, Harmon & Arzuaga, *supra* note 63 at 14. The term "soft law" is often used to refer to instruments that are not legally binding. For a discussion of the role of soft law as a regulatory tool used by public authorities, see Greg Weeks, *Soft Law and Public Authorities: Remedies and Reform* (United Kingdom: Bloomsbury Publishing, 2016).
[179] Mandel, *supra* note 160 at 78.
[180] Marian Döhler, "Regulation" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 518 at 531.
[181] *Ibid* at 518.
[182] Haines, "Paradox", *supra* note 9 at 8.
[183] Harmon, Laurie & Haddow, *supra* note 53 at 26. Ubaka Ogbogu et al, "Research on Human Embryos and Reproductive Materials: Revisiting Canadian Law and Policy" (2018) 13:3 Healthcare Policy 10.

traditional command-and-control instruments. He points to the role of information, persuasion, and education, as well as to efforts to facilitate voluntary individual action, as examples of ways the state can play a role in social transformation while empowering the governed.[184]

Another way the relationship between governance and regulation has been framed is the suggestion that regulation is about the exercise of power by the state or its delegates (e.g. via hard law, incentives, control of information, etc.), whereas governance is the broader framework within which that power is exercised (e.g. accounting for the roles of the state along with other actors such as community-based organizations, public interest groups, or international bodies).[185] Along a similar vein, regulation has been presented as being a narrow subset of governance, insofar as regulation is "about steering the flow of events and behavior" while governance is more about "providing and distributing".[186] Pahl-Wostl suggests that "[g]overnance embraces the full complexity of regulatory processes and their interaction",[187] which again suggests that governance can be viewed as including but extending beyond regulation. How to frame the boundaries of regulation and governance to maximize their respective conceptual strengths for the purpose of this research is a challenge. It is important to avoid overly narrow constructions that foreclose valuable lines of analysis while also providing sufficient boundaries so that the concepts do not try to simultaneously capture everything and nothing. My proposed strategy for where and how to draw those boundaries is outlined in the next section.

2.4 A proposed conception of regulation, governance, and their relationship

The foregoing discussion admittedly only scratches the surface of regulatory and governance scholarship which, notwithstanding the noted conceptual challenges, have much to contribute to our understanding of how society functions and responds to challenges including those related to managing unproven medical interventions. Importantly, they allow for both explanatory and normative analyses,[188] which are critical for transformative work that seeks to learn from past experiences to improve or strengthen future approaches. For example, Solomon's analysis of how three distinct cases could perhaps have been more effectively addressed if they had drawn on new governance models demonstrates the utility of using regulatory and governance theory to analyze past scenarios with a view to strengthening future strategies.[189] Interpretations of regulation and governance that support these types of efforts are the most useful for my research agenda.

To that end, I adopt an understanding of regulation as an intentional, goal-oriented, state-driven activity, potentially involving varied policy instruments and the participation of non-state actors insofar as they are acting under the state's ultimate authority. This approach can be

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[184] Howse, *supra* note 104.
[185] This conception of the distinction between regulation and governance is drawn in part from the work of Fairbairn, Fulton & Pohler, *supra* note 64.
[186] John Braithwaite, Cary Coglianese & David Levi-Faur, "Can regulation and governance make a difference?" (2007) 1 Regulation & Governance 1 at 3.
[187] Claudia Pahl-Wostl, "A conceptual framework for analysing adaptive capacity and multi-level learning processes in resource governance regimes" (2009) 19 Global Environmental Change 354 at 355.
[188] Braithwaite, Coglianese & Levi-Faur, *supra* note 185 at 4-5; see also Holley & Shearing, *supra* note 136 at 170; Solomon, *supra* note 176 at 593.
[189] Solomon, *supra* note 176. Solomon's three case studies included: (i) data privacy and security; (ii) the marketing and sales of soda to children, and (iii) the regulation of cross-jurisdictional speech by internet service providers.

characterized as a "centred" definition of regulation because it revolves around the state as the central actor.[190] Correspondingly, I view governance as a broader concept that captures how the interactions of multiple actors serve to influence activity in a particular domain, using a wide variety of instruments.

Under this approach, governance may or may not involve agreement about goals or deliberately coordinated activity by these different actors. Although this conception of governance is not state-centric, the state still holds a privileged position because of its unique powers and responsibilities. As described by Hood in his seminal work in public administration literature, government can use its nodality (ability to collect and distribute information), authority (law making power), treasury (spending powers), and organization (direct provision or control) to influence action.[191] My proposed approach also aligns with Hirst, who similarly suggests that the state is best placed to play a coordinating role in distributed governance because of its place as the focus of political identity for citizens, its democratic legitimacy, and its law-making and enforcement powers.[192] It is the state that provides "ground rules for governance and the regulatory order in and through which governance partners can pursue their aims", serves as a "court of appeal" for disputes that arise, and bears ultimate political responsibility for governance failures.[193]

Although the state is important in this understanding of governance, the approach I adopt also recognizes the power and influence of non-state actors in agenda-setting and 'steering'. These non-state actors may (and likely often do) have their own agendas that do not necessarily align with those of the state and, in some cases, may actively resist the state's exercise of authority.[194] This conception of governance could thus be described as a form of metagovernance. With this perspective, regulation (which, as noted, captures a range of activities) falls under the umbrella of governance, as a way the state exerts influence.

This understanding of regulation and governance avoids conceptual overstretch,[195] while still allowing sufficient room to account for complexity. For instance, focusing a regulatory analysis on state-driven efforts can facilitate a more coherent evaluation of the respective contextual merits of different strategies such as command and control, self-regulation, incentives, market-harnessing controls, information-based strategies, direct action, rights and liabilities laws, and public compensation,[196] while also allowing for concrete recommendations that can be made to an identifiable decision-maker. Correspondingly, adopting the governance approach outlined above can facilitate the identification of relevant state and non-state actors with influence in a particular sphere, set boundaries around what kinds of activities are pertinent to an analysis of what occurred or is occurring in a particular case, and give structure to theorizing about what might be done differently or prospectively in future. The "openness" of how governance is

[190] Black, "Critical Reflections", *supra* note 6.
[191] Christopher Hood, *The Tools of Government* (London: Macmillan, 1983); see also Christopher Hood & Helen Margetts, *The Tools of Government in the Digital Age* (New York: Palgrave Macmillan, 2007).
[192] Paul Hirst, "Democracy and Governance" in Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) 13 at 31.
[193] Jessop, *supra* note 143 at 116.
[194] Rhodes and Bevir discuss this potential for struggle and resistance between subordinate actors and the powerful élites in the context of a decentred approach to governance. See Rhodes & Bevir, *supra* note 146.
[195] Döhler, *supra* note 180 at 531.
[196] Baldwin & Cave, *supra* note 1 at 57-58.

conceptualized can be "both a strength and a weakness", insofar as it can be used in many contexts while also being difficult to identify and evaluate in a concrete setting.[197] It is my hope that the approach I have outlined will respond to calls for future governance scholarship to both refine and extend the concept, "so that it is indeed both more precise and more widely applicable".[198]

The proposed conceptions of regulation and governance outlined here may prompt questions about whether it is necessary to draw on both fields, or whether using one or the other would be sufficient to explore the issues at the heart of this research agenda. For example, adopting one of the broader conceptions of regulation outlined above such as, for example, decentred regulation that accounts for the involvement of both state and non-state actors and the use of varied instruments,[199] could perhaps suffice. Another alternative would be to blend the two concepts. For example, Scott uses the term "regulatory governance" to describe an approach wherein the state is one of a number of actors, alongside market and community actors, that play a role in both developing and implementing responses to "key public policy challenges".[200] Similarly, Brownsword, Scotford, and Yeung also use "regulatory governance" to capture decentred approaches to risk management that may be undertaken by states but also by nongovernmental entities (i.e. civil society organizations, industry).[201] Pelly and Saner adopt a similar definition, suggesting regulatory governance is "the process whereby governments, industry and civil society make decisions about how to regulate (or otherwise influence the course of) …[a particular technology], determine whom they involve, and how they render account".[202]

Evaluating the respective merits of different conceptions of regulation and governance is largely subjective. As Rhodes points out, choosing between different definitions of governance and their associated approaches will depend on who is asking the questions, and on what those questions are.[203] There seems to be little support for the proposition that any one conception of regulation or governance is correct, and it is not my intent here to make such a claim. Rather, my proposition is that when seeking theoretical concepts intended to serve both explanatory and normative purposes, there are merits in drawing on both the fields of regulation and governance because each has its advantages, and together they provide the foundation for a more nuanced analysis than either would alone. In brief, using the conceptions of regulation and governance proposed above supports rich analysis of the current state surrounding access to unproven medical interventions, including oversight and facilitative mechanisms, and consideration of future strategies. More specifically, a regulation-based analysis serves to address government priorities, evaluate legal frameworks, and consider other agenda-setting and limit-enforcing

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[197] Peters, *supra* note 126 at 301, 306.
[198] *Ibid*.
[199] Black, "Critical Reflections", *supra* note 6.
[200] See Colin Scott, "The regulatory state and beyond" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 265 at 267, 280.
[201] Brownsword, Scotford & Yeung, *supra* note 49 at 9.
[202] Jennifer Pelley & Marc Saner, "International Approaches to the Regulatory Governance of Nanotechnology" (2009), Regulatory Governance Initiative, online (pdf): <www.nanowerk.com/nanotechnology/reports/reportpdf/report127.pdf> at 1. Pelley and Sacner's work focuses on nanotechnology, but the underlying principles can be applied to other fields.
[203] Rod Rhodes, "Governance and Public Administration" in Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) 54.

mechanisms. It facilitates focused identification of, and reflection upon, the merits of different regulatory strategies in varied contexts including, for example, by drawing on empirical insights regarding the merits of different instruments.[204] At the same time, a corresponding governance analysis can account for the roles of non-state actors such as international scientific bodies, private sector entities (e.g. patient advocacy organizations, non-profits, industry), and other institutions (e.g. research ethics oversight bodies) in shaping the field under study. Using the lens of governance may not lend itself to prescriptive recommendations. However, it can facilitate understanding of present realities and identify potential opportunities or avenues of influence to advance particular goals or objectives, some of which may be achieved at least in part by way of regulation by individual governments. As Pierre argues,

> governance theory helps us analytically separate the normative and institutional dimensions of the collective interest, or, to put it slightly differently, to separate the objectives of the collective will from the institutional structures of the state [which, in my proposed construction, will be captured under the lens of regulation]. Such a separation, in turn, opens up possibilities for a number of analyses of alternative strategies to pursue the collective interest, something which is at the heart of governance.[205]

There is a great deal of valuable conceptual work to be done in these fields, particularly with respect to how the concepts can be brought together such that the whole is greater than the sum of the parts. For example, Sellers suggests that the next generation of governance scholarship will need to develop new conceptualizations that can respond to and capture more nuanced patterns of state-society interactions, including those that involve informal as well as formal mechanisms, and the "flexibility, versatility, and responsiveness inherent in these mechanisms".[206] Attempting to mobilize theoretical and sometimes highly descriptive notions of regulation and governance into understandings intended to inform policy and practice may be a challenging undertaking,[207] but is nonetheless well worth doing. I will approach this challenge using a conceptual framework grounded in both bodies of scholarship. Testing this conceptual framework and identifying the merits and challenges of such an approach are important aspects of the contribution this research will make to the fields of regulation and governance scholarship.

2.5 Conceptual framework

In this section, I will present the conceptual framework I have devised to guide my case study analysis. I will explain how it was applied to each case study in Chapter 3. As discussed in Chapter 1, I have both explanatory and normative goals in this research. More specifically, the purpose of this case study analysis is to explore current and past regulation and governance of access to unproven medical interventions in Canada, with the goal of using the resulting enhanced understanding to identify lessons or principles that could inform and strengthen future

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[204] Sunstein, *supra* note 111.
[205] Jon Pierre, "Conclusions: Governance Beyond State Strength" in Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) 241 at 246.
[206] Sellers, *supra* note 145 at 137-138.
[207] Jessop, *supra* note 143 at 120. Looking at this type of work in the context of metagovernance in particular, Jessop suggests it must be approached with an "ironic" spirit and "risks throwing the whole notion of metagovernance into disrepute".

strategies.[208] My research sub-questions ask: (1) how can we characterize different examples (past and present) of regulation and governance of access to unproven medical interventions provided by physicians in Canada, and what lessons or principles can we draw from these examples?; (2) What is the role of law in setting the parameters within which regulation and governance of access to medical interventions take place and as an instrument of regulation and governance?; (3) What features of regulation and governance of access to unproven medical interventions are particularly important for effective oversight in the Canadian context (see Chapter 1, Section 1.3).

To answer these questions, I constructed a conceptual framework that outlined the features of regulation and governance I intended to look for and assess. Conceptual frameworks serve several purposes including situating the work in existing literature and disciplinary traditions and helping shape the work through conceptual guidance.[209] They can be tested by empirical analysis, which also supports legal scholarship that is both descriptive and normative.[210] My conceptual framework is grounded in the regulatory and governance scholarship reviewed above. It does not reflect a comprehensive collection of all potential features of regulation or governance, but rather those which I identified as most relevant to my research. It is important to note that the conceptual framework presented in Table 1, below, is the final, revised version. As will be discussed in Chapter 3, I revised my original conceptual framework (found in Appendix) in an iterative manner as I conducted my analysis.

Table 1.1: Conceptual Framework (Revised)

Features of Regulation & Governance	Description	Elements & Considerations
Actors	Organizations, bodies, institutions, or identifiable individuals with influence over access to unproven medical interventions	*Authority & Influence*: the source and scope of an actor's ability to impact access and related factors (e.g. access demands) *Coordination*: the extent to which actors demonstrate cooperation or collaboration
Instruments	Modes of regulation or governance; the tools or strategies used to exert influence (i.e. to steer conduct), such as information, incentives,	*Target*: the subject or focus of the intervention *Design*: includes any empirical foundations for the approach, and alignment with broader priorities (e.g.

[208] Regulatory and governance scholarship lends itself well to this combined purpose. Braithwaite, Coglianese & Levi-Faur, *supra* note 186 at 4-5; see also Holley & Shearing, *supra* note 137 at 170; Solomon, *supra* note 176 at 593.
[209] Robert K. Yin, *Case Study Research; Design and Methods*, 5th ed (California: Sage Publications, 2014). Yin discusses the value of using theoretical propositions to guide the data collection strategies and subsequent analysis.
[210] Sanne Takema, "Theoretical and Normative Frameworks for Legal Research: Putting Theory into Practice" (2018) L & Method doi:10.5553/REM/.000031.

	disincentives, and coercive measures (e.g. hard law)	supporting individuals' abilities to make informed medical decisions) *Complementarity*: how different instruments, potentially used by different actors, relate to (i.e. reinforce, conflict with, etc.) one another
Purpose	The goals or objectives that frame or motivate regulation and governance activities	*Clarity*: the extent to which the purpose or intention behind the regulatory or governance activity is clear and expressed, either explicitly (e.g. via mandates, purpose statements) or implicitly *Context*: relevant priorities, imperatives, or constraints that influence or shape the activity *Fit:* the extent to which the instruments used are reflective of, and consistent with, the purpose
Legitimacy	Contextual factors involved in decision-making and implementation processes that support or detract from the lawfulness or credibility of regulation and governance actors and their activities	*Jurisdiction:* accounts for division of powers considerations, mandate, and scope of authority *Influences on decision-making*: what shapes or impacts decision-making; includes considerations of expertise, evidence, political priorities, and advocacy *Process:* includes considerations of transparency, fairness, conflicts of interest, collaboration, and engagement (i.e. whether and how different stakeholders participate or have voice)

		Compliance & Enforcement: captures the styles or modes of enforcement used, and acceptance of that authority or influence (buy-in) by the targets
Responsiveness & Adaptability	The ability and willingness to adjust strategies; includes the degree of nimbleness and adaptive capacity reflected in the approaches taken by regulatory and governance actors	*Timing*: captures the extent to which activities are proactive or reactive *Flexibility*: adjustments or shifts of approach in relation to changing circumstances, uncertainty, or evolving information *Learning*: whether and to what extent responses build on, or respond to, past experience

CHAPTER 3: RESEARCH STRATEGY

In this chapter, I will set out the case study approach I used for this research and explain my data collection strategies. I will then describe my data analysis, and review how I used the conceptual framework presented in Chapter 2, Table 1, as a guide for that work. My research questions were presented in Chapter 1, but for ease of reference I will repeat them here:

> Primary research question: What can we learn from current and past practices to inform and improve future strategies for regulation and governance of access to unproven medical interventions in Canada?
>
> Sub-questions:

(1) How can we characterize different examples (past and present) of regulation and governance of access to unproven medical interventions provided by physicians in Canada, and what lessons or principles can we draw from these examples?
(2) What is the role of law in setting the parameters within which regulation and governance of access to medical interventions take place and as an instrument of regulation and governance?
(3) What features of regulation and governance of access to unproven medical interventions are particularly important for effective oversight in the Canadian context?

3.1 Case study approach

I used a qualitative case study approach for this research. It is important to acknowledge at the outset that there is debate between and within different disciplines about whether case studies are most appropriately characterized as a method, a research design, a methodology, or something else entirely. There are also different definitions of each of these concepts as well as varied views regarding what constitutes a case study.[1] In her leading text on case study research, Simons explains that referring to case study research as an "approach" acknowledges that case studies have a methodological purpose (a way of approaching or seeking knowledge), and can involve different methods (techniques of research, or ways of gathering data).[2] It was beyond the scope of this project to engage in research methods-related terminology debates.[3] For the purpose of this research, I accepted the following definition:

> Case study is an in-depth exploration from multiple perspectives of the complexity and uniqueness of a particular project, policy, institution, programme or system in a 'real life' context. It is research-based, inclusive of different methods and is evidence-led. The primary purpose is to generate in-depth understanding … to generate knowledge and/or inform policy development, professional practice and civil or community action.[4]

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[1] See Gary Thomas, "A Typology for the Case Study in Social Science Following a Review of Definition, Discourse, and Structure" (2011) 17:6 Qualitative Inquiry 511.
[2] Helen Simons, *Case Study Research in Practice* (California: Sage Publications, Inc, 2009) at 3.
[3] For a review of different definitions of case studies and associated literature regarding their uses, see Rob VanWynsberghe & Samia Khan, "Redefining case study" (2007) 6:2 Intl J Qualitative Methods 80.
[4] Simons, *supra* note 2 at 21.

Further, I adopted the following definition of a case: *an intensive study of a single unit for the purpose of understanding a larger class of (similar) units*.[5] In this project, the units or individual cases are individual examples of unproven medical interventions from a class of unproven medical interventions and, more specifically, how regulation and governance of access to such interventions has been approached in the Canadian context.

A case study approach offered several benefits and was well suited to this research agenda. According to Yin's seminal work in case study research, case studies are a good fit for research like this project that seeks to explore "how" or "why" questions in real-life contexts, where the researcher does not have control over the phenomenon being studied.[6] They also lend themselves well to exploratory work and research that seeks to understand mechanisms rather than causal effects, which captured much of the intent of this project.[7] Case study research is also recognized for its utility in both validating and building theory.[8] This potential was particularly valuable in light of my interest in helping advance understandings of regulation, governance, and their relationship to one another in applied contexts. Using a case study approach for this research not only facilitated detailed contextual analysis which added important nuance to the consideration of my research questions, it also provided a concrete foundation for my application and exploration of the theoretical concepts and conceptual framework that I set out in Chapter 2.[9] In other words, using a case study approach helped "shed empirical light" on the theoretical concepts that guided this research.[10] I present the theoretical reflections that I developed as part of this analysis in Chapter 8.

The case study approach also provided a mechanism for me to develop an in-depth understanding of regulation and governance of access to these three different cases of unproven medical interventions in Canada, which can ideally be used to inform future policy and practice. As VanWynsberghe and Khan note, "[c]ase studies can contain translatable evidence that move beyond the case itself. Translating case studies can serve broad social functions to describe the values of our society, explore contradictions in our lives, offer new insights on what has been and should be done, and present new perspectives and interpretations on events".[11]

Case studies are also inherently flexible, which was another advantage in the context of this research project. According to Webley, the case study method,

> caters for a wide range of modes of enquiry: the investigation may be exploratory (explore why or how something is the way it is), descriptive (describe why or how something is the way it is) or explanatory (determine which of a range of rival hypotheses, theories etc. explain why or how X is the way it is). Some categorise case studies as those designed to be theory orientated, and those designed to be practice orientated. Thereafter the design scope is very broad; the data

[5] John Gerring, "What is a Case Study and What Is It Good for?" (2004) 98:2 American Political Science Rev 341 at 342 [emphasis in original].
[6] Robert K. Yin, *Case Study Research; Design and Methods*, 5th ed (California: Sage Publications, 2014).
[7] Gerring, *supra* note 5 at 352.
[8] Yves-C. Gagnon, *The Case Study as a Research Method; A Practical Handbook* (Quebec: Presses de l'Universite du Quebec, 2010).
[9] For more depth on the use of case studies to advance work of this nature, see *Ibid*; see also Yin, *supra* note 6.
[10] Yin, *supra* note 6 at 40.
[11] VanWynsberghe & Khan, *supra* note 3 at 86-87.

> collected may be qualitative and/or quantitative, collected via a variety of methods, and the case study may be a single case or be made up of a small number of cases.[12]

Further, case studies are "transparadigmatic" (i.e. not specific to any one research paradigm, such as positivism, constructivism, critical realism) and "transdisciplinary" (i.e. suitable for multiple disciplines, including research that crosses various disciplines).[13] Together with flexibility, these characteristics of case studies were another reason why they were a good fit for my work. As reflected in Chapter 2, relevant literature on regulation and governance is interdisciplinary and I did not limit this research to a particular research paradigm or discipline. The issues raised by access to unproven medical interventions are multi-faceted, engaging questions of law, policy, and professional ethics, among others. Case studies can draw on multiple data sources and can involve combinations of different methods such as historical analysis, doctrinal legal study, policy analysis, statistical analysis, surveys, and interviews, among others.[14] Accordingly, as described below, I drew on data from varied sources in this project to develop a rich understanding of these multi-faceted cases. Adopting this broad and inclusive approach to my data collection and analysis with room for contributions from multiple disciplines strengthened my understanding of the cases and, I hope, has enhanced the practical utility of my findings from a policy perspective.

As is true of all methodological choices and research strategies, case studies are not without their difficulties and weaknesses. They tend to be very time-consuming and often involve a large volume of material that can be challenging for researchers to manage. They are not designed for reproducibility or to produce generalizable results. To the contrary, their strengths with respect to detail and specificity in relation to the contexts studied can run counter to efforts to identify broadly applicable rules or principles.[15] As can be true of other forms of qualitative research, they can also be criticized for their subjectivity. I present a more fulsome review of the limitations of this work in Chapter 8. Although it was critical to acknowledge the potential challenges and limitations of case study research, my assessment was that they did not outweigh the advantages that a case study approach offered to this research.

3.2 Data collection strategies, inclusion criteria, and data management

In this section, I describe and explain the two phases of this research for this project and important aspects of my data collection and analysis strategies.

3.2.1 Phase I – Contextual considerations and regulatory and governance mapping

In the first phase of this research, I mapped relevant regulatory and governance frameworks related to access to unproven medical interventions in Canada along with relevant

[12] Lisa Webley, "Stumbling Blocks in Empirical Legal Research" (2016) L & Method doi:10.5553/REM/.000020 at 3.
[13] VanWynsberghe & Khan, *supra* note 3 at 80-81.
[14] Webley, *supra* note 12 at 5.
[15] Gagnon, *supra* note 8 at 3.

contextual factors, some of which (e.g. *Charter* jurisprudence) are uniquely Canadian.[16] The purposes of this exercise were to identify key institutional and contextual factors relevant to regulation and governance of access to unproven medical interventions in Canada, as well as to lay the groundwork for identifying opportunities and constraints including potential gaps, ambiguities, and areas of overlap. I present what I suggest are the most broadly relevant contextual considerations in Chapter 4, with case-specific elements addressed in Chapters 5 – 7. The contextual considerations that I identify and discuss are not a comprehensive or exhaustive selection. There is undoubtedly considerable room for alternative approaches to both the selection and framing of these considerations and their relevance in the context of this research. However, the considerations that I address in Chapter 4 have strong connections to and help support the conceptual framework I developed to guide my analysis of the case studies, which was the central objective of this mapping phase.

3.2.2 Phase II – Case studies

The second phase of the project consisted of the three case study analyses (results presented in Chapters 5 – 7) and the cross-case analysis (discussed in Chapter 8). In the sub-sections that follow, I will describe and explain the three cases I selected for analysis. I will then describe my data collection and analysis processes, and address how they were guided by the conceptual framework I presented in Chapter 2.

3.2.2.1 Case selection and justification

I selected the following three cases for analysis:

a. Provision of chelation therapy for treatment of conditions other than heavy metal poisoning[17] (Chapter 5).

b. The CCSVI or "liberation therapy" movement in Canada[18] (Chapter 6);

c. The Canadian market for unproven stem cell interventions[19] (Chapter 7);

I selected these cases using a form of "purposive sampling" (sometimes referred to as judgment sampling). Purposive sampling is common in qualitative research, particularly for

[16] Mike McConville & Wing Hong Chui, eds, *Research Methods for Law* (Edinburgh: Edinburgh University Press, 2007) at 18-19. The authors suggest that doctrinal legal research of this nature (i.e. that identifies, describes, and analyzes the law as it applies to a particular area) can be normative or theoretical.

[17] For a recent example relating to the use of chelation therapy to treat autism in children, see Nicole Ireland, "Treatment to remove metals from children with autism unproven and risky, but no clear regulations" (30 August 2018), online: <www.cbc.ca/news/health/autism-chelation-therapy-unproven-and-dangerous-1.4803423>; for a non-pediatric example, see Martin Mittelstaedt, "The chelation debate" (27 August 2002; updated 17 April 2018), online: <www.theglobeandmail.com/life/the-chelation-debate/article1025775/>.

[18] Darryl Pullman, Amy Zarzeczny & Andre Picard, "Media, politics and science policy: MS and evidence from the CCSVI Trenches" (2013) 14:6 BMC Medical Ethics https://doi.org/10.1186/1472-6939-14-6; Roger Chafe et al, "The rise of people power" (2011) 472 Nature 410.

[19] Isreal Berger et al, "Global Distribution of Businesses Marketing Stem Cell-Based Interventions" (2016) 19:2 Cell Stem Cell 158; Tom Blackwell, "Canadian clinics begin offering stem-cell treatments experts call unproven, possibly unsafe" *The National Post* (3 July 2017), online: <nationalpost.com/news/canada/canadian-clinics-begin-offering-stem-cell-treatments-experts-call-unproven-possibly-unsafe/wcm/f73a696e-a34f-4f4f-9d92-ca8a26707a03>.

comparative research. It describes an approach where the researcher selects cases using their judgment regarding what cases are likely to provide the most useful information, with consideration given to both ensuring the cases' elements are relevant to the phenomenon under study, and that there is some diversity to explore different dynamics.[20]

I selected these three cases for several reasons. There are important similarities among them. Each case involved a medical intervention that falls into the "unproven" category as described in Chapter 1 and are (or have been) provided by physicians (among others) in Canada. Each case engaged diverse interests and varied stakeholders including, though not necessarily limited to, the state, healthcare providers, professional regulatory bodies, patients, and members of the scientific community. Each case has attracted attention in the public domain with some individuals seeking access to the intervention. Each case also triggered debate and often conflicting perspectives about the merits of different types of regulatory and governance responses. Finally, each case has been associated with scientific uncertainty or evolving evidence.

There are also important contrasts among the cases that were illustrative. There are important distinctions in how the interventions have been characterized (e.g. complementary and alternative medicine, surgical intervention, or drugs). One of the interventions (liberation therapy) has been used for one specific medical condition (multiple sclerosis), while the other two have been used to treat a wide range of conditions. There are also temporal differences among the cases. First, of the three case studies, chelation therapy dates back the farthest and controversy surrounding its unproven applications has persisted for decades. It involves an intervention that is the established standard of care for treatment of heavy metal toxicity, but it remains an unproven medical intervention in other contexts for which it has been marketed, such as to treat autism.[21] Second, while recent enough to be relevant to current governance and regulatory questions, the liberation therapy case study was primarily retrospective. Much of the debate surrounding this intervention has been resolved by clinical research results that largely discredited the theory.[22] As a result, demands for access and corresponding regulatory and governance activities have for the most part abated. Finally and in contrast to the other two cases, the market for unproven stem cell-based interventions in Canada and associated regulatory and governance responses are still evolving.[23] Although ongoing developments presented somewhat

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[20] Loleen Berdahl & Jason Roy, *Explorations; Conducting Empirical Research Studies in Canadian Political Science,* 4th ed (Ontario: Oxford University Press, 2021) at 103.

[21] See e.g. Government of Alberta, "Chelation Therapy" (modified 20 December 2019), online: *MyHealthAlberta* <myhealth.alberta.ca/Health/Pages/conditions.aspx?hwid=ty3205spec>; see also Mike Hughes, "EDTA Chelation: Rise of the Undead Therapy" (29 October 2015), online: *The University of British Columbia Centre for Blood Research* <cbr.ubc.ca/edta-chelation-rise-of-the-undead-therapy/>; the College of Physicians and Surgeons of Saskatchewan has provided specific performance standards for members providing "chelation therapy for purposes other than treatment of heavy metal poisoning", while also noting "the College of Physicians and Surgeons is not convinced of the efficacy of chelation therapy, and does not endorse its use for any purpose other than heavy metal poisoning, it recognises that there is public demand for safe access to this treatment". College of Physicians and Surgeons of Saskatchewan, "Regulatory Bylaws for Medical Practice in Saskatchewan" (March 2018), online (pdf): <medicine.usask.ca/documents/pgme/policy/RegulatoryBylaws.pdf> at 22.2(b) and (a).

[22] See e.g. Claudio Baracchini, Matteo Atzori & Paolo Gallo, "CCSVI and MS: no meaning, no fact" (2013) 34:3 Neurological Sciences 269; Paolo Zamboni et al. "Efficacy and Safety of Extracranial Vein Angioplasty in Multiple Sclerosis; A Randomized Clinical Trial" (2017) 75:1 J American Medical Assoc Neurology 35.

[23] Leigh Turner, "Direct-to-consumer marketing of stem cell interventions by Canadian businesses" (2018) 13:6 Regenerative Medicine 643. See Government of Canada, "Health Canada Policy Position Paper – Autologous Cell

of a challenge from a data collection perspective, using a current case offered an opportunity to study the issues at the heart of this research agenda in real time. It also presents opportunities for this work to inform decision-making in the field. To date, the cases have unfolded along divergent paths in Canada with key actors including governments and medical regulatory bodies taking different approaches. These differences have enriched my analysis of relevant options and constraints in regulation and governance of access to unproven medical interventions in Canada.

Each of these cases was illuminating on its own and contained features relevant to an in-depth analysis of regulation and governance of access to unproven medical interventions in Canada.[24] However, exploring these three cases together provided greater insight into the core research question than a single case exploration could have done.[25] I discuss key insights from my cross-case analysis in Chapter 8.

3.2.2.2 Data collection

Similar to the selection of my cases, my data collection strategy can also be described as purposive. I identified a series of initial data sources, described below. My objective in using these varied sources was to obtain as fulsome a picture as possible of the relevant regulatory and governance landscape for each of the case studies, while also maintaining a feasible scope for this research project. I selected these particular data sources based on my work in Phase I and my previous research in related areas. Using the multiple data sources described here added richness to the case study analyses, and their diversity increased my confidence in the soundness of my conclusions.

I used a systematic and consistent approach to collecting data from each of the sources described below for each case study. Specifically, in my initial data collection I searched the same sources for each case study using the same search strategies, except for specific search terms, which naturally were tailored to each case. Although not all my data searches were fruitful, I think it is nonetheless important to identify and describe my initial data sources and associated search strategies to present a complete picture of my data collection process:

(i) *Literature* - I conducted a literature review to identify relevant literature on each case.[26] The initial question guiding these reviews was the following: "What is known about the regulation and governance of [case details], including options, constraints, challenges and opportunities?" I drew on different sources for this review including electronic library databases (Academic Search Complete, Lexis Advance Quicklaw – secondary materials, Heinonline, PubMed (Medline) WebofScience, and the University of Regina Quick Find service), reference lists, internet searches (including Google Scholar), and existing networks.[27] To keep the scope manageable, I focused on literature that was either directly

Therapy Products" (15 May 2019), online: <www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/cell-therapy-policy.html>; Carly Weeks, "Health Canada orders halt to unproven stem cell-based injection treatments" *The Globe and Mail* (7 July 2019), online: <www.theglobeandmail.com/canada/article-health-canada-in-overdue-crackdown-on-unproven-stem-cell-based/>.

[24] Gagnon, *supra* note 8 at 44.

[25] Webley, *supra* note 12 at 13-14.

[26] Hilary Arksey & Lisa O'Malley, "Scoping studies: towards a methodological framework" (2005) 8:1 Intl J Soc Research Methodology 19.

[27] *Ibid* at 23.

related to the Canadian context, was referred to in Canadian sources, or appeared to have influenced regulation or governance in Canada. Where applicable, I limited search results to peer reviewed journals and English language materials. As part of this review, I identified a series of key terms commonly used to discuss each of the case studies. I used these terms in my subsequent data collection searches.

(ii) *Legislation & Regulations* – I identified important examples of legislation and regulations that shape the broader institutional and contextual frameworks for regulation and governance of access to unproven medical interventions in Canada (e.g. provincial health insurance funding legislation) in Phase I (described above) and they are addressed in Chapter 4. However, I also searched CanLII, LexisNexis Academic, and the Library of Parliament for any case-specific legislation.

(iii) *Government Documents* – My goal was to collect as a broad a sample as possible of documents and information relating to direct government involvement in each case (e.g. funding announcements, public advisories, white papers, information alerts, guidance documents, etc.). I used the following strategies to do so:

a. *Government websites* - I used the search function on the main page of each provincial and territorial government in Canada, as well as the federal government and Health Canada, with a variety of search terms for each case study. For example, with the second case study I did independent searches using "liberation therapy", CCSVI, and "chronic cerebrospinal venous insufficiency".

b. *Library collection* – I searched the University of Regina Library's collection of government documents, using the same search terms as applied on the government websites.

c. *Internet searches* - I also conducted plain language internet searches to try to capture additional government documents that may not have been identified through the foregoing approaches. I again used the same selection of search terms for each case study, in combination with the name of each province and territory, and adding the term government (e.g. CCSVI Alberta government, liberation therapy Alberta government, etc.). I excluded media and research publications from my results, and generally reviewed between 5 – 10 pages of search results, stopping my review when I reached more than one page with no relevant results.

(iv) *Legislative and Parliamentary Debates* - I searched the Hansard (the official record of legislative and parliamentary debates) for each province and territory as well as the federal government for key terms related to each of the three cases and collected all relevant materials, including debate transcripts and committee reports. Where search abilities were more limited (e.g. data or session specific) including New Brunswick and Newfoundland & Labrador, I searched by index where available.

(v) *Case Law and Professional Discipline* – I used CanLII and LexisNexis Academic to search for relevant jurisprudence and professional disciplinary decisions regarding access to each of the unproven medical interventions in these case studies. I also did plain language internet searches using Google, adding the terms "professional misconduct",

"unprofessional conduct", "college of physicians and surgeons", discipline, and negligence, to the case-specific search terms.

(vi) *Professional Regulatory & Guidance Activity* – To collect data, including policy statements, guidance documents, advisories, or other information about professional regulatory and professional guidance activity related to the case studies, I looked to the following sources:

a. *Colleges of physicians and surgeons* – I used the search functions on the website of each college of physicians and surgeons across Canada, as well as the Royal College of Physicians and Surgeons of Canada, and the College of Family Physicians of Canada to collect relevant data, again using the search terms identified in my literature review (above).

b. *Medical associations* – I used the search function on the websites of the provincial and territorial (where available) medical associations (e.g. Doctors of BC, Alberta Medical Association, Saskatchewan Medical Association, Doctors Manitoba, etc.) as well as the Canadian Medical Association to collect relevant data, again using the search terms identified in my literature review (above). Where available, I also did manual title searches of their collections of practice standards and professional guidelines.

(vii) *News Media* – The purpose of this aspect of my data collection was not to conduct a comprehensive or in-depth media analysis. Rather, my strategy was to collect examples of how the media framed issues of access, patient demand, regulation, and governance in relation to these cases.[28] Reviewing media coverage was also part of my snowball search strategy (discussed below), to identify additional sources and relevant material not located in my initial data collection. I used the Canadian Major Dailies database, described in the University of Regina ProQuest search function as the core of the Canadian Newsstand collection. It includes national and major regional papers such as the National Post, Calgary Herald, Edmonton Journal, Montreal Gazette, Ottawa Citizen, Regina Leader Post, Vancouver Sun, and the Victoria Times-Colonist. With the addition of limitations including to English content, I searched blogs, podcasts, websites, and newspapers, again using a combination of search terms for each case study, as drawn from my literature review. I scanned initial results and removed duplicates and any that were not directly relevant to my research questions (e.g. where CCSVI was mentioned only tangentially, in the context of another unrelated discussion). I did a detailed review of a purposive sample of the coverage for each case study, with consideration of the timing and topic of publication.

[28] The way in which new biotechnologies and purported treatment options are portrayed in the media, and the manner in which different perspectives are presented, likely has an impact on public understanding and expectations. See Woody Chang, Tracey C. Bank & Christopher T. Scott, "Fit to Print? Media Accounts of Unproven Medical Treatments Across Time" (2014) 5:1 AJOB Empirical Bioethics 33. Chang et al. compared media portrays of two unproven interventions in different time periods, Laetrile in the late 1970's and stem cell interventions between 2006-2011. They found that overall, little has changed and "Individualism, autonomy, resistance to regulation, and the hope for cures characterize patient portrayals in the media" (at 40).

(viii) *Patient Advocacy Activity* – Using internet searches and following reference trails from other sources (e.g. literature, media stories, etc.) I collected information about patient advocacy activity related to each case (e.g. advocacy websites, promotional materials, information campaigns, social media engagement).

My primary data collection period was between September and November of 2020. Through my data collection, I also used a form of "snowball" searching. Snowball sampling often refers to approaches whereby additional research participants (or in this case, data sources) are identified through recommendations or other information provided by initial participants.[29] Here, I use the term to describe my practice of noting and following up on potentially relevant sources identified through my initial data collection. For example, several media articles about liberation therapy (Chapter 6) discussed patient advocacy efforts, including those based in social media groups, on which I then gathered more information through focused searches. I also followed up on citations and identified in my literature reviews source that appeared potentially relevant to my research questions.

I kept an audit trail to document my data collection strategies and used research memos to document decisions made along the way. Memo documentation can assist with evaluating the validity and reliability of results and facilitates greater transparency regarding potential researcher bias.[30] I used these memos to ensure I was consistent in my search strategies in each of the cases, and to track the evolution of my thinking regarding the conceptual framework, which is discussed in the next sections.

3.3 Analysis and application of the conceptual framework

I used NVivo to store and organize my different data sources, and to support my analysis of the materials. NVivo is data management and analysis software. NVivo allows a user to import and store data from a wide variety of sources (e.g. documents, websites, audio-visual materials). Once data is imported into NVivo (e.g. by uploading a PDF or word document, screenshot, image, etc.), the software helps a researcher to organize and explore the data through a variety of searching and coding options. Importantly, it does not drive or complete the analysis for the researcher. NVivo is user-driven, meaning that it is still the researcher who makes the decisions at each point throughout the analysis regarding how the data will be classified and interpreted.[31] For my purpose, the ability to create and continually update categories and nodes made it easier to analyze the data in relation to the concepts that I presented in my conceptual framework. Practically speaking, NVivo was also a useful tool for keeping my data organized, which was particularly important given the large amount of data I was working with from varied sources.

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[29] See Lindsay Prior, "Content Analysis" in Patricia Leavy, ed, *The Oxford Handbook of Qualitative Research* (New York: Oxford University Press, 2014) 359 at 361; see also Brenda Phillips, "Qualitative Disaster Research" in Patricia Leavy, ed, *The Oxford Handbook of Qualitative Research* (New York: Oxford University Press, 2014) 533 at 540, 542; see also Lyn Richards & Janice Morse, *Readme First for a User's Guide to Qualitative Methods,* 3rd ed (California: Sage Publications Inc, 2013) at 221-222.

[30] Webley, *supra* note 12 at 15.

[31] Benght Edhlund, *NVivo 8 Essentials*; *The Ultimate Help When You Work with Qualitative Analysis* (Sweden: Form & Kunskap, 2007); see also Patricia Bazeley & Lyn Richards, *The NVivo Qualitative Project Book* (London: Sage Publications Ltd, 2000).

Once I gathered my initial data, the first step in my analysis was to synthesize the multiple sources of data and build a narrative account of each case study using rich (or "thick") description. In this context, thick description describes a narrative or story-telling approach to case study research that emphasizes context and connections between different elements or actors.[32] These narrative accounts are presented in the first sections of Chapters 5 – 7, respectively. They provided an important foundation for the subsequent within-case analyses by helping me develop "a rich familiarity with each case".[33] This step began with "skimming" (i.e. an initial high-level review) to get a sense of the breadth of the data, and to start to identify important relationships and themes that related to my research questions and the conceptual framework. I then proceeded with a thorough reading and assessment of each item using a systematic document analysis approach.[34] Although it can have varied meanings, my use of document analysis (which is sometimes described as content analysis) refers to:

> a systematic procedure for reviewing or evaluating documents—both printed and electronic… [T]he analytic procedure entails finding, selecting, appraising (making sense of), and synthesising data contained in documents. Document analysis yields data—excerpts, quotations, or entire passages—that are then organised into major themes, categories, and case examples specifically through content analysis.[35]

Document analysis can be a particularly good fit for qualitative case studies that seek to produce rich descriptions and understanding of phenomena or events, which was the case with my research.[36] As Bowen notes, although document analysis is often used alongside methods such as interviews or surveys, it can also be used as a "stand-alone" method.[37] In selecting this approach, I adopted the following proposition:

> that both qualitative and quantitative legal research is empirical research. What makes research empirical is that it is based on observations of the world, in other words, data, which is just a term for facts about the world. These facts may be historical or contemporary, or based on legislation or case law, the results of interviews or surveys, or the outcomes of secondary archival research or primary data collection. Data can be precise or vague, relatively certain or very uncertain, directly observed or indirect proxies, and they can be anthropological, interpretive, sociological, economic, legal, political, biological, physical, or natural. As long as the facts have something to do with the world, they are data, and as long as research involves data that is observed or desired, it is empirical.[38]

I developed a preliminary coding frame based on the features and elements of regulation and governance identified in my original conceptual framework (see Appendix) and explored the

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[32] Albert Mills, Gabrielle Durepos & Elden Wiebe, "Thick Description" in *Encyclopedia of Case Study Research* (California: Sage Publications, Inc, 2010) 942 at 942-943.
[33] Kathleen Eisenhardt, "Building theories from case study research" (1989) 14:4 Academy Management Rev 532 at 540.
[34] See George Bowen, "Document analysis as a qualitative research method" (2009) 9:2 Qualitative Research J 27 at 32; see also Gagnon, *supra* note 8 at 77.
[35] *Ibid* at 27-28.
[36] *Ibid* at 29.
[37] *Ibid*.
[38] McConville & Chui, *supra* note 16 at 18.

data from each case study with a focus on looking for evidence and examples that related to these elements and considerations. For example, some of my initial nodes (categories to which I coded content) included purpose, jurisdiction, nature of expertise, evidence of learning, and timing of intervention, among others. I continued to add and refine these categories as I worked through the data, using what is often referred to in qualitative research as an 'iterative" approach. I continually revisited and reflected on my conceptual framework, adjusting it throughout the data collection, analysis, and writing processes in response to what I was observing in the data, and how those findings connected to the theoretical concepts discussed in Chapter 2. This reflexive approach reflects a conception of social research as "a dialogue between **ideas** and **evidence**".[39] For example, although I originally identified compliance and enforcement as independent features of regulation, my analysis of the data led me to believe they are more helpfully viewed in this context as elements or considerations of legitimacy. Within this context, it is important to note that I have adopted a narrow perspective on compliance and enforcement for the purpose of this research, as compared to some of the broader and more varied approaches in related literature.[40] More specifically, I have considered compliance primarily as being reflected in adherence to rules or policies intended to shape behaviour, such as Health Canada requirements, and enforcement as capturing how regulatory and governance actors respond to non-adherence. Other important aspects of compliance and enforcement that are often addressed in the literature, including how the choice and design of regulatory and governance interventions may impact the responses of regulatory targets, are captured to some extent in the elements of the conceptual framework that consider instruments and responsiveness. The revised conceptual framework presented in Chapter 2 reflects the changes made throughout my analysis.

Building on the narrative accounts of each case study and my evolving conceptual framework, I worked on drawing insights from the multiple sources of data to answer my research questions.[41] Doing so involved drawing descriptive inferences. Gerring argues that descriptive inference is an important yet undervalued approach for the social sciences. It does not involve assertions about causal relationships but it can support classifying relationships.[42] My findings from each case study are presented in Chapters 5-7. Following this in-depth within-case analysis, I then completed a cross-case analysis by looking to identify patterns in the data across the three cases.[43] The overarching purpose of this analysis was to identify key lessons and develop insights about what features emerged as being particularly important for effective and appropriate regulation and governance of access to unproven medical interventions in Canada, and what considerations might guide future regulation and governance strategies. In completing this cross-case analysis, I drew on my conceptual framework to explore the extent to which my findings corroborate, modify, reject, or otherwise advance the theoretical constructs identified at

[39] Charles C Ragin, *Constructing social research; the unity and diversity of method* (California: Pine Forge Press, 1994) at 55 [emphasis in original]. See also Webley, *supra* note 12 at 17.

[40] As noted in Chapter 2, Section 2.1.3, there is valuable scholarship exploring varied factors and mechanisms that may influence compliance and enforcement behaviours. For example, there are instructive principles to be drawn from work on environmental regulation. See e.g. Carolyn Abbot, *Enforcing Pollution Control Regulation; Strengthening Sanctions and Improving Deterrence* (Oxford & Portland, Oregon: Hart Publishing, 2009). Although beyond the scope of this project, future research exploring deterrence-based theories and other mechanisms for inducing behaviour change in the context of unproven medical interventions would be worthwhile.

[41] Yin, *supra* note 6.

[42] Gerring, *supra* note 5.

[43] Eisenhardt, *supra* note 33 at 540.

the outset of this work and discussed in Chapter 2.[44] The results of this analysis and my corresponding reflections on the conceptual framework are presented in Chapter 8.

[44] Gagnon, *supra* note 8 at 41.

CHAPTER 4: MAPPING THE REGULATORY AND GOVERNANCE LANDSCAPE FOR ACCESS TO UNPROVEN MEDICAL INTERVENTIONS IN CANADA

4.1 Introduction

Many of the legal and policy issues associated with access to unproven medical interventions are global in nature. However, my research is focused on regulation and governance of access to unproven medical interventions provided by physicians in Canada, which has some unique contextual features. Before proceeding to discuss the three case studies in detail, it is important to set out the relevant legal and policy landscape for this research, including the roles and authority of regulatory and governance actors that feature centrally in the case studies, particularly for the benefit of readers who may not be familiar with Canadian health law and policy. Accordingly, the modest goal of this chapter is to map the relevant regulatory and governance landscape for the ensuing case study analyses. As noted in Chapter 1, the role of law serves a boundary setting function in this research. Thus, this mapping exercise concentrates on contextual considerations and oversight mechanisms that are primarily facilitated or constrained by law, rather than on broader factors such as socio-political, historical, philosophical, or economic considerations. This bounded approach is also reflected in how related questions of compliance and enforcement are approached in the ensuing case study analyses, where the emphasis is largely on legal mechanisms.

There are two broad categories of oversight that are particularly relevant for this research. The first focuses on the interventions themselves, and key ways in which access to them is facilitated, controlled or restricted, and sometimes challenged. Federal, provincial, and territorial governments play a central role in this area, as do the courts when individuals pursue rights-based claims for access to medical interventions. The second category focuses on oversight of providers (here, physicians) and their practices. It includes the involvement of medical professional regulation, tort law, and research ethics frameworks. All of these areas are complex and this will not be a comprehensive discussion of their histories or nuances. This chapter will merely outline the features of the Canadian health law landscape that are most relevant to the case study data and the accompanying regulation and governance analyses.

4.2 Government oversight of access to medical interventions

Governments are engaged with matters of access to medical interventions, both proven and unproven, in a variety of ways. Some of these activities facilitate access, while others serve to restrict or more generally control it. As described by a former Senior Scientific Advisor with Health Canada, government regulators have responsibilities both as an "enabler", to facilitate access, and as a "gatekeeper", to protect health.[1] In Canada, there are important distinctions between the activities and responsibilities of the federal government, provincial, territorial, and municipal governments. This discussion will focus on the respective roles of the federal, provincial, and territorial governments as they are most directly relevant to the case study data.

[1] Robyn Lim, "The Path to Adaptive Drug Regulation: A Regulator's Perspective on Balancing Benefits, Harms and Related Uncertainties in Practice", IRGC International Conference 2013: From Crisis Management to Risk Governance, 9-11 January 2013, China, online (pdf): <irgc.org/wp-content/uploads/2018/09/2.-Robyn-LIM_Adaptive-Licensing-reg-persp_IRGC-Beijing-Jan-2013.pdf>.

4.2.1 Constitutional division of powers with respect to health

Canada has two constitutionally recognized levels of government: federal and provincial. The powers of each level of government are set out in ss. 91-95 of the *Constitution Act, 1867*.[2] Health is not an identified head of power under the Constitution. In the exercise of their enumerated powers, both levels of government can legislate in ways that impact and shape health policy. Federal jurisdiction over health includes powers of quarantine, criminal law, peace, order and good government, and all matters not exclusively assigned to provincial authority, as well as spending powers.[3] The federal government's exercise of its spending power via the *Canada Health Act*[4] is what shapes the medicare system in Canada.[5] The federal government also has jurisdiction over regulation of trade and commerce,[6] which it uses to support the *Competition Act*,[7] discussed further below.

Provincial jurisdiction over health flows from authority over hospitals, property and civil rights, municipal institutions, and matters of a primarily local or private nature.[8] These powers are generally interpreted to recognize jurisdiction over healthcare funding and delivery (with some exceptions, including healthcare for members of the armed forces and First Nations Peoples).[9] They also recognize provincial regulation over key areas including hospitals and healthcare facilities, health records and insurance, and professional regulation of healthcare providers.[10] Although Parliament has jurisdiction over the territories (the Northwest Territories, Yukon, and Nunavut), it has delegated broad powers to their elected councils including the s.92 heads of provincial powers most relevant to health (hospitals, property, and civil rights).[11]

The boundaries between federal, provincial, and territorial authority are often far from clear in practice. For instance, the Supreme Court of Canada (SCC)'s decision in *Reference re Assisted Human Reproduction Act*[12] provides an instructive example of the jurisdictional tensions that can arise when the federal government attempts to use its criminal law powers under s. 91(7) of the *Constitution Act, 1867* to regulate matters of health.[13] A valid exercise of

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[2] *Constitution Act, 1867* (UK), 30 & 31 Vict, c 3 [*Constitution Act, 1867*].
[3] *Ibid*. s. 91.
[4] RSC 1985, c C-6 [*Canada Health Act*].
[5] See Peter Hogg & Wade Wright, *Constitutional Law of Canada*, 5th ed (Ontario: Thomson Carswell, 2007) at 6:8.
[6] *Constitution Act, 1867*, *supra* note 2 at s. 91(2).
[7] RSC 1985, c C-34 [*Competition Act*]. See *General Motors of Canada Ltd. v. City National Leasing*, 1989 CanLII 133 (SCC), [1989] 1 SCR 641.
[8] *Constitution Act, 1867*, *supra* note 2 at s. 92.
[9] William Lahey, "The Legal Framework for Intergovernmental Health Care Governance: Making the Most of Limited Options", in Katherine Fierlbeck & William Lahey, eds, *Health Care Federalism in Canada; Critical Junctures and Critical Perspectives* (Montreal: McGill-Queen's University Press, 2013) 71 at 74.
[10] Martha Jackman, "Constitutional jurisdiction over health in Canada" (2000) 8 Health LJ 95 [Jackman, "Constitutional Jurisdiction"].
[11] *Yukon Act*, SC 2002 c 7; *Northwest Territories Devolution Act*, SC 2014, c 2; *Nunavut Act*, SC 1993, c 28.
[12] 2010 SCC 61 [*AHRA Reference*].
[13] See Barbara von Tigerstrom, "Federal Health Legislation and the Assisted Human Reproduction Act Reference" (2011) 74:1 Sask L Rev 33 [von Tigerstrom, "Federal Health Legislation"]; Graeme Mitchell, "Not a General Regulatory Power: A Comment on Reference re Assisted Human Reproduction Act" (2011) 54 SCLR (2d) 633. It is important to note that this decision also raises other important issues, such as the relationship between federalism and *Charter* analyses - See e.g. Mark Carter, "Federalism Analysis and the Charter" (2011) 74:1 Sask L Rev 5 - and questions related to the regulation of assisted reproductive technologies - see e.g. Dave Snow, "The Judicialization

criminal law requires a prohibition that is backed by a penalty, and which is based on a valid criminal law purpose.[14] A valid criminal law purpose may include matters of public peace, order, security, health, or morality (among others).[15] The use of criminal law powers to control a particular area is highly relevant to this research as it is the means by which the federal government exerts authority over key aspects of health and medical interventions including, for example, the safety and efficacy of drugs (see Section 4.2.2).[16]

In *AHRA Reference*, the SCC was asked to provide an opinion on whether Parliament had acted outside its jurisdiction by the way in which it used the criminal law power to regulate aspects of assisted human reproduction and related areas of research.[17] A majority of the SCC deemed large portions of the *Assisted Human Reproduction Act*[18] as *ultra vires* the federal government's authority, falling instead under provincial jurisdiction over hospitals, medical facilities, and the practice of medicine. One point of debate that has arisen from this decision is what role evidence and potential harm play with respect to drawing jurisdictional boundaries around regulation of health using criminal law powers.[19] For example, health law scholar Ogbogu focuses on LeBel and Deschamps JJ's views regarding the need for a "concrete basis and reasoned apprehension of harm", which he suggests "provides a sensible and useful demarcation between federal interest in regulating criminal aspects of health, and provincial interests in regulating health as a matter engaged by various heads of provincial powers".[20] Lebel and Deschamps JJ also stressed that the need for a reasonable apprehension of harm and a real evil as the foundation of a public purpose to justify the use of criminal law powers also applies where the legislation seeks to protect morality. In other words, their reasons emphasize the limits that apply to Parliament's ability to use its criminal law power to protect morality, safety, and public health.[21]

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of Assisted Reproductive Technology Policy in Canada: Decentralization, Medicalization, and Mandatory Regulation" (2012) 27:2 CJLS 169 - but these are beyond the scope of this research.

[14] *Reference re Firearms Act (Can.)*, 2000 SCC 31 at para 27.

[15] *Reference Re Validity of Section 5(a) of the Dairy Industry Act*, (1948), [1949] SCR 1 at 50, [1949] 1 DLR 433, aff'd [1950] 4 DLR 689, [1951] AC 179 (PC). *R. v. Big M Drug Mart*, [1985] 1 SCR 295 at 354. See also Aaron Fritzler, "Reference re Assisted Human Reproduction Act: An Argument for Chief Justice McLachlin's Position" (2017) Sask L Rev online: <sasklawreview.ca/comment/reference-re-assisted-human-reproduction-act-an-argument-for-chief-justice-mclachlins-position.php>. Fritzler discusses health and morality as playing a central role in the SCC's split reasoning in the AHRA reference decision.

[16] *R. v. Wetmore* (County Court Judge), [1983] S.C.J. No. 74, [1983] 2 SCR 284 at 288, per Laskin C.J. See also Mitchell, *supra* note 13.

[17] For a detailed overview of the legislation and the decision, see Ubaka Ogbogu, "Reference re Assisted Human Reproduction Act and the future of technology-assisted reproduction and embryo research in Canada" (2011) 19 Health LJ 153.

[18] S.C. 2004, c. 2.

[19] Ubaka Ogbogu, "The *Assisted Human Reproduction Act Reference* and the Thin Line Between Health and Crime" (2013) 22:1 Constitutional Forum 93. The nuances of the three decisions in this case have been interpreted in different ways including with respect to the substantive consideration of what constitutes a valid criminal law purpose and regarding the need for evidence supporting a risk of harm. See e.g. Fritzler, *supra* note 15. See also Mitchell, *supra* note 13 at 659-660.

[20] Ogbogu, *supra* note 19 at 94.

[21] *AHRA Reference*, *supra* note 12 at paras 234 – 243.

The extent of the federal government's power to use criminal law to regulate in a health-related area was tested again in *Reference re Genetic Non-Discrimination Act*.[22] The legislation at issue prohibited several activities related to genetic testing including requiring a genetic test as a condition of providing goods or services, entering into a contract or agreement, or offering or continuing specific terms or conditions; requiring disclosure of genetic test results for the same; and collecting, using or disclosing someone's genetic test results without their consent for any of those purposes.[23] The issue before the court was whether these prohibitions were *ultra vires* the federal government's jurisdiction over criminal law. The SCC was divided in their views.

Abella, Karakatsanis, and Martin JJ. found the legislation to be constitutional. They held that it serves to prevent threat of harm from genetic discrimination (or fear of it) to public interests including autonomy, privacy, equality, and public health, and that this is a valid criminal law purpose.[24] Concurring in the result, Moldaver and Côté JJ. agreed that the impugned provisions were a valid exercise of the federal criminal law power. They disagreed however regarding Karakatsanis J.'s characterization of the pith and substance of the legislation, holding that rather than preventing and prohibiting genetic discrimination, it primarily serves to protect health by prohibiting actions that deprive individuals of control over their genetic test results.[25] Wagner, Brown, Rowe, and Kasirer JJ. dissented, holding that the legislation's prohibitions are *ultra vires* the federal government's criminal law powers and fall instead under provincial authority over property and civil rights under s. 92(13) of the *Constitution Act, 1867*. They determined the pith and substance of the impugned provisions focuses on the regulation of contracts, including insurance and employment, as well as provision of goods and services, all of which fall under provincial jurisdiction.[26] They further noted the absence of an adequate evidentiary foundation of harm, which they suggest is necessary for valid criminal law.[27]

The closely split nature of this decision, like the *AHRA Reference*, reflects the complexity and evolving nature of division of powers issues with respect to the federal government's regulation of health using its criminal law powers. In work that pre-dated the *AHRA Reference* and *Reference re Genetic Non-Discrimination* cases, Jackman pointed to the SCC's reasoning in *RJR-MacDonald*[28] and in *R. v. Hydro-Québec*[29] as indications that the federal government may

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[22] *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17 [*Genetic Reference*]. This reference case initiated from Quebec. It is worth noting that somewhat unusually, the Attorney General of Canada joined the Attorney General of Quebec in arguing the legislation is unconstitutional. The Quebec Court of Appeal was left to appoint an *amicus curiae*, or friend of the court, to argue for its constitutionality.

[23] *Genetic Non-Discrimination Act*, SC 2017, c. 3. Violating these prohibitions is an offence punishable by either summary conviction or indictment (s. 7).

[24] *Genetic Reference*, *supra* note 22 at para 4.

[25] *Ibid* at paras 109-112.

[26] *Ibid* at paras 154, 203.

[27] *Ibid* at paras 259-267.

[28] *RJR-MacDonald Inc. v. Canada (Attorney General)*, 1995 CanLII 64 (SCC), [1995] 3 SCR 199 [*RJR-MacDonald*]. In *RJR-MacDonald*, a majority of the SCC held that it was within the jurisdiction of Parliament to enact the *Tobacco Products Control Act*, which included broad prohibitions of advertising and promotion of tobacco products, under the criminal law power or for the peace, orde,r and good government of Canada.

[29] *R. v. Hydro-Québec*, 1997 CanLII 318 (SCC), [1997] 3 SCR 213 [*Hydro- Québec*]. In *Hydro- Québec*, the SCC considered the constitutionality of environmental legislation that included prohibitions against toxic substances. The SCC held that it was a valid exercise of the federal government's criminal law power. Notably, the majority noted that the broad language of the act was unavoidable given the breadth and complexity of environmental protection.

legitimately use its criminal law power to support complex regulatory schemes intended to address activities that create risk to human health.[30] von Tigerstrom made a similar observation:

> In the case of the *Food and Drugs Act* regulatory scheme, as long as the aim of ensuring the safety, efficacy, and quality of medical products continues to be accepted as a legitimate criminal law purpose, we can probably be quite confident in saying that the regulatory scheme is a means to this end, rather than an attempt to regulate medical research and practice per se. This might even mean that the federal government has been more cautious than it needs to be in excluding matters that are considered part of medical practice (though this might be good policy for other reasons).[31]

For this research, it is sufficient to acknowledge that there are important and often controversial questions of jurisdiction when it comes to legislative authority over matters of health. These jurisdictional tensions are particularly relevant in relation to the use of criminal law to ground federal government regulation in areas otherwise generally considered to fall under provincial jurisdiction, including many aspects of health-related regulation.[32] Mitchell observes that while jurisprudential debates used to focus largely on how to define a valid criminal law purpose, the more pressing issue in recent decades has been on "how far is the reach of the criminal law power's regulatory function".[33] When considering federal government involvement in regulation and governance of access to unproven medical interventions, it will be important to account for the constitutional framework that shapes the division of powers in Canada. In the following sections I will discuss specific actors and areas of federal, provincial, and territorial activity that are important for regulation and governance of access to unproven medical interventions in Canada.

4.2.2 Federal government – important players

The federal government is engaged in the regulation and governance of access to unproven medical interventions in a variety of ways, including most notably in regulating the safety and efficacy of different kinds of health interventions, and in controlling aspects of the health information environment, including how health-related products and services are marketed to consumers. Health Canada and the Competition Bureau each play particularly relevant roles in this space, as does the federal government more broadly through the operation of the *Canada Health Act*[34], and via the Minister of Health. Each of these actors will be discussed in turn below, with reference to empowering legislation.

Health Canada is a federal department with the broad mission of "helping the people of Canada maintain and improve their health".[35] It does so via a wide range of activities including

[30] Martha Jackman, "Constitutional Jurisdiction", *supra* note 10.
[31] von Tigerstrom, "Federal Health Legislation", *supra* note 13 at 68.
[32] Mitchell, *supra* note 13.
[33] *Ibid* at 657.
[34] *Canada Health Act*, *supra* note 4.
[35] Health Canada, "About Mission, Values, Activities" (last modified 12 October 2011), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/mission-values-activities.html>.

"[p]roviding leadership in the development and enforcement of policy and regulations" with respect to biotechnology and health.[36] Health Canada's role in regulating health products including drugs, medical devices, and natural health products is particularly relevant for this research. Health Canada's public-facing communications stress that it does not authorize health products for sale unless it is "satisfied that: its benefits outweigh its risks; the evidence supports its health claims; the risks and uncertainties can be managed".[37] Health Canada uses a Decision-Making Framework to identify and manage health risks,[38] and its regulatory activities are divided among different units, each of which has particular expertise.

Health Canada's Therapeutic Products Directorate regulates the approval and advertising of prescription drugs in Canada pursuant to the authority of the *Food and Drugs Act*[39] and its regulations[40], which employ the federal government's criminal law powers.[41] The *Food and Drug Regulations*[42] establish requirements for various aspects of the sale of foods as well as prescription and non-prescription drugs, including their manufacture, labelling, distribution, and sale. They also set out requirements for clinical trials.[43] The *Medical Devices Regulations*[44] provide a classification framework for medical devices consisting of four risk classes, based on escalating risk of harm, with different requirements for each level. *The Safety of Human Cells, Tissues and Organs for Transplantation Regulations*[45] establish a regulatory framework, administered by the Biologics and Genetic Therapies Directorate, Health Products and Food Branch of Health Canada, that governs transplants of human cells, tissues, and organs in Canada. These regulations are relevant for unproven medical interventions that involve transplants of this nature.[46]

In exercising these regulatory responsibilities, Health Canada has an active communication agenda in which it seeks to engage with stakeholders including the public,

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[36] See Government of Canada, "Our Role; Canada's Biotechnology Strategy" (last modified 19 January 2006), online: <www.canada.ca/en/health-canada/services/science-research/emerging-technology/biotechnology/role.html>.
[37] Health Canada, "Regulating health products" (last modified 10 August 2020), online: <www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-regulates-1/health-products.html>.
[38] Health Canada, "Decision-Making Framework for Identifying, Assessing, and Managing Health Risks" (2000), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html>.
[39] *Food and Drugs Act*, RSC 1985, c F-27
[40] *Ibid*; *Food and Drug Regulations*, CRC, c 870 [*Food & Drug Regs*].
[41] Its constitutionality has been tested and confirmed on several occasions. Martha Jackman, "Constitutional Jurisdiction", *supra* note 10; See also Nola Ries, "Legal Foundations of Public Health in Canada" in Nola Ries, Tracey Bailey & Timothy Caulfield, eds, *Public Health Law and Policy in Canada*, 3rd ed (Markham, ON: LexisNexis, 2013) 7 at 13. For example, in *Canadian Generic Pharmaceutical Assn. v. Canada (Minister of Health)*, 2010 FCA 334 at para 122, the Federal Court of Appeal held that the *Food and Drug Regulations* provisions that protect the public from unsafe or ineffective drugs serve a valid criminal law purpose.
[42] *Food & Drug Regs, supra* note 40.
[43] A discussion of the specific merits and limitations of this regulatory regime is beyond the scope of this chapter. For deeper descriptions, see Paul B. Miller, "Institutional Oversight of Clinical Trials and the Drug Approval Process" (2006) 44 Osgoode Hall LJ 679 at para 43; Ron A. Bouchard & Monika Sawicka, "The Mud and the Blood and the Beer: Canada's Progressive Licensing Framework for Drug Approval" (2009) 3 McGill JL & Health 49.
[44] *Medical Devices Regulations*, SOR/98-282.
[45] *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, SOR/2007-118.
[46] For e.g. see Jolene Chisholm et al, "Workshop to Address Gaps in Regulation of Minimally Manipulated Autologous Cell Therapies for Homologous Use in Canada" (2017) 19:12 Cytotherapy 1400.

regulated parties, and the private sector. It does so "to facilitate the development of guidance documentation, and more broadly to ensure awareness of and promote compliance with regulatory requirements".[47] For example, Health Canada maintains a Guidance Document regarding Notice of Compliance for new drug submissions that is published by the Health Products and Food Branch, under the authority of the Minister of Health.[48] It sets out processes for drug products that have shown promising clinical benefit, high quality, and an acceptable safety profile as determined by an assessment of its risks and benefits.[49] This document confirms that Health Canada's guidance documents do not have force of law and allow for flexibility in approach. Its policy objectives stress the balance between facilitating "access to promising new drugs for patients suffering from serious, life-threatening or severely debilitating diseases or conditions for which no drug is presently marketed in Canada or for which a significant increase in efficacy or a significant decrease in risk is demonstrated in relation to an existing drug marketed in Canada", and promoting transparency and mechanisms to complete trials in order to verify the clinical benefits of such drugs.[50]

Together with the Public Health Agency of Canada, which is another federal institution under the government's Health portfolio,[51] Health Canada also uses a Strategic Risk Communication Framework intended to provide support with managing and communicating about risk with stakeholders.[52] In this vein, Health Canada produces alerts and information updates tailored for different audiences, including the public and healthcare professionals, regarding emerging safety issues associated with different medical interventions.[53] Accordingly, Health Canada has varied regulatory and governance instruments at its disposal when it comes to influencing access to medical interventions in Canada. The case studies presented in Chapters 5-7 will include discussions of several of these different instruments, and accompanying evidence regarding the apparent goals or purposes underlying the associated regulatory or governance activities.

The federal Competition Bureau has significant powers of oversight with respect to the information environment for health products and services. More specifically, it is responsible for

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[47] Health Canada, "Policy on Providing Guidance on Regulatory Requirements" (last modified 31 March 2019), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/interpretation-policy.html>.

[48] Health Canada, "Guidance Document: Notice of Compliance with conditions (NOC/c)" (2002, last modified16 September 2016), online (pdf): *Health Products and Food Branch* <www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.pdf>.

[49] *Ibid* at 2.

[50] *Ibid* at 1-2.

[51] The Public Health Agency of Canada (PHAC) is engaged in varied activities related to public health including, though not limited to, disease surveillance, immunization and vaccine programs, health promotion, and emergency preparedness and response. It does not play a large role with respect to the subject of this research but may be relevant where it engages in monitoring and managing public health risks and communicating with the public.

[52] Health Canada, "Risk Communications" (last modified 9 January 2007), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/risk-communications.html>.

[53] For an example relating to a purported treatment for COVID-19, see Health Canada, "Chloroquine and hydroxychloroquine can have serious side effects. These drugs should be used only under the supervision of a physician" (last modified 15 June 2020), online: <www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72885a-eng.php>.

the administration and enforcement of the *Competition Act*,[54] and seeks to protect and promote competitive markets as well as enable "informed consumer choice".[55] Among other functions, the *Competition Act* prohibits false or misleading representations and deceptive marketing practices. It includes both civil[56] and criminal law[57] enforcement mechanisms. Its jurisdiction covers representations made "to the public", which is not confined to the Canadian public,[58] and addresses products and services. Whether a representation is false or misleading in a material respect is governed using the general impression test, which looks not only at the literal meaning of the representation, but the general impression it conveys.[59] Although enforcement is a separate and important question, the *Competition Act*'s regulatory regime is a noteworthy mechanism for restricting deceptive marketing practices regarding unproven medical interventions, including in online contexts.[60]

Broader discussions of the federal government's role in health governance often focus on the use of its spending power, exercised through the *Canada Health Act*[61], which is the vehicle for federal health transfers to the provinces.[62] The *Canada Health Act* establishes the five principles generally considered to define the nature of Canada's Medicare system. These principles include public administration, comprehensiveness, universality, portability, and accessibility.[63] In theory, provinces and territories must comply with these principles in order to be eligible to receive their full share of the Canada Health Transfer,[64] though enforcement under the *Canada Health Act* has historically been minimal.[65] Unproven medical interventions are generally provided on a private market basis, outside the bounds of publicly funded healthcare systems in Canada, and thus do not necessarily engage the principles of the *Canada Health Act*. Nonetheless, demands for public funding for these interventions may engage broader related debates about the future of public and private healthcare in Canada.

Finally, in addition to areas of specific legislative powers, including those outlined above, the *Department of Health Act*[66] also provides the federal Minister of Health with general powers,

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[54] *Competition Act*, *supra* note 7.
[55] Competition Bureau Canada, "False or Misleading Representations and Deceptive Marketing Practices" (last modified 20 January 2022), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.Nsf/eng/03133.html>.
[56] *Competition Act*, *supra* note 7 at s 74.01(1)(a).
[57] *Ibid* at s. 52.
[58] *R v Stucky*, 2009 ONCA 151.
[59] *Competition Act*, *supra* note 7 at s 52(4), s 52.01(5), s 74.011(4).
[60] For example, the Competition Bureau issued public notices and compliance warnings to businesses in Canada that were making potentially false or misleading claims regarding the ability of their products or services to prevent COVID-19. See Competition Bureau Canada, "COVID-19: What the Competition Bureau is doing" (last modified 20 January 2022), online: <www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/h_04525.html>.
[61] *Canada Health Act*, *supra* note 4 at s 7.
[62] As von Tigerstrom observes, the *Canada Health Act* relies on the federal government's spending power for its jurisdictional validity. See von Tigerstrom, "Federal Health Legislation", *supra* note 13 at 34.
[63] *Canada Health Act*, *supra* note 4 s 7.
[64] *Ibid*.
[65] Katherine Fierlbeck, *Health Care in Canada: A Citizen's Guide to Policy and Politics* (Toronto: University of Toronto Press, 2011) at 22; Barbara Sibbald & Matthew Stanbrook, "Canada Health Act needs bite" (2016) 188(16) CMAJ 1133; for a summary of new Government of Canada initiatives regarding enforcement of the *Canada Health Act* in the context of diagnostic services (i.e. to eliminate user fees), see Government of Canada, "Backgrounder: New Canada Health Act Initiatives" (August 2018), online: < www.canada.ca/en/health-canada/services/health-care-system/canada-health-care-system-medicare/canada-health-act/new-initiatives.html>.
[66] *Department of Health Act*, SC 1996, c 8.

duties, and functions "relating to the promotion and preservation of the health of the people of Canada not by law assigned to any other department, board or agency of the Government of Canada".[67] Accordingly, the Minister of Health has broad and far reaching influence beyond the particulars of specific legislation, which is relevant to considerations of options regarding regulation and governance of access to unproven medical interventions.

4.2.3 Provincial government – areas of engagement

Provincial and territorial governments are responsible for several areas of healthcare organization and administration that are particularly relevant for access to unproven medical interventions. This section will focus on funding and oversight by way of regulation. Provinces and territories decide what health products and services will receive public funding within their respective health insurance programs or, in other words, what is deemed to be medically necessary and falling in the "medicare basket".[68] For example, in Saskatchewan, the *Saskatchewan Medical Care Insurance Act*[69] and its regulations provides the authority and mechanisms for the province's medical care insurance program and payments to physicians.[70] These funding decisions are critically important when it comes to meaningful access to medical interventions. In the absence of public funding, the high cost of some medical interventions can effectively preclude access for many Canadians, particularly those who lack sufficient resources to self-fund their care or the ability to advocate effectively for other sources of support where private insurance is not available. These concerns sometimes rise in public prominence in the context of high-cost pharmaceuticals,[71] or surgical delays.[72] Funding decisions can also serve a vetting role when medical interventions without sufficient evidence of safety and efficacy are not supported through public funding. To some extent, this process is reflected in some provincial and territorial rules regarding reimbursement for non-emergent out-of-country medical expenses. For example, Ontario's *Health Insurance Act*[73] sets out the framework for Ontario's Health Insurance Plan, and its *General Regulation*[74] establishes conditions under which out of country medical or surgical services are deemed insured services eligible for payment. Included among these conditions is the requirement that the service be "generally accepted by the medical

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[67] *Department of Health Act*, SC 1996, c 8 at s 4.
[68] Colleen Flood, Mark Stabile & Carolyn Tuohy, *Defining the Medicare "Basket"* (Canadian Health Services Research Foundation, 2008).
[69] *Saskatchewan Medical Care Insurance Act*, RSS 1978, c S-29, RSS 1978, c S-29.
[70] *The Insured Services (Physicians) Access Regulations*, 1987, RRS c S-29 Reg 12; *The Insured Services (Physicians) Payment Schedule Review Regulations*, 1989, RRS c S-29 Reg 15; Details of payment schedules are made by agreement between the provincial Minister of Health and the Board of Directors of the Saskatchewan Medical Association. See e.g. online: <https://www.ehealthsask.ca/services/resources/Resources/SMA-agreement.pdf>.
[71] For an overview of provincial and territorial reimbursement strategies for rare diseases see Devidas Menon, Derek Clark & Tania Stafinksi, "Reimbursement of Drugs for Rare Diseases through the Public Healthcare System in Canada: Where Are We Now?" (2015) 11:1 Healthcare Policy 15. For an example of media coverage, see Amanda Pfeffer, "Patient with rare disease pleads for life-saving drug funding", *CBC News* (17 June 2019), online: <www.cbc.ca/news/canada/ottawa/rare-disease-rituximab-payment-pharmacare-1.5172457>.
[72] *Cambie Surgeries Corporation v British Columbia (Attorney General)*, 2020 BCSC 1310, aff'd 2022 BCCA 245 [*Cambie*] was an unsuccessful *Charter* challenge to British Columbia's legislative prohibition against private billing by physicians enrolled in the Medical Services Plan based on alleged infringement of patients' s.7 *Charter* rights. It tested the question of rights as they relate to surgical waits.
[73] RSO 1990, c H.6.
[74] RRO 1990, Reg 552.

profession in Ontario as appropriate for a person in the same medical circumstances as the insured person" and that it be "medically necessary".[75]

Provinces and territories can also exert influence over access to medical interventions, both established and unproven, via their regulation of healthcare facilities. Specific approaches vary across the country, but in general provinces use legislation and regulations to establish requirements for the operation of both public and private hospitals and non-hospital facilities, such as clinics of various forms.[76] For example, in Saskatchewan *The Health Facilities Licensing Act*[77] establishes licensing requirements for health facilities,[78] and provides broad regulatory powers to the Lieutenant Governor in Council, including regarding quality and standards, employee qualifications, and the care, treatment, and services that are provided in the facility.[79] The *Health Facilities Licensing Regulations*[80] establish the College of Physicians and Surgeons of Saskatchewan's accreditation program as the prescribed program for health facilities where physician services are provided.[81] Whether current frameworks provide sufficient oversight and enforcement of private clinics across Canada is an open question and a matter of some debate.[82] Nonetheless, provinces and territories arguably have jurisdiction to provide oversight of facilities where unproven medical interventions are provided in order to ensure, at minimum, that basic safety standards are met.[83]

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[75] *Ibid*, s 28.4(2). Advance written approval from the General Manager is also required for services rendered in non-emergent circumstances.

[76] For example, Ontario regulates public and private hospitals separately. See *Public Hospitals Act*, R.S.O. 1990, c. P.40 and *Private Hospitals Act*, R.S.O. 1990, c. P.24.

[77] *The Health Facilities Licensing Act*, SS 1996, c H-0.02.

[78] "Health facilities" are defined as "any place or facility where a diagnostic or therapeutic medical procedure is provided", excepting those operated by the minister, provincial health authority or an affiliate, and any prescribed in regulation to not be a health facility. See *The Health Facilities Licensing Act*, SS 1996, c H-0.02 at s 2.

[79] *The Health Facilities Licensing Act*, SS 1996, c H-0.02 at s 29.

[80] RRS c H-0.02 Reg 1 at s 3.

[81] The College of Physicians and Surgeons of Saskatchewan has adopted the following: College of Physicians and Surgeons of Alberta, "Non-Hospital Surgical Facility General Standards" (2015), online (pdf): <cpsa.ca/wp-content/uploads/2015/03/NHSF_Standards.pdf>. See College of Physicians and Surgeons of Saskatchewan, "Non-Hospital Treatment Facilities" (last visited 23 May 2022), online: <www.cps.sk.ca/imis/CPSS/Programs_and_Services/Non-Hospital_Treatmeant_Facilities.aspx?NonHospitalCCO=1#NonHospitalCCO>, and College of Physicians and Surgeons of Saskatchewan, "Bylaw 26.1 - Operation of Non-Hospital Treatment Facilities in the Province of Saskatchewan" (last visited 23 May 2022), online (pdf): <www.cps.sk.ca/imis/Documents/Programs%20and%20Services/NHTF/Bylaw%2026.1.pdf>..

[82] Dan Lett, "Private health clinics remain unregulated in most of Canada" (2008) 178:8 CMAJ 986; see also Charlene R. Pries, Sharon Vanin & Rosario G. Cartagena, "Regulation and Oversight of Independent Health Facilities in Canada" (2014) 34:3 Health L Can 61 at 61; see also Louise Shap, "Private Clinics in Ontario: What They Are and What They Are Not Clearing the Muddied Waters" (2006) 27:1 Health L Can 1.

[83] Efforts to strengthen regulation of such facilities would accord with ongoing regulatory improvement initiatives. See e.g. Health Quality Ontario, "Building an Integrated System for Quality Oversight in Ontario's Non- Hospital Medical Clinics" (last visited 23 May 2022), online (pdf): <www.hqontario.ca/Portals/0/documents/healthquality/building-an-integrated-system-quality-oversight-en.pdf> at 4; College of Physicians and Surgeons of Ontario, "Submission: The Regulation of Facilities: Looking Forward" (2015), online (pdf): <www.cpso.on.ca/CPSO/media/documents/CPSO%20Members/OHPIP/HQO-Submission.pdf> at 6, 9-12.

4.2.4 The courts, the *Charter*, and rights-based access claims

When governments limit or restrict access to medical interventions, including unproven medical interventions, individuals may have the option of turning to the courts to seek a remedy. There is no constitutionally entrenched right to health or healthcare in Canada.[84] This is a source of some criticism including the suggestion that Canada is failing with respect to its international human rights obligations.[85] However, the *Charter* protects several rights that are potentially engaged by issues relating to access to healthcare interventions and, as such, gives individuals a vehicle to advance rights-based claims for access to medical interventions.[86] *Charter* jurisprudence regarding health-related access issues is nuanced and complex, and there is a rich body of scholarship surrounding both leading decisions and broader debates about the role of the *Charter* in this area,[87] much of which exceeds the scope of this chapter. In this section, I will provide a 'big picture' overview of how the *Charter* might factor into claims for access to unproven medical interventions in Canada. This discussion will proceed in three parts. I will first provide a brief overview of the *Charter* and its application. I will then present examples of what I see as the most likely types of *Charter* claims in the context of access to unproven medical interventions, and will situate these examples within SCC jurisprudence. I will conclude the section by acknowledging the limits of rights-based access claims.

The *Charter* protects the rights of individuals against unreasonable limitation by federal, provincial, and territorial governments.[88] Arms-length and potentially even private entities, such as hospitals, can also be subject to the *Charter* in relation to their implementation of government policy and provision of publicly funded healthcare services,[89] as can administrative decision-makers, such as professional regulatory bodies.[90] Courts have broad powers to remedy breaches

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[84] Health does not feature as a heading in the *Constitution*, nor is it directly addressed in the *Charter*. Courts have also consistently held that the *Charter* does not ground a right to healthcare. E.g. see *Flora v. Ontario (Health Insurance Plan, General Manager)*, 2008 ONCA 538.

[85] Canada is party to several international human rights treaties that recognize a right to health, including the *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 2200A (XXI) GA (entered into force 3 January 1976), Art. 12. Although a detailed discussion of the use of human rights frameworks in the context of health claims is beyond the scope of this paper, there is a body of literature addressing this issue. For example, see Barbara von Tigerstrom, "Human Rights and Health Care Reform: A Canadian Perspective" in Timothy A. Caulfield & Barbara von Tigerstrom, eds, *Health Care Reform & the Law in Canada; Meeting the Challenge* (Edmonton: University of Alberta Press, 2002) 157; see also Martha Jackman, "The Future of Health Care Accountability: A Human Rights Approach" (2016) 47:2 Ottawa L Rev 437.

[86] See Nola Ries, "Charter Challenges" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds, *Canadian Health Law and Policy*, 4th ed (Toronto: LexisNexis, 2011) 615 [Ries, "Charter Challenges"]; Martha Jackman, "Charter Review of Health Care Access" in Joanna E. Erdman, Vanessa Gruben & Erin Nelson, eds, *Canadian Health Law and Policy*, 5th ed, (Toronto: LexisNexis, 2017) 71 [Jackman, "Charter Review"].

[87] The importance of social, political, and economic factors in limiting the power of rights-based strategies must also be acknowledged. See Colleen Flood & Y Brandon Chen, "Charter Rights & Health Care Funding: A Typology of Canadian Health Rights Litigation" (2010) 19 Ann Health L 479; Mark Tushnet, "The Critique of Rights" (1993) 47 SMU L Rev 23.

[88] *Canadian Charter of Rights and Freedoms*, s 7, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, s 32 [the *Charter*].

[89] *Eldridge v. British Columbia (Attorney General)*, [1997] S.C.J. No. 86, [1997] 3 SCR 624. See also Martha Jackman, "The Application of the Canadian Charter in the Health Care Context" (2000) 9:2 Health L Rev 22; see also Ries, "Charter Challenges", *supra* note 86 at 618.

[90] Administrative decisions that engage *Charter* rights are reviewed using what is commonly referred to as the *Doré/Loyola* framework, set out in *Doré v. Barreau du Québec*, 2012 SCC 12 and *Loyola High School v. Quebec (Attorney General)*, 2015 SCC 12. In the recent companion cases of *Law Society of British Columbia v. Trinity*

of *Charter* rights.[91] Section 24(1) of the *Charter* provides that "[a]nyone whose rights or freedoms, as guaranteed by this Charter, have been infringed or denied may apply to a court of competent jurisdiction to obtain such remedy as the court considers appropriate and just in the circumstances".[92] Section 52 of the *Constitution Act, 1982* provides that "any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect".[93] These provisions provide a mechanism for the courts to play an influential role in clarifying the content of Canadians' rights and freedoms and in shaping the law (e.g. with declarations of invalidity, striking down offending provisions, reading in, orders of mandamus, etc.) to ensure compliance with the *Charter*.[94]

Charter rights are not absolute. Whether or not infringements can be justified depends on an analysis under s. 1 of the *Charter* which provides as follows:

> 1. The Canadian Charter of Rights and Freedoms guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Section 1 of the *Charter* only applies to limitations of rights or freedoms that are "prescribed by law". In other words, the limitation must be legally authorized by, for example, a statute, regulation, government policy, or common law rule. The phrase "prescribed by law" requires that the law be publicly accessible and sufficiently precise, such that it enables people to use it to guide their behaviour and to apply it.[95] Pursuant to the framework established in *R. v. Oakes*[96], in determining whether a limitation to a *Charter* right that is prescribed by law is justified, courts will first consider whether the objective of the law that imposes the limitation is pressing and substantial. Laws that pass the first step are then subject to a proportionality analysis. The first consideration of the proportionality analysis is whether the law in question is rationally

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Western University, 2018 SCC 32 and *Trinity Western University v. Law Society of Upper Canada*, 2018 SCC 33, the SCC outlined that under the *Doré/Loyola* framework, courts reviewing an administrative decision that engages *Charter* rights for reasonableness must consider whether the administrative decision reflects a proportionate balancing of the *Charter* rights with the administrative decision-maker's statutory mandate. The court must also consider whether there were other reasonable alternatives, and must balance the extent of the *Charter* limit or infringement against the benefits of the statutory objectives.

[91] For an historical look at the evolution of remedies under sections 24(1) and 52(1) of the *Charter*, see Debra McAllister, "Charter Remedies and Jurisdiction to Grant Them: The Evolution of Section 24(1) and Section 52(1)" (2004) 25 SCLR (2d) 1.

[92] *Charter*, *supra* note 88, s 24(1).

[93] *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11, s 52.

[94] Section 33 of the *Charter* provides Parliament and provincial legislatures with the power to pass legislation notwithstanding a provision in section 2 or sections 7-15 of the *Charter*. However, the Notwithstanding Clause, as it is commonly referred to, is often observed to be a (potentially) politically laden and controversial option. See Dwight Newman, "Canada's Notwithstanding Clause, Dialogue, and Constitutional Identities" (2017), online: <papers.ssrn.com/sol3/papers.cfm?abstract_id=301978>; Mark Carter, "Diefenbaker's Bill of Rights and the Counter-Majoritarian Difficulty: The Notwithstanding Clause and Fundamental Justice as Touchstones for the Charter Debate" (2019) 82:2 Sask L Rev 121 at 141-142; Meghan Campbell, "Reigniting the Dialogue: The Latest Use of the Notwithstanding Clause in Canada" (2018) 1 Public Law 1 at 2.

[95] See Hogg & Wright, *supra* note 5 at 38:7; see also *Greater Vancouver Transportation Authority v. Canadian Federation of Students — British Columbia Component*, 2009 SCC 31, where the SCC held that the government policies at issue were authorized by statute and intended to be binding, and thus satisfied the "prescribed by law" requirement in section 1 of the *Charter*.

[96] [1986] 1 SCR 103, 26 DLR (4th) 200.

connected to the objective. Courts will then consider whether the law is minimally impairing and, finally, whether there is proportionality between the limitations' harms and benefits. The balancing exercise embedded within the s.1 analysis has played a critical role in *Charter* jurisprudence, including with respect to health-related entitlement and access claims, and will likely continue to be highly influential as this body of jurisprudence evolves.[97]

To date, the most influential *Charter* claims relating to access to healthcare interventions have been based on the fundamental justice (s.7) and equality (s.15) provisions of the *Charter* which provide as follows:

> 7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.
>
> …
>
> 15. (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.[98]

When considering whether an individual's s. 7 rights have been violated, courts first look at whether there has been a deprivation of life, liberty, or security of the person. If so, the next step is for the court to consider whether that deprivation violated one or more principles of fundamental justice, which include principles against arbitrariness, overbreadth, and gross disproportionality.[99] In order to establish that their s. 15(1) rights have been violated, a plaintiff must first show that the impugned law creates a distinction, on the face of the law or in its impact, based on an enumerated or analogous ground.[100] The second step of a s.15(1) analysis focuses on whether the distinction imposes a burden or denies a benefit in a way that reinforces, perpetuates, or exacerbates disadvantage.[101] The SCC's approach to this question has evolved over time. Most recently, it has emphasized the importance of a substantive equality analysis that considers the context, including but not limited to historical discrimination.[102]

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[97] Sections 1 and 7 are noted to have a particularly complex relationship in *Charter* jurisprudence, in part because s 7 contains its own limiting provision – "except in accordance with the principles of fundamental justice", which has its own tests. For a recent analysis of the evolving relationship between these sections, see Mark Carter, "Sections 7 and 1 of the Charter after Bedford, Carter and Smith: Different Questions, Same Answers?" (2017) 64 Crim LQ 108.
[98] *Charter, supra* note 88, ss 7 & 15.
[99] *Carter, supra* note 40 at paras 55 and 72.
[100] Enumerated grounds are those listed in s 15(1). Analogous grounds are similar to enumerated grounds in that they are immutable or unchangeable personal characteristics, such as sexual orientation. See *Egan v. Canada*, [1995] 2 SCR 513; see also *Reference re Same-Sex Marriage*, [2004] 3 SCR 698.
[101] The SCC's approach to the s 15(1) analysis has continued to develop and shift since it formalized its original three-part test in *Law v. Canada*, [1999] 1 SCR 497. The current approach noted here reflects evolutions in the court's approach following its decisions in *R. v. Kapp*, 2008 SCC 41, *Withler v. Canada (Attorney General)*, 2011 SCC 12, *Quebec (Attorney General) v. A*, 2013 SCC 5, *Kahkewistahaw First Nation v. Taypotat*, 2015 SCC 30. For a summary of the history of this evolution, see Robert Mason, "Section 15 of the Canadian Charter of Rights and Freedoms: The Development of the Supreme Court of Canada's Approach to Equality Rights Under the Charter (Hill Studies)", Publication No. 2013-83-E (Ottawa: Library of Parliament, 2022), online (pdf): <lop.parl.ca/staticfiles/PublicWebsite/Home/ResearchPublications/HillStudies/PDF/2013-83-E.pdf>.
[102] See *Fraser v. Canada (Attorney General)*, 2020 SCC 28.

Section 7 of the *Charter* has been used with some success by litigants who have framed healthcare-related access claims within a "negative rights" framework, challenging regulatory regimes based on criminal law. Negative rights are often characterized as rights of non-interference or, in other words, as requiring government to abstain from curtailing rights or to remove barriers that amount to a breach of a fundamental right. For example, in *R. v. Morgentaler*[103], the SCC struck down the *Criminal Code* provisions prohibiting abortion after finding that they unjustifiably infringed women's s.7 rights to security of the person, which include being able to access medical treatment for conditions threatening life or health without fear of criminal sanction.[104] In *Carter v. Canada*[105], the SCC held that the *Criminal Code* prohibitions against physician-assisted death for competent adults experiencing enduring and intolerable suffering due to a grievous and irremediable medical condition unjustifiably infringed s.7 rights to life, liberty, and security of the person in a manner that violated the principles of fundamental justice, and issued a declaration of invalidity.[106] In *Smith*[107], the SCC held that the prohibition on possession of non-dried forms of medical marihuana violated s.7 by arbitrarily and unjustifiably limiting liberty and security of the person, insofar as it imposed threat of imprisonment and forced choice "between a legal but inadequate treatment and an illegal but more effective one".[108] The SCC declared the impugned provisions to be "of no force and effect, to the extent that they prohibit a person with a medical authorization from possessing cannabis derivatives for medical purposes".[109]

In the context of rights-based access claims to unproven medical interventions, a negative rights claim could, for example, take the shape of a s. 7 *Charter* challenge to the *Food and Drugs Act* and its regulations which restrict access to unproven stem cell therapies (as discussed in Chapter 7).[110] It is possible the above line of cases could be used to argue that government intrusions restricting individuals from accessing that particular medical intervention violate a "sphere of autonomy in which government should not interfere".[111] Such a claim would require the applicant to demonstrate that the prohibitions or restrictions deprive them of life, liberty, or security of the person, and in a manner that violates the principles of fundamental justice. Even if a litigant were successful in persuading the court that their s. 7 *Charter* rights had been breached, whether any such *Charter* violation would be saved under s. 1 of the *Charter* would depend on the circumstances and evidence before the court. Generally, where a court finds a violation of s. 7 of the *Charter*, it is unlikely it will be saved under s.1 because of the overlap between some of

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[103] [1988] 1 SCR 30 [*Morgentaler*].
[104] Similar reasoning was later applied in *R v. Parker*, 49 OR (3d) 481, 188 DLR (4th) 385 (ON CA).
[105] *Carter*, *supra* note 40.
[106] See *Ibid* at paras 68 and 86, where the SCC finds the prohibition to be overbroad. The SCC suspended the declaration of invalidity for 12 months to give federal and provincial governments time to respond by enacting new legislation (at paras 126-128).
[107] 2015 SCC 34 [*Smith*].
[108] *Ibid* at para 18.
[109] *Ibid* at para 31. The impugned provisions were ss 4(1) and 5(2) of the *Controlled Drugs and Substances Act*, SC 1996, c. 19.
[110] For an overview of regulation of advanced medicinal products in Canada current to 2015, see Sowmya Viswanathan & Tania Bubela, "Current practices and reform proposals for the regulation of advanced medicinal products in Canada" (2015) 10:5 Regenerative Medicine 647. Penalties for offences relating to therapeutic products under the *Food and Drugs Act*, RSC 1985, c F-27, s 31 or its regulations include fines and/or imprisonment.
[111] Nola Ries, "Section 7 of the Charter: A Constitutional Right to Health Care? Don't Hold Your Breath" (2003) 12:1 Health L Rev 29 at paras 7-8 [Ries, "Section 7"].

the points of analysis in these sections. However, it is still conceivable that a law found to violate s.7 for overbreadth could be saved under s. 1, for example, by being minimally intrusive.[112]

Chaoulli v. Quebec (Attorney General)[113] and *Cambie Surgeries Corporation v British Columbia (Attorney General)*[114] were two other high-profile *Charter* cases where the plaintiffs used negative rights-based arguments under s. 7 (*Chaoulli* and *Cambie*) and s.15 (*Cambie*) of the *Charter* to challenge provincial legislation. Although the facts, specific claims, and outcomes of these cases were different, both focused on legislation that in effect served to limit the availability and accessibility of private market options for healthcare services that were also available in the publicly funded healthcare systems. This focus on publicly funded, medically necessary healthcare services and on the impacts of long wait times in the public system distinguishes these cases from the unproven medical interventions that are the subject of this research. Accordingly, while these cases prompted widespread debate about their implications for the future of private and public healthcare in Canada[115], they likely do not help us anticipate the probable outcome of possible future *Charter* challenges focused on access to unproven medical interventions that are not available in the public system.

In contrast to negative rights claims which focus on not intervening or removing barriers, positive rights require governments to act, typically by providing programs, services, or funding.[116] Litigants seeking funding or other access to health-related services have used both s. 7 and s. 15 of the *Charter* to ground positive rights-based access claims. However, thus far the SCC and other courts have typically declined to impose positive obligations on governments to fund healthcare interventions,[117] preferring instead to exercise considerable deference to government choices where there are resource allocation implications.[118]

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[112] Carter, *supra* note 97 at 2 (cited to pdf). Carter notes there are enforcement and other practical reasons for why this distinction might be drawn.

[113] 2005 SCC 35 [*Chaoulli*]. In *Chaoulli*, a patient and a physician challenged Quebec's legislation that prohibited private health insurance. In a divided opinion (3:3:1), the majority held that the impugned provisions violated the *Quebec Charter of Human Rights and Freedoms* in violating right to life and personal inviolability by increasing risk of mortality, causing pain, and reducing quality of life, and that they could not be saved under s 9 because of a lack of proportionality. The court was split on whether the restrictions also violated the *Charter*.

[114] *Cambie, supra* note 72.

[115] See e.g. Colleen Flood, "Chaoulli's Legacy for the Future of Canadian Health Care Policy" (2006) 44 Osgoode Hall LJ 273. Flood referred to *Chaoulli* as a "fork in the road" for Canadian medicare; see also Mel Cousins, "Health Care and Human Rights after Auton and Chaoulli," (2009) 54 McGill LJ 717. Cousins suggests courts have taken a "limited view of Chaoulli"; see also Danielle Martin et al, "Canada's universal health-care system: achieving its potential" (2018) 391:10131 Lancet 1718; see also Colleen Flood, "Two-tier healthcare after Cambie" (2021) 34:4 Healthcare Management Forum 221.

[116] Ries, "Charter Challenges", *supra* note 86 at 616; see also Matthew Voell, "PHS Community Services Society v. Canada (Attorney General): Positive Health Rights, Health Care Policy, and Section 7 of the Charter" (2012) 31 Windsor Rev Leg Soc Issues 41 at 53-54.

[117] Ries, "Section 7", *supra* note 111.

[118] Lawrence David, "Resource Allocation and Judicial Deference on Charter review: The Price of Rights Protection According to the McLachlin Court" (2015) 73:1 UT Fa L Rev 35 at para 12. It is important to note that this distinction is not without its critics, including those who argue that it is incompatible with substantive equality, which focuses on equality of outcome rather than formal equality. See Cara Wilkie & Meryl Zisman Gary, "Positive and Negative Rights Under the Charter: Closing the Divide to Advance Equality" (2011) 30 Windsor Rev Leg Soc Issues 37.

For example, in *Cameron v. Nova Scotia*[119], the Nova Scotia Court of Appeal held that although the exclusion of certain assisted reproductive technologies as insured services under the publicly funded healthcare system violated s. 15 of the *Charter*, the exclusion was justified under s.1 given the need to control healthcare costs in the context of limited financial resources. In *Auton (Guardian ad litem of) v. British Columbia (Attorney General)*[120], the SCC held that the province's failure to fund ABA/IBI treatment for all autistic children between 3-6 years of age did not violate the claimants' s. 15 rights because funding for all medically required treatment is not a benefit provided by law, and there was no exclusion based on disability.[121] Similarly, in *Flora v Ontario*[122], the province's decision not to fund a life-saving organ transplant that was deemed not to be an "insured service" did not violate the claimant's s. 7 *Charter* rights. The Ontario Court of Appeal held that s. 7 does not impose a positive obligation on government to fund out of country medical treatments, even if they are life-saving.[123] Rather, a government's obligation is to not act in a discriminatory manner when implementing policy. This obligation was reflected in the SCC's decision in *Eldridge v. British Columbia (Attorney General)*[124], where the SCC held that the failure of provincial legislation to provide sign language interpretation where necessary for effective communication violated the s.15 *Charter* rights of deaf persons. The court directed the government of British Columbia to administer the legislation in a manner consistent with s.15. Although notable for its foray into a matter of provincial funding, *Eldridge* has been characterized narrowly to require provision of services in a non-discriminatory manner, but not to require an increase or expansion of services.[125]

In the context of this research, it seems most likely that a positive rights claim might take the shape of a claimant using s. 7 or s. 15 of the *Charter* to argue that government should fund or provide a particular unproven intervention. For example, arguments of this nature were made in relation to liberation therapy to treat multiple sclerosis (see Case 2, Chapter 6). There is some support in the literature for an expanded approach to s. 7 that might encourage positive rights claims of this nature, including those that "enable individuals to take control of their lives".[126] There is also an argument that a more fulsome application of s. 15 in the context of access claims to health services, with greater consideration of the equality rights

[119] (1999), 177 DLR (4th) 611; 1999 CanLII 7243 (NS CA), cited to CanLII [*Cameron*] at paras 208 and 234-245. When considering whether particular assisted reproduction technologies were medically necessary, the Nova Scotia Court of Appeal accepted the trial judge's conclusion that determinations regarding what is and is not medically necessary are policy decisions towards which it is appropriate that courts show considerable deference (at para 101).
[120] [2004] 3 SCR 657, 2004 SCC 78 [*Auton*].
[121] It is worth noting that medical necessity is a fraught concept. See e.g. Timothy Caulfield, "Wishful thinking: defining 'medically necessary' in Canada" (1996) 4 Health LJ 63; see also J.C. Herbert Emery & Ronald , "The challenge of defining Medicare coverage in Canada" (2013) SPP Res Paper No. 6-32, online: <papers.ssrn.com/sol3/papers.cfm?abstract_id=2341234>.
[122] *Flora v Ontario (Health Insurance Plan, General Manager)*, 2008 ONCA 538.
[123] *Ibid* at para 108.
[124] 1997 CanLII 327 (SCC), [1997] 3 SCR 624.
[125] Ries, "Charter Challenges", *supra* note 86 at 628.
[126] Kai Möller, "Two Conceptions of Positive Liberty: Towards an Autonomy-based Theory of Constitutional Rights" (2009) 29:4 Oxford J Leg Studies 757 at 758; see also Hilary Young, "A Proposal for Access to Treatment Contrary to Clinical Judgment" (2017) 11:2 McGill JL & Health 1 at para 5; see also Margot Young, "The Other Section 7" (2013) 62 SCLR (2d) 3 at paras 5 & 95.

implications of these cases, would be valuable and provide clearer guidance to governments regarding their rights obligations.[127]

However, other legal scholars have pointed to the jurisprudence and argued that it is unlikely the SCC will interpret s. 15 or 7 to include a positive right to publicly funded healthcare services.[128] The allocation of limited healthcare resources is generally acknowledged to be a matter of policy meriting considerable judicial deference, which is likely to impede successful constitutional rights-based challenges seeking funding for particular services.[129] Such a challenge seems even less likely to succeed in the case of an unproven medical intervention, where evidence regarding safety and efficacy is lacking. It is also worth noting that legal rights-based victories do not necessarily translate to effective policy implementation or meaningful access.[130] In summary, it seems unlikely that positive rights-based funding claims will factor significantly into changing the landscape regarding access to unproven medical interventions in Canada any time soon. The potential success of a negative rights-based access claim seeking to remove barriers that prevent access is another matter. It is conceivable that such a claim for access to other unproven medical interventions could succeed, depending on the facts and evidence before the court.

4.3 Oversight of Providers

In the following sections, we will turn our focus to three critical areas of oversight for the professional conduct of physicians who provide unproven medical interventions. These forms of oversight include the role of medical professional self-regulation, tort law, and research ethics frameworks.

4.3.1 The role of medical self-regulation

Professional regulation is an important part of health system governance in Canada and a vital consideration in the regulatory and governance landscape regarding access to medical

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[127] See e.g. Emmett Macfarlane, "Dialogue, Remedies, and Positive Rights: Carter v Canada as a Microcosm for Past and Future Issues Under the Charter of Rights and Freedoms" (2017) 49:1 Ottawa L Rev 107; see also Jackman, "Charter Review", *supra* note 86 at 74, where Jackman critiqued "undue judicial deference to governments' funding choices".

[128] Ries, "Section 7", *supra* note 111; see also Barbara Billingsley & Peter Carver, "Sections 7 and 15(1) of the Charter and Access to the Public Purse: Evolution in the Law?" (2007) 36 SCLR (2d) 221 at para 53. Billingsley and Carver's conclusion from reviewing judicial decisions for over 15 years was that there is no "judicial evolution toward the recognition of rights of entitlement to government-funded benefit programs under section 7 or section 15(1) of the Charter".

[129] Sarah Burningham, "Courts, Challenges, and Cures: Legal Avenues for Patients with Rare Diseases to Challenge Health Care Coverage Decisions" (2015) Canadian J Comparative & Contemporary L 317 at 349. Burningham also considered other legal avenues for challenging medical coverages decisions in Canada, including administrative law, human rights legislation, international law, and tort law. She suggested that the policy element, which is central to health care allocation decisions, is likely to prompt considerable judicial deference across these varied spheres (at 349).

[130] *Morgentaler* is perhaps the most widely recognized example of a constitutional rights "victory" framed under a negative rights umbrella that has nonetheless failed to achieve the broader objective of access to safe and timely abortions. See Ries, "Charter Challenges", *supra* note 86 at 633; see also Jackman, "Charter Review", *supra* note 86.

interventions that are provided by regulated healthcare professionals, including physicians.[131] As discussed above, Health Canada is responsible for oversight of drugs and medical devices in Canada. However, interventions that fall outside these categories and which are characterized as being within the scope of medical practice (e.g. surgeries) are under provincial authority and are the delegated responsibility of medical professional regulatory bodies.[132] In the context of special access regimes, where patients can be approved to receive still experimental treatments on the recommendation of their physician, professional regulatory bodies have been identified as an important component of a potentially fragmented regulatory matrix. In that context, as is the case here, their ability "to provide rigorous, consistent oversight" is both a matter of importance and an open question.[133]

By way of brief background, there are different models of professional self-regulation.[134] The term is generally used to describe systems where the state grants authority to a profession to regulate itself, often via entry standards, overseeing practice, and managing disciplinary processes.[135] Baldwin and Cave define self-regulation as "when a group of firms or individuals exerts control over its own membership and their behavior".[136] Black defines self-regulation as a process of "collective government", suggesting it describes "a group of persons or bodies, acting together, performing a regulatory function in respect of themselves and others who accept their authority".[137] She uses the term "mandated self-regulation" to describe when government requires a profession to devise and enforce rules within a prescribed framework, and "coerced self-regulation" for when a profession self-organizes to set and enforce rules in response to a threat that if it does not do so, government will intervene.[138]

In Canada, as noted above, the provinces have legislative jurisdiction to regulate the medical profession. They have each done so by way of delegation to provincial colleges of physicians and surgeons. In Yukon, the Yukon Medical Council is empowered with regulatory

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[131] For an overview of the role of professional regulation in healthcare, including types of regulation, sources of regulatory authority, advantages, and criticisms, see Amy Zarzeczny, "The Role of Regulation in Health care – Professional and Institutional Oversight" in Joanna Erdman, Vanessa Gruben & Erin Nelson eds, *Canadian Health Law and Policy*, 5th ed (Toronto: Lexis Nexis Canada, 2017) 161.

[132] By way of example, medical regulatory bodies in Canada played a critical role in providing guidance and standards of conduct for physicians regarding access to cannabis for medical purposes under the previous *Marihuana for Medical Purposes Regulations*, SOR/2013-119 [Repealed, SOR/2016-230, s 281] and *Access to Cannabis for Medical Purposes Regulations,* SOR/2016-230 [Repealed, SOR/2018-147, s 33]. See Nola Ries, "Prescribe with Caution: the Response of Canada's Medical Regulatory Authorities to the Therapeutic Use of Cannabis" (2016) 9:2 McGill JL & Health 215.

[133] Barbara von Tigerstrom & Emily Harris, "Access to Experimental Treatments: Comparative Analysis of Three Special Access Regimes" (2016) 24 JL & Medicine 119 at 149.

[134] Margot Priest, "The Privatization of Regulation: Five Models of Self-Regulation" (1997-1998) 29 Ottawa L Rev 233. Priest identifies the following five models of self-regulation: (1) Codes of Conduct; (2) Statutory Self-Regulation; (3) Firm-Defined Self-Regulation; (4) Supervised Self-Regulation; (5) Regulatory Self-Management.

[135] Tracey L. Adams, "Professional Regulation in Canada: Past and Present" (2007) Canadian Issues 14. Self-regulation is sometimes framed as a core or defining characteristic of a profession. See Eliot Freidson, *Professionalism: The third logic* (Chicago: University of Chicago Press, 2001).

[136] Robert Baldwin & Martin Cave, *Understanding Regulation; Theory, Strategy, and Practice* (Oxford: Oxford University Press, 1999) at 125.

[137] Julia Black, "Constitutionalising Self-Regulation" (1996) 59 Modern L Rev 24 at 27.

[138] *Ibid*. In contrast, Black uses "voluntary self-regulation" to describe when there is no state influence or involvement in the self-regulation.

authority by the *Medical Profession Act*[139]. In Nunavut and the Northwest Territories, the *Medical Profession Act*[140], and *Medical Profession Act*[141], respectively empower a Medical Registration Committee to oversee matters of licensing, and a Board of Inquiry to investigate allegations of improper conduct. Some provinces, such as Ontario, use what is called an "umbrella" approach, where one overarching piece of legislation sets out a general regulatory framework that applies to a number of healthcare professions; this umbrella legislation is accompanied by profession-specific legislation or regulations that deal with matters particular to individual professions.[142] Other provinces use a profession-specific approach where each healthcare profession is governed by an independent statute.[143]

For example, in Saskatchewan, the College of Physicians and Surgeons of Saskatchewan is established and empowered by the *Medical Profession Act.*[144] The College of Physicians and Surgeons of Saskatchewan is responsible for medical licensing, developing and enforcing standards of practice, investigating complaints, and disciplining physician members who fail to meet "standards of medical care, ethics or professional conduct".[145] Fulfilling these responsibilities, which are similar to those of other provincial colleges of physicians and surgeons across Canada, is critical for medical regulators such as the College of Physicians and Surgeons of Saskatchewan to maintain their independence and authority. Self-regulation has been described as both a "privilege" and a "burden".[146] The privilege element refers to the benefits of maintaining professional autonomy and protection of market share, while the burden captures the professional commitment to act ethically, competently, in the public interest, and for the wellbeing of patients.[147]

Much of the scholarship addressing professional self-regulation focuses on it being part of a "social contract"[148] or "bargain" with the state, where the profession is granted considerable professional autonomy with the privilege of self-regulation in exchange for acting in the public interest.[149] In some cases, the requirement for professional regulatory bodies to act in the public

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[139] RSY 2002, c 149.
[140] RSNWT (Nu) 1988, c M-9.
[141] SNWT 2010, c 6.
[142] Ontario's umbrella legislation is the *Regulated Health Professions Act*, 1991, SO 1991, c 18; the medical profession is also governed by the accompanying *Medicine Act*, 1991, SO 1991, c 30 [*Ontario Medicine Act, 1991*].
[143] See e.g. Merrilee Rasmussen, "Umbrella Professions Legislation: A Made in Saskatchewan Approach" (2010) 73:2 Sask L Rev 285. Rasmussen provides a brief history of professional regulation in Saskatchewan and discusses the merits of an umbrella approach.
[144] *Medical Profession Act*, 1981, SS 1980-81, c M-10.1 [*Medical Profession Act*].
[145] The College of Physicians and Surgeons of Saskatchewan, "About Us" (last visited 23 May 2022), online: <www.cps.sk.ca/imis/CPSS/About_Us/CPSS/AboutUs/About_Us.aspx?hkey=c06fff19-cb2e-4b79-9267-412efa3a656d>.
[146] Roger Collier, "Professionalism: the privilege and burden of self-regulation" (2012) 184:14 CMAJ 1559.
[147] Amir Kaliq, Ari Mwachofi & Robert W Broyles, "Physician Autonomy vs. Self-Regulation: You Can't Have One Without the Other" (2010) 26:2 Ethics & Medicine 111 at 112; see also Jordan Cohen, "Tasking the 'Self' in the Self-governance of Medicine" (2015) 383:18 J American Medical Assoc 1839. Cohen suggests trust in physicians is the foundation for the social contract that underpins self-regulation of medicine, and stresses that trust must be earned by physicians acting in a professional manner.
[148] William Sullivan, "Medicine under threat: Professionalism and professional identity" (2000) 162:5 CMAJ 673 at 673.
[149] Tracey Adams, "Professional Self-Regulation and the Public Interest in Canada" (2016) 6:3 Professions & Professionalism https://journals.hioa.no/index.php/pp/article/view/1587. Adams' work also suggests that conceptions of what is in the public interest have changed over time in relation to professions, with the historical

interest is directly imposed by the legislation that empowers them.[150] For example, Ontario's *Regulated Health Professions Act, 1991*, provides: "[i]t is the duty of the Minister to ensure that the health professions are regulated and co-ordinated in the public interest".[151] Similarly, British Columbia's *Health Professions Act* sets out the duty of a college as being "to serve and protect the public, and to exercise its powers and discharge its responsibilities under all enactments in the public interest".[152] The requirement for medical professional regulators to act in the public interest is particularly important given the asymmetry of information in healthcare, where healthcare providers hold specialized knowledge and training, and the associated power imbalance between healthcare providers and patients.[153] This imbalance may be heightened when dealing with medical interventions that are novel, experimental, or unproven, particularly if there is a high degree of enthusiasm or expectation surrounding the purported treatment or unmet medical needs.

In Canada, our medical profession enjoys a relatively strong form of professional self-regulation in that medical members still generally outnumber lay members in medical colleges across the country.[154] However, this standing should not be taken for granted. For example, medical regulation in the United Kingdom has moved away from a largely independent self-regulation approach to a more state-directed one with larger roles for lay members following loss of trust in the medical profession after several high-profile medical scandals.[155] A Government of British Columbia Steering Committee on Modernization of Health Profession Regulation released recommendations in 2020 for regulatory modernization.[156] This report acknowledged similar concerns that the current model of professional regulation in British Columbia has enabled some professions to promote their own interests over those of the public and has allowed for a lack of transparency of regulatory college activities.[157] This trend suggests that the relative autonomy enjoyed by medical self-regulatory bodies in Canada could be at risk of being limited by governments if the medical colleges do not fulfill their responsibilities to govern in the public interest when responding to concerns about unproven medical interventions provided by

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focus on expertise giving way to greater emphasis on competition and cost reduction. For a discussion of this proposition in the context of self-regulation of the legal profession, see John Flood, "The re-landscaping of the legal profession: Large law firms and professional reregulation" (2011) 59:4 Current Sociology 507 at 509-510.

[150] For e.g. see Ontario's *Regulated Health Professions Act, 1991,* SO 1991, c18, s 3 [*Ontario HPA*], which provides "It is the duty of the Minister to ensure that the health professions are regulated and co-ordinated in the public interests."

[151] *Ibid,* at s 3.

[152] *Health Professions Act*, RSBC 1996, c 183, at s 16.

[153] Tracey Epps, "Regulation of Health Care Professionals" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds, *Canadian Health Law and Policy,* 4th ed (Ontario: LexisNexis Canada, 2011) 75.

[154] C. David Naylor, Rocco Gerace & Donald Redelmeier, "Maintaining Physician Competence and Professionalism" (2015) 313:18 J American Medical Assoc 1825.

[155] Collier, *supra* note 146; see also Mary Dixon-Woods, Karen Yeung & Charles L. Bosk, "Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors" (2011) 73 Soc Science & Medicine 1452.

[156] Government of British Columbia Steering Committee on Modernization of Health Profession Regulation, "Recommendations to modernize the provincial health profession regulatory framework" (August 2020), online (pdf): <www2.gov.bc.ca/assets/gov/health/practitioner-pro/professional-regulation/recommendations-to-modernize-regulatory-framework.pdf>.

[157] *Ibid* at 4.

physicians. Doing so arguably requires ensuring standards of practice are in place and enforcing those standards through diligent oversight and, when necessary, disciplinary action.

All provincial colleges of physicians and surgeons in Canada have policies and standards that have implications for provision of unproven medical interventions. Policies and standards regarding non-standard of care interventions, including complementary and alternative medicine, human subject research activities, and advertising practices are all particularly relevant for this research. As an example of the first category, Ontario's *Medicine Act*, 1991, provides the following:

> A member shall not be found guilty of professional misconduct or of incompetence under section 51 or 52 of the Health Professions Procedural Code solely on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient's health than the traditional or prevailing practice.[158]

Variations of this provision can also be found in Alberta, Manitoba, and British Columbia.[159] Other provincial colleges place greater emphasis on the importance of following the standard of care, apart from approved research activities. For example, the College of Physicians and Surgeons of Prince Edward Island's Regulations define professional misconduct as including:

> making a claim respecting the utility of a remedy, treatment, device, or procedure that cannot be supported as a reasonable professional medical opinion… and prescribing, administering or assisting any person in the use of any drugs or therapy in a manner that is not consistent with generally accepted professional standards and procedures in the practice of medicine, unless in the context of a research protocol approved by a research ethics committee acceptable to Council.[160]

Some colleges have policies regarding provision of "uninsured services". Saskatchewan's policy, for example, commences with a preamble that states it must be read along with the College of Physicians and Surgeons of Saskatchewan's policies on conflicts of interest, and notes that because payment for uninsured services is not subject to external monitoring, "patients paying privately for uninsured services rely on the honesty and integrity of physicians to ensure that their needs and interests are prioritized".[161] To that end, it requires physicians providing and billing patients for uninsured services to "do so in a manner that is in keeping with their professional, ethical and legal obligations", and to "not exploit their patients' trust for their own personal advantage, financial or otherwise".[162]

Some colleges have specific standards to address provision of complementary and alternative therapies or medicine (often referred to as CAM) by physicians. CAM is an umbrella

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[158] *Ontario Medicine Act, 1991*, *supra* note 142 at s 5.1.
[159] *Health Professions Act*, RSA 2000, c. H-7, Schedule 21, s 5; *The Medical Act*, CCSM c M90, s 36.1 and *Health Professions Act*, RSBC 1996, c 183, s 25.4.
[160] College of Physicians and Surgeons of Prince Edward Island, "Regulations" (1 May 2014), online (pdf): <cpspei.ca/wp-content/uploads/2015/08/REGULATIONS-FOR-PEI-Approved-Changes-as-of-May-12014.pdf>.
[161] College of Physicians and Surgeons of Saskatchewan, "Policy; Uninsured Services" (September 2019), online (pdf): <www.cps.sk.ca/iMIS/Documents/Legislation/Policies/POLICY%20-%20Uninsured%20Services.pdf>.
[162] *Ibid* at 2.

term that is often used to describe interventions that fall outside conventional (generally meaning Western) medical practice, such as acupunture, homeopathy, and reiki.[163] For example, the College of Physicians and Surgeons of British Columbia's Practice Standard regarding complementary and alternative therapies sets out a number of requirements for physicians.[164] These requirements include (among others) practising "in a manner that is informed by medical evidence and science and is in keeping with their professional, ethical and legal obligations", ensuring informed consent is obtained by advising the patient "unambiguously" about the safety and effectiveness of the intervention if it is contrary to generally accepted views within the medical profession, and never exploiting "the emotions, vulnerability, or finances of a patient for personal gain or gratification".[165]

Physicians who engage in research with human participants (including their patients) must comply with the research-related policies of their professional regulatory body. The Canadian Medical Association (CMA)'s Code of Ethics and Professionalism indicates that in the context of the patient-physician relationship, physicians must ensure any research they do is "evaluated both scientifically and ethically and is approved by a research ethics board that adheres to current standards of practice".[166] They also must recognize the potential for conflicts of interest to result from competing roles, including as researchers,[167] and inform potential "participants about anything that may give rise to a conflict of interest, especially the source of funding and any compensation or benefits".[168] This code has been adopted in different ways by medical regulatory bodies across Canada.[169] For example, in Saskatchewan it is incorporated into the College of Physician and Surgeons of Saskatchewan's Regulatory Bylaws.[170] Contravening or failing to comply with the Code of Ethics is deemed "unbecoming, improper, unprofessional or discreditable conduct",[171] meriting professional discipline pursuant to the *Medical Profession Act.*[172]

The CMA's Code of Ethics and Professionalism also sets out one of physicians' professional responsibilities as being to "[r]ecommend evidence-informed treatment options".[173]

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[163] Nola Ries & Katherine Fisher, "The Increasing Involvement of Physicians in Complementary and Alternative Medicine: Considerations of Professional Regulation and Patient Safety" (2013) 39:1 Queens' LJ 273 at 274. It is beyond the scope of this discussion to delve into the complexities of this term, its history, and of determining an operational definition of CAM. For greater depth on this topic, see L Susan Wieland, Eric Manheimer & Brian Berman, "Development and classification of an operational definition of complementary and alternative medicine for the Cochrane Collaboration" (2011) 17:2 Alternative Therapies Health & Medicine 50.

[164] College of Physicians and Surgeons of British Columbia, "Practice Standard – Complementary and Alternative Therapies" (last modified 11 May 2020), online (pdf): <www.cpsbc.ca/files/pdf/PSG-Complementary-and-Alternative-Therapies.pdf>.

[165] *Ibid*.

[166] Canadian Medical Association, "CMA Code of Ethics and Professionalism" (2018), online (pdf): < policybase.cma.ca/documents/policypdf/PD19-03.pdf> at C-9.

[167] *Ibid* at C-29.

[168] *Ibid* at C-27.

[169] See e.g. College of Surgeons of Alberta, "Code of Ethics & Professionalism; Standard of Practice" (1 July 2019), online: <cpsa.ca/physicians/standards-of-practice/code-of-ethics/>; College of Physicians and Surgeons of Manitoba, "Code of Ethics" (July 2019), online: <www.cpsm.mb.ca/laws-and-policies/code-of-ethics>.

[170] College of Physicians and Surgeons of Saskatchewan, "Regulatory Bylaws" (February 2020), online (pdf): <www.cps.sk.ca/iMIS/Documents/Legislation/Legislation/Regulatory%20Bylaws.pdf>.

[171] *Ibid* at s 7.1(c).

[172] *Medical Profession Act*, *supra* note 144.

[173] Canadian Medical Association, *supra* note 166, at 4.

Quebec's Code of Ethics of Physicians similarly provides: "A physician must, with regard to a patient who wishes to resort to insufficiently tested treatments, inform him of the lack of scientific evidence relative to such treatments, of the risks or disadvantages that could result from them, as well as the advantages he may derive from the usual care, if any".[174] As will be discussed throughout the remainder of this thesis, questions of evidence can be complex with different interpretations. Nonetheless, the importance of evidence-based decision-making, assessing risk, and facilitating informed consent are themes that are emphasized to varying degrees throughout medical professional self-regulatory frameworks across the country. However, an equally important consideration is the question of enforcement and whether the colleges have the expertise, capacity, and the will to monitor and enforce compliance with relevant standards. This critical question will be considered as part of the case study analyses presented in Chapters 5-7, and the ensuing discussion in Chapter 8.

4.3.2 Tort law and physicians' legal obligations

As noted above, in addition to their professional obligations, physicians in Canada have legal duties that have been established through judicial decisions. Apart from Quebec, which has a civil code, Canada is a common law system. As such, courts have played an important role in clarifying and framing legal requirements for the provision of healthcare often, though not exclusively, through medical negligence cases under the umbrella of tort law. A successful cause of action in negligence requires that the defendant owed the plaintiff a duty of care, that the defendant breached the standard of care, that the plaintiff suffered harm (injury, loss) as a result of that breach, and that the defendant's breach of the standard of care caused the plaintiff's harm.[175] The standard of care is the degree of care and skill that could reasonably be expected of a prudent and diligent physician, with the same training.[176] Specialists are held to the standard of an average specialist in the field, and any physician who holds themselves out as being a specialist or having that degree of skill and knowledge is held to that same standard.[177] Both the course of treatment and the way it is administered factor into the standard of care. Accordingly, any physician intending to provide an unproven medical intervention is required to ensure they do so in accordance with the standard of care that would be required of a prudent and diligent physician in the same circumstances. They also must take care not to hold themselves out as having expertise they do not have, because they will be held to that higher standard if the patient suffers harm and sues for negligence.

A physician can also be liable for negligence if they fail to obtain informed consent from the patient or their substitute decision-maker. In brief, the requirements for valid consent are that it must be voluntary (free from coercion, duress, fraud, misrepresentation, or unconscionability), specific (relate to a particular treatment provided by a particular person), and given with capacity (either by the individual, or an appropriate substitute decision-maker).[178] If a medical

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[174] *Code of Ethics of Physicians*, CQLR c M-9, r 17 at s 49.
[175] For more in-depth discussion of the elements of a negligence claim, see Erin Nelson & Ubaka Obgogu, *Law for Healthcare Providers* (Toronto: LexisNexis Canada Inc, 2018) at 25-40; Lorian Hardcastle, "Medical Negligence Law in Canada", Joanna E. Erdman, Vanessa Gruben & Erin Nelson, eds, *Canadian Health Law and Policy*, 5th ed (Toronto: LexisNexis, 2017) at 307-316.
[176] *Crits v. Sylvester*, [1956] O.J. No. 526 at para 13, 1 DLR (2nd) 502 (Ont. C.A.), affd [1956] S.C.J. No. 71.
[177] *Ter Neuzen v. Korn*, 1995 CanLII 72 (SCC), [1995] 3 SCR 674 at para 33.
[178] Patricia Peppin, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds, *Canadian Health Law and Policy*, 4th ed (Ontario: LexisNexis, 2011) 153 at 156.

intervention is provided without valid consent, the provider may be liable in battery. If consent is not also informed, the provider may be liable in negligence. The standard of disclosure for informed consent is what a reasonable person in the patient's circumstances would want to know,[179] and has been summarized to include: "the nature of the treatment and its gravity; the material risks…special or unusual risks; the alternatives and their risks, including the risk of not proceeding with the treatment; and the answers to any questions asked by the patient".[180]

With interventions that lack evidence regarding safety and efficacy, there may be many unknowns regarding potential risks, but that challenge does not negate physicians' obligations to obtain informed consent. To the contrary, the standard may be even more arduous with respect to experimental and non-standard of care interventions.[181] The scope of the standard of disclosure is also generally greater with elective procedures, where courts take a broad view of materiality.[182] Although unproven medical interventions provided with the goal of clinical benefit are different from participation in research (discussed further in the ensuing section), instructive principles about the scope of informed consent may be drawn from the research context, where there can also be high levels of uncertainty.

In the widely cited precedent-setting decision of *Halushka v. the University of Saskatchewan*,[183] the Saskatchewan Court of Appeal considered the circumstances of Walter Halushka who was a participant in research trialing a new anesthetic drug. He was informed by the researchers that the procedure was safe, notwithstanding the fact that the risks of the drug were largely unknown. He suffered irreversible harm during the procedure and the court held that researchers are held to a higher standard of disclosure than physicians providing treatment. Researchers must disclose any and all information that a reasonable person would want to know when deciding whether to participate in research. In *Weiss v. Solomon*[184], the Quebec Superior Court confirmed that researchers must disclose even remote risks as part of the consent process for research participation.[185] Although these cases are dated, the precedent they set remains today and suggests that physicians providing unproven medical interventions would likely be prudent to advise patients that, at minimum, there is not enough experience with the treatment to be able to predict with certainty whether there is any likelihood of benefit or what the chances of harm might be.[186] In their leading health law text, Picard and Robertson similarly advise that physicians providing innovative procedures should inform the patient that the procedure is innovative or experimental.[187]

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[179] *Reibl v. Hughes*, [1980] 2 SCR 880.
[180] Peppin, *supra* note 178 at 164.
[181] Ellen Picard & Gerald Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Ontario: Thomson Carswell, 2007) at 178.
[182] *Ibid* at 145-146.
[183] *Halushka v. University of Saskatchewan*, 1965 CanLII 439 (SK CA).
[184] *Weiss c Solomon*, [1989] JQ no 312, [1989] RJQ 731, JE 89-532, 48 CCLT 280.
[185] Weiss participated in a study exploring indomethacin eye drops to reduce retinal edema. The consent form described only minor risks including potential allergic reaction. Weiss suffered cardiac arrest following injection of the fluorescein dye and died. Weiss' family sued on several grounds including insufficient screening processes and inadequate resuscitation resources, but the deficiencies in the consent process are most relevant for this work.
[186] For a discussion of similar issues in the specific context of complementary and alternative medicine, see Timothy Caulfield, "Commentary: the law, unproven CAM and the two-hats fallacy" (2012) 17:1 Focus on Alternative & Complementary Therapies 4.
[187] Picard & Robertson, *supra* note 181 at 178.

It is important not to overstate the role of tort law as a governance mechanism because it engages some complex policy questions. The outcomes of court decisions can and have had a significant impact on shaping physicians' legal obligations in healthcare contexts, including regarding provision of medical interventions of varied types. However, relying on tort law to shape practice in a particular area raises concerns regarding disproportionate burdens on plaintiffs.[188] It is also highly reactive in nature in that it requires a harm or wrong to have occurred. As such, it should not be viewed as a replacement for deliberate policy design. Further, although in theory liability in tort may serve a deterrent function by discouraging problematic conduct by physicians, it is far from certain whether it has that effect.

4.3.3 The role of research ethics oversight

In addition to their professional and legal obligations, physicians who provide medical interventions in a research context may also be subject to research ethics oversight. It is important to emphasize that this project focuses on unproven interventions provided as a treatment intended to benefit the individual, which I distinguish from experimental interventions provided in the context of research ethics approved study.[189] However, it is nonetheless worthwhile to briefly review the research ethics context in Canada as it relates to physicians' practices. This discussion is necessary for two primary reasons. First, as is discussed in the liberation therapy case study presented in Chapter 6, participating in clinical research can be viewed and promoted as a form of access to (unproven) medical interventions. Second, some providers of unproven medical interventions have framed their activities under the umbrella of clinical innovation when they would likely more appropriately be framed as research. For example, in discussing "innovative therapy", which it defines as "the use of novel medical devices, procedural techniques or off-label medications outside of a clinical study to evaluate their efficacy", the Royal College of Physicians and Surgeons of Canada's research ethics guidance notes that "[s]ome physicians have used "innovative therapy" as a means to avoid REB scrutiny for research".[190]

This section is not intended to present a comprehensive review or an in-depth analysis of research ethics oversight in Canada.[191] It will also not delve into the long and complicated

[188] Defendant physicians are typically supported by the formidable resources of the Canadian Medical Protective Association. According to Hardcastle, "The CMPA successfully defends up to 80 percent of the cases that proceed to trial each year. Of those that do not make it to trial, approximately 60 percent are withdrawn and approximately one third settle out of court". See Lorian Hardcastle, *Introduction to Health Law in Canada* (Toronto: Emond Publishing 2019) at 30. See also Vanessa Milne, Sachin Pendharkar & Michael Nolan, "Is Canada's medical malpractice system working?" (2014) Healthy Debate healthydebate.ca/2014/11/topic/cmpa-medical-malpractice.
[189] Chapter 1, *above*, addresses terminology tensions and includes a more in-depth discussion of how I have defined unproven medical interventions, including in relation to surgical or medical innovation and research.
[190] Andrew McRea, "Research Ethics; Royal College of Physicians and Surgeons of Canada Bioethics Primer", online: <www.royalcollege.ca/rcsite/bioethics/primers/research-ethics-e>. Special access programs are another example of a practice that challenges conventional distinctions between research and medical practice and their associated regulatory oversight mechanisms. See Mary Jean Walker, Wendy A Rogers & Vikki Entwistle, "Ethical justifications for access to unapproved medical interventions: an argument for (Limited) patient obligations" (2014) 14:3 American J Bioethics 3 at 13.
[191] For more in-depth discussion, see Jennifer Llewellyn, Jocelyn Downie & Robert Holmes, "Protecting Human Research Subjects: A Jurisdictional Analysis" (2003) Special Ed Health LJ 207; see also Trudo Lemmens, "Federal Regulation of REB Review of Clinical Trials: A Modest but Easy Step Towards an Accountable REB Review

history behind research ethics frameworks, including the many egregious abuses perpetrated by physicians.[192] Both of these topics are rich areas of study and important topics for law and public policy, but they fall beyond the scope of this project. The modest purpose of this section is to provide a foundation for considering how research ethics oversight frames physicians' engagement in research with patients.[193]

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCSP2* (2018)[194] is the principal research ethics guidance document in Canada. It is a joint policy of Canada's three federal research agencies, including the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, collectively referred to as the "Agencies". It binds researchers and institutions (e.g. universities, hospitals) who receive funding from one or more of the Agencies. Failure to comply with the TCPS2 may result in future funding ineligibility from the Agencies, which is a potentially serious consequence given that they are a major source of research funds in Canada.[195] Accordingly, physicians who have academic appointments at universities or affiliations with other institutions that receive Tri-Council funding are bound by the TCPS2, in addition to their professional obligations. Unless voluntarily adopted, the TCPS2 does not govern research in private settings that do not receive funding from the Agencies, which creates a potential gap in research ethics oversight.

The TCPS2 governs research involving human participants. In the TCPS2,

> "research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community.
>
> …
>
> "human participants" (referred to as "participants") are those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s)[196]

Structure in Canada" (2005) 13:2&3 Health L Rev 39; see also Michael McDonald, "Canadian Governance of Health Research Involving Human Subjects: Is Anybody Minding the Store?" (2001) 9 Health LJ 1.

[192] See e.g. Megan Gannon, "Germany to probe Nazi-era medical science" (2017) 355:6320 Science 13; see also César Chelala, "Clinton apologises to the survivors of Tuskegee" (1997) 349:9064 The Lancet 1529; see also Ian Mosby, "Administering Colonial Science: Nutrition Research and Human Biomedical Experimentation in Aboriginal Communities and Residential Schools, 1942–1952" (2013) 46:91 University Toronto Press 145.

[193] This discussion of research ethics is distinct from related avenues of oversight for clinical research, including Health Canada's regulation of clinical trials and professional policies and standards of medical professional regulatory bodies, both of which were introduced earlier in this chapter.

[194] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (December 2018), online (pdf): <www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf>.

[195] CIHR's planned spending for 2019-2020 exceeds $1 billion. See Canadian Institutes of Health Research, "2019-2020 Departmental Plan" (last modified 19 May 2021), online: <cihr-irsc.gc.ca/e/51283.html#4.1>.

[196] TCPS2, *supra* note 194, Article 2.1.

Subject to a limited number of exceptions[197], the TCPS2 requires that research involving living human participants and human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells, be reviewed and approved by a research ethics board (REB) before it starts.[198] The TCPS2 contains specific rules relating to key aspects of research including consent and conflicts of interest, and detailed interpretation notes.[199]

There are several aspects of the TCPS2 that are particularly relevant to the provision of medical interventions that fall outside the standard of care. Clinical trials have a dedicated chapter that outlines the specific rules for what the TCPS2 deems "the most regulated type of research".[200] The TCPS2 defines clinical trials as:

> any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies.[201]

TCPS2 advises that clinician-researchers (physicians who engage in research with their patients) must attend to conflicts of interest from this dual role and must consider the potential for therapeutic misconception.[202] Therapeutic misconception is defined for the purpose of TCPS2 as "when trial participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them. It also occurs when participants enter trials without understanding the ways in which elements of a clinical trial design may interfere with their own health care objectives".[203] Clinician-researchers are also cautioned against creating "unrealistic expectations". Although the TCPS2 focuses on research, there is a

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[197] TCPS2, *supra* note 194, Article 2.2 (publicly available information and information in the public domain), 2.3 (observation in public places), 2.4 (secondary use of anonymous information), 2.5 (quality assurance and improvement, program evaluation, etc.), 2.6 (creative practice).

[198] *Ibid*, Article 2.1. The TCPS2 also provides details regarding the composition of REBs and process and approaches to ethics reviews (see Chapter 2, B). Jurisdictions use different terminology to describe research ethics oversight bodies that otherwise often function in similar ways. The term Research Ethics Board (REB) is the common descriptor in Canada, while in the United States, Institutional Review Board (IRB) is more common. See United States Food & Drug Administration, "Information Sheet: Institutional Review Boards Frequently Asked Questions" (January 1998), online: <www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions>. In England, Research Ethics Committees is more widely used. See NHS Health Authority Research, "Research Ethics Service and Research Ethics Committees", (last visited 15 June 2022), online: <www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/>.

[199] Chapter topics include the following: consent (Chapter 3), Fairness and Equity in Research Participation (Chapter 4), Privacy and Confidentiality (Chapter 5), Governance of Research Ethics Review (Chapter 6), Conflicts of Interest (Chapter 7), Multi-Jurisdictional Research (Chapter 8), Research Involving First Nations, Inuit and Métis Peoples of Canada (Chapter 9), Qualitative Research (Chapter 10), Clinical Trials (Chapter 11), Human Biological Materials including Materials Relating to Human Reproduction (Chapter 12), and Human Genetic Research (Chapter 13).

[200] TCPS2, *supra* note 194, Chapter 11, at Introduction.

[201] *Ibid.*

[202] *Ibid.*

[203] *Ibid.*

similar concern about patients' unrealistic expectations with respect to unproven medical interventions provided in treatment contexts.

The potential for therapeutic misconception and unrealistic expectations illustrates why it is important that physicians exercise care when engaging in research with patients and offering unproven medical interventions, particularly given the power differential and information asymmetry that can exist in the doctor-patient relationship. A key tenet of research is that medical and scientific understandings change and develop over time, as does the context within which medical care and research activities are situated. As discussed in Chapter 1, today's healthcare context is largely influenced by the internet and the global nature of healthcare markets. The kinds of unproven medical interventions that are the subject of this research are often provided outside the bounds of Canada's publicly administered healthcare systems and advertised on a direct-to-consumer basis. Looking at related issues in the context of the pharmaceutical industry, Dyck and Stewart identify patient consumers "as the new research subjects. They are complicit and willing subjects by virtue of their participation, while the context of information and thus informed consent, reaches new degrees of uncertainty".[204] They refer to the marketplace, which includes pharmaceuticals used for both on and off-label purposes as "the ultimate human trial".[205] Patients who pursue other forms of unproven medical interventions on the private market could be characterized in a similar manner.

The merits of using research ethics review processes to provide oversight and potentially restrict access to new treatments are not universally accepted. For example, Edwards argues against limiting access to potential new treatments to research contexts including clinical trials. She suggests that doing so may weaken participants' consent by creating a type of inducement whereby patients agree to participate in research seeking personal benefit, even though the focus of research is generally on knowledge creation to the benefit of future patients.[206] As will be discussed in more detail in the liberation therapy case study (Chapter 6), casting participation in research as a form of access to a medical intervention can be premised upon an implicit assumption of likely benefit from the new treatment, which may be inaccurate.[207] These nuances highlight the importance of clear consent processes, and the merits of systems of oversight that ensure they are adhered to in both treatment and research contexts.

4.4 Conclusion

In this chapter, I have taken a broad and high-level approach to mapping elements of the relevant legal and policy landscape for this research. In doing so, I have identified key regulatory and governance actors, and have highlighted relevant frameworks for oversight of unproven medical interventions and the physicians who provide them. The primary purpose of this exercise was to establish a foundation for the ensuing case study analyses presented in the three chapters that follow. As outlined in Chapter 1, each case study analysis is presented in a

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[204] Erika Dyck & Larry Stewart, eds, *The Uses of Humans in Experiment: Perspectives from the 17th to the 20th Century* (Leiden: Brill, 2016) at 24.
[205] *Ibid* at 24.
[206] Sarah Edwards, "Restricted Treatments, Inducements, and Research Participation" (2006) 20:2 Bioethics 77. For a similar perspective, arguing for stronger expanded access regimes outside of research contexts, see John Robertson, "Controversial medical treatment and the right to health care" (2006) 36:6 Hastings Centre Report 15.
[207] Scholars have made similar observations in relation to special access regimes. See e.g. Walker, Rogers & Entwistle, *supra* note 190 at 9.

distinct chapter, in the following order: chelation therapy (Chapter 5), liberation therapy (Chapter 6), and unproven stem cell interventions (Chapter 7).

CHAPTER 5: CASE STUDY 1 - CHELATION THERAPY

In this chapter, I will present the results of my case study analysis of the regulation and governance of access to chelation therapy in Canada, for indications other than heavy metal toxicity. For brevity, when discussing chelation therapy in this case study I will be referring only to non-standard of care applications. This discussion will begin with a narrative account of the case study data. This narrative account will include an introduction to chelation therapy and a review of unproven applications of chelation therapy in Canada. Given chelation therapy's extensive history, this will not be an exhaustive review. Rather, the discussion will focus on points that I find to be most relevant to my research questions. Following this narrative account, I will describe and characterize key features of regulation and governance of access to unproven applications of chelation therapy, using the conceptual framework set out in Chapter 2 (Table 1). I will conclude the chapter by reflecting on important lessons and future priorities that emerged from this case study. Ideally, these lessons could help inform and strengthen future strategies for regulation and governance of access to other unproven medical interventions in Canada.

5.1 Narrative account of chelation therapy in Canada

5.1.1 Chelation therapy – an overview

Chelation therapy involves the administration of substances called "chelators". Chelators attach to certain types of metals, such as lead, mercury, arsenic, iron, and copper, in the bloodstream and some types of body tissues, which make it easier for the body to eliminate them (i.e. through the kidneys). Chelation therapy is generally given by pill or intravenous injection,[1] though unapproved over the counter chelation products also come in other forms such as "nasal sprays, suppositories, liquid drops, and clay baths".[2] There are different types of chelating agents used for different kinds of metals.[3] Ethylenediaminetetraacetic acid (EDTA) is one of the most common chelating agents and has been approved by Health Canada for treatment of lead poisoning. Chelation therapy is a standard of care treatment for heavy metal toxicity, such as may be caused by heavy metal poisoning or thalassemia (a blood disorder that can involve elevated levels of iron in the blood).[4] A typical course of treatment generally involves approximately 30 sessions of intravenous administration of EDTA, often in combination with other vitamins and minerals, with each session lasting between 1.5 – 3 hours.[5]

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[1] Alberta Health Services, "Chelation FAQ" (last visited 22 May 2022), online (pdf): <www.albertahealthservices.ca/assets/healthinfo/Padis/hi-padis-faq-chelation.pdf>.

[2] The FDA has issued warnings to companies marketing OTC chelation products, which it deems to be unapproved drugs. See e.g. Rebecca Voelker, "FDA Warning Targets OTC Chelation Products" (2010) 304:19 J American Medical Assoc 2112; United States Food & Drug Administration, "Questions and Answers on Unapproved Chelation Products" (last modified 2 February 2016), online: <www.fda.gov/drugs/medication-health-fraud/questions-and-answers-unapproved-chelation-products>.

[3] Richard Bedlack et al, "Complementary and Alternative Therapies in Amyotrophic Lateral Sclerosis" (2015) 33 Neurologic Clinics 909 at 922.

[4] Guido Crisponi et al, "Kill or cure: Misuse of chelation therapy for human diseases" (2015) 284 Coordination Chemistry Rev 278. Thalassemia is an inherited blood disorder that involves abnormally elevated levels of iron in the blood.

[5] Dugald Seely, Ping Wu & Edward Mills, "EDTA chelation therapy for cardiovascular disease" (2005) 5:32 BMC Cardiovascular Disorders doi:10.1186/1471-2261-5-32.

Chelation therapy is generally considered to be unproven for all other applications.[6] For example, there is a long history of debate about chelation therapy's utility in treating different cardiac conditions including atherosclerosis and coronary artery disease.[7] The underlying theory of this application is that EDTA can bind with and help clean out the calcium deposits in arteries that contribute to heart disease. Public interest in this proposed application of chelation therapy is sometimes traced to a series of books published in the early 1980s,[8] and it has had strong critics in medical and scientific communities. As early as 1985, chelation therapy was referred to as the "Laetrile of cardiology".[9] There have been reports and studies of varied forms and quality on the use of chelation therapy for heart disease since the 1960s, but at the time of writing this application remains unproven.[10]

A double-blind, randomized, placebo controlled trial conducted between 1996-2000 in Calgary, Alberta, found "no evidence to support a beneficial effect of chelation therapy in patients with ischemic heart disease, stable angina, and a positive treadmill test for ischemia".[11] Another systematic review current to 2005 found that the "best available evidence does not support the therapeutic use of EDTA chelation therapy in the treatment of cardiovascular disease".[12] A 2020 Cochrane review confirmed that there is insufficient evidence to determine whether or not chelation therapy is effective in improving clinical outcomes in cases of atherosclerotic cardiovascular disease, and identified a need for high-quality, randomised controlled trials.[13] This review updated a similar review in 2002, which was prompted by the following premise:

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[6] See e.g. Anne Hume, "Chelation: Therapy or quackery?" (2013) Pharmacy Today 22.

[7] See e.g. Robert Patterson, "Chelation therapy and Uncle John" (1989) 140 CMAJ 829; see also Merlin Nelson, "Health Professions and Unproven Medical Alternatives" (1988) J Pharmacy Technology 60. Nelson reviewed several alternative therapies and noted that EDTA was being used in chelation clinics for treatment of arteriosclerosis as well as being promoted for angina, heart attacks and stroke, without evidence to support the safety or effectiveness of these treatments. See also Crisponi et al, *supra* note 4.

[8] Texts referenced in this context include Elmer Cranton, *Bypassing Bypass: The New Technique of Chelation Therapy* (Maddison Books, 1985) and Morton Walker, *Chelation therapy: How to prevent or reverse hardening of the arteries* (Cancer Control Society, 1986). Chelation therapy as a proposed treatment for heart disease dates back to the 1950s-60s.

[9] Allan Parachini, "Chelation Therapy Under a Cloud: Treatment Claims Challenged by Medical Establishment", *Los Angeles Times* (14 April 1985), online: <www.latimes.com/archives/la-xpm-1985-04-14-vw-8381-story.html>. This quotation was from Dr. Peter Frommer, then deputy director of the United State's National Heart, Lung and Blood Institute. Laetrile was an unproven treatment for cancer that was particularly prominent in the 1950s, notwithstanding the lack of supporting clinical data and its risks, which include cyanide poisoning. See Stefania Milazzo, Markus Horneber & Edzard Ernst, "Laetrile treatment for cancer" (2015) 4 Cochrane Database Systematic Revs, online: <DOI: 10.1002/14651858.CD005476.pub4>. Another article from 1986 discussed chelation therapy along with laetrile and other therapies as being dangerous and unproven for treating heart disease and cancer. See Victor Herbert, "Unproven (Questionable) Dietary and Nutritional Methods in Cancer Prevention and Treatment" (1986) 58 Cancer 1930.

[10] Government of Alberta, "Chelation Therapy" (modified 20 December 2019), online: *MyHealthAlberta* <myhealth.alberta.ca/Health/Pages/conditions.aspx?hwid=ty3205spec> [Government of Alberta, "Chelation Therapy"].

[11] Merril Knudston et al, "Chelation therapy for ischemic heart disease: a randomized controlled trial" (2002) 287:4 J American Medical Assoc 481 at 481.

[12] Seely, Wu & Mills, *supra* note 5.

[13] Maria Villarruz-Sulit et al, "Chelation therapy for atherosclerotic cardiovascular disease" (2020) 5:5 Cochrane Database Systematic Rev CD002785, online: <doi: 10.1002/14651858.CD002785.pub2>. This paper updated earlier work from 2002 that came to the same conclusion.

> Chelation therapy is being promoted and practiced all over the world as a form of alternative medicine in the treatment of atherosclerotic cardiovascular disease. It has been recommended as a safe, relatively inexpensive and non-surgical method of restoring blood flow in atherosclerotic vessels. At present the benefit of chelation therapy remains controversial at best.[14]

The Trial to Assess Chelation Therapy (TACT) was a particularly high-profile, 10-year, multi-site, double blind, placebo-controlled study involving sites in both the United States and Canada. Its purpose was to determine whether EDTA lowers the risk of repeat heart attacks.[15] It was also hoped that it would "put an end to controversy" about whether or not chelation is an effective treatment for heart disease.[16] It launched in 2003, but encountered challenges with recruitment and retention, criticisms of the informed consent process at some sites, and issues regarding the professional discipline history of several study investigators.[17] Preliminary results from TACT showed some reduction of risk for adverse cardiovascular outcomes following EDTA chelation therapy as compared to a placebo group,[18] but the concerns about the study led commentators to urge caution in interpreting those results.[19] An evaluation of the final results reflected the following conclusion:

> based on full consideration of the strengths and limitations of TACT, the conclusion is clear and should influence practice—these findings do not support the routine use of chelation therapy as secondary prevention for patients with previous myocardial infarction and established coronary disease. Whether chelation therapy may have any role in the prevention and treatment of cardiovascular disease remains to be determined.[20]

At two years post-chelation treatment, there was also no detectable effect on quality of life in stable, predominantly asymptomatic coronary disease patients with a history of myocardial infarction.[21] At the time of writing, a follow-up TACT2 study is in progress.[22]

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[14] Maria Villarruz, Antonio Dans & Flordeliza Tan, "Chelation therapy for atherosclerotic cardiovascular disease" (2002) 4 Cochrane Database Syst Rev CD002785, online: <doi: 10.1002/14651858.CD002785>.
[15] United States National Library of Medicine, "Trial to Assess Chelation Therapy", online: *ClinicalTrials.gov* <clinicaltrials.gov/ct2/show/study/NCT00044213>. Gervasio Lamas et al, "Design of the Trial to Assess Chelation Therapy (TACT)" (2012) 163:1 American Heart J 7.
[16] Paul Taylor, "Chelation therapy tested" *Globe and Mail* (11 May 2007) L8.
[17] Ewen Callaway, "Chelation-therapy heart trial draws fire" (2012) 491 Nature 313.
[18] Gervasio Lamas, Christine Goertz & Robin Boineau, "Effect of Disodium EDTA Chelation Regimen on Cardiovascular Events in Patients With Previous Myocardial Infarction; The TACT Randomized Trial" (2013) 309:12 J American Medical Assoc 1241.
[19] Hume, *supra* note 6 at 22. Follow-up analysis suggested that patients with diabetes who were on insulin therapy while receiving chelation therapy may have seen the greatest benefit. Esteban Escolar et al, "Possible differential benefits of edetate disodium in post-myocardial infarction patients with diabetes treated with different hypoglycemic strategies in the Trial to Assess Chelation Therapy (TACT)" (2020) 34:8 J Diabetes Complications 107616.
[20] Howard Bauchner, Phil Fontanarosa & Robert Golub, "The Scientific Process, Peer Review, and Editorial Scrutiny" (2013) 309:12 J American Medical Assoc 1291.
[21] Daniel Mark et al, "Quality-of-life outcomes with a disodium EDTA chelation regimen for coronary disease: results from the trial to assess chelation therapy randomized trial" (2014) 7:4 Circulation. Cardiovascular Quality & Outcomes 508.
[22] CTVNews.ca Staff, "New study could help decide whether chelation benefits the heart" *CTV News* (15 April 2018), online: <www.ctvnews.ca/health/new-study-could-help-decide-whether-chelation-benefits-the-heart-

Chelation therapy is also often characterized as a form of complementary and alternative medicine (CAM).[23] Additional unproven uses of chelation therapy include treatment for chronic inflammatory diseases (e.g. lupus, arthritis, scleroderma), based on the theory that EDTA serves as an antioxidant, protecting against inflammation. Research on patients' crowd-funding campaigns for self-described homeopathic treatment revealed several campaigns seeking funding for chelation therapy as a treatment for cancer.[24] Chelation therapy has also been identified as a common form of CAM tried by patients with Amyotrophic Lateral Sclerosis (ALS), notwithstanding the lack of evidence that heavy metal toxicity causes or contributes to ALS, or that chelation therapy is a useful treatment for this disease.[25] As noted in Chapter 4, though not an uncomplicated or uncontroversial concept, CAM is often used to describe a broad array of practices that are distinguished from current Western medical practices.[26] Chelation therapy has also reportedly been used as a mercury detoxification for people concerned about the long-term impact of their silver dental fillings,[27] and as treatment for children's behaviour challenges.[28]

One of the most well-known and controversial unproven applications of chelation therapy for children is as a treatment for autism.[29] A 2015 Cochrane review found no clinical trial evidence to suggest chelation therapy is an effective intervention for autism, and recommended that "[g]iven prior reports of serious adverse events, such as changes to calcium levels in blood, kidney impairment and reported death, risks of using pharmaceutical chelating agents for ASD currently outweigh proven benefits".[30] The authors suggested that before clinical trials are conducted, it would be important to have evidence that heavy metals cause or exacerbate autism severity, as well as evidence about the safety of chelating agents for target recipients. In 2013, the National Institute for Health and Care Excellence in the United Kingdom recommended against the use of chelation therapy to manage autism in children and youth.[31] Chelation is also

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1.3886264>. For more information on TACT2, see the trial site, online: <https://tact2.org/>. As of October 1, 2021, no results were reported.

[23] See e.g. Timothy Caulfield, "Commentary: the law, unproven CAM and the two-hats fallacy" (2012) 17:1 Focus on Alternative & Complementary Therapies 4 at 4. See also Richard Haigh, "Reconstructing Paradise: Canada's Health Care System, Alternative Medicine and the Charter of Rights" (1999) 7 Health LJ 141 at para 15.

[24] Jeremy Snyder & Timothy Caulfield, "Patients' crowdfunding campaigns for alternative cancer treatments" (2019) 20 Lancet Oncology 29.

[25] Bedlack et al, *supra* note 3 at 922.

[26] L Susan Wieland, Eric Manheimer & Brian Berman, "Development and classification of an operational definition of complementary and alternative medicine for the Cochrane Collaboration" (2011) 17:2 Alternative Therapies Health & Medicine 50.

[27] Rebecca Wigod, "Mercury Rising: Silver amalgam dental fillings are causing some patients to seek chelation therapy. But mainstream medicine says it's a fringe treatment that serves only as a placebo" *The Vancouver Sun* (25 May 1998) B10.

[28] Rebecca Wigod, "Lead blamed for 'twins from hell'" *The Vancouver Sun* (24 August 1995) B4.

[29] Chelation therapy for autism received considerable public attention when it was promoted by celebrity Jenny McCarthy, who allegedly used it to 'cure' her son's autism, which she controversially claimed was caused by vaccines. See Michael Specter, "Jenny McCarthy's Dangerous Views", *The New Yorker* (15 July 2013), online: <www.newyorker.com/tech/annals-of-technology/jenny-mccarthys-dangerous-views>. For a review of when testing may be appropriate to demonstrate no need for chelation therapy as a treatment for autism, see Jeffrey Brent, "Commentary on the Abuse of Metal Chelation Therapy in Patients with Autism Spectrum Disorders" (2013) 9 J Medical Toxicology 370.

[30] S James et al, "Chelation for Autism Spectrum Disorder (ASD) (Review)" (2015) 5 Cochrane Database Systematic Revs CD010766, online: <doi: 10.1002/14651858.CD010766.pub2> at 2.

[31] National Institute for Health and Care Excellence, "Guidance: Autism – management of autism in children and young people" (August 2013), online: <www.nice.org.uk/donotdo/do-not-use-chelation-to-manage-autism-in-any-

listed on England's National Health Service website as one of several "Fake and harmful autism 'treatments'".[32] Even among some CAM proponents, chelation therapy for autism has been characterized as unsafe, based on basic theoretical flaws, and as a treatment that should be discouraged.[33]

One of the major concerns regarding unproven applications of chelation therapy is that this treatment has potential risks. In addition to removing toxic metals, chelators can remove other vitamins and minerals that are important for health, such as calcium. Other risks associated with chelation therapy include the possibility that it can cause Stevens–Johnson syndrome (a serious skin peeling condition), liver and kidney dysfunction, low neutrophils (white blood cells), headache, nerve pain, burning sensations (paresthesia), fatal hypocalcaemia (low calcium), and "significant iron deficiency".[34] It can also cause high blood pressure, rash, low blood sugar, and blood clots (thrombophlebitis).[35] The high-profile death of a 5-year old from the United Kingdom who suffered cardiac arrest while receiving chelation therapy for autism in the US triggered heightened attention to its risks.[36] There is also concern about harm that may occur if someone delays or avoids effective treatments in favour of chelation therapy.[37]

Notwithstanding its risks and the lack of conclusive evidence of safety or the efficacy of chelation therapy for unproven applications, there has long been a private market where individuals can access chelation therapy for a wide variety of indications. As early as 1985, the out-of-pocket costs of chelation therapy in the private market were noted as ranging from $3,000-$10,000 USD.[38] Over time, this market has expanded to the internet, triggering the observation that "the magnitude reached by 'chelation therapy' on the web is astonishing", with chelation therapy "passed off as being the panacea for a variety of disorders".[39] The claims made on chelation therapy clinic websites have notable parallels to other forms of unproven medical interventions such as stem cell interventions (Chapter 7). The claims include their purported ability to safely and effectively treat a wide range of conditions such as high cholesterol, diabetes, stroke, coronary heart disease, and arthritis.[40] Although there are unproven chelation

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context-in-children-and-young-people>. NICE provides national guidance on health and social care in the United Kingdom. This guidance was reviewed and maintained in June 2021.

[32] National Health Service, "Fake and harmful autism 'treatments'" (last visited 18 April 2019), online: <www.nhs.uk/conditions/autism/autism-and-everyday-life/fake-and-harmful-treatments/>.

[33] R. Scott Akins, Kathy Angkustsiri & Robin Hansen, "Complementary and Alternative Medicine in Autism: An Evidence-Based Approach to Negotiating Safe and Efficacious Interventions with Families" (2010) 7 Neurotherapeutics: J American Society for Experimental NeuroTherapeutics 307 at 311-312.

[34] *Ibid* at 312. Stevens-Johnson syndrome is a rare but serious disorder that affects the skin and mucous membrane and is usually caused by a reaction to medication.

[35] Government of Alberta, "Chelation Therapy", *supra* note 10. Thrombophlebitis is an inflammatory process that can cause blood clots.

[36] Arla Baxter & Edward Krenzelok, "Pediatric fatality secondary to EDTA chelation" (2008) 46 Clinical Toxicology 1083; see also Ed Pilkington, "Parents sue after boy dies during autism treatment" *The Guardian* (10 July 2007), online: < www.theguardian.com/world/2007/jul/10/usa.edpilkington>.

[37] Seely, Wu & Mills, *supra* note 5; see also Alberta Health Services, *supra* note 1.

[38] Parachini, *supra* note 9.

[39] Crisponi et al, *supra* note 4 at 284.

[40] See e.g. Michael Greenberg, "Chelation Therapy: Never Validated or Scientifically Proven" (2002) 24:7 Emergency Medicine News 29. This article presents one clinic as an example. It described a course of chelation therapy as typically including 10-30 sessions at 1.5-2 hours each, with 2-3 sessions per week. In 2002, each block of 10 sessions was $1200 USD.

products that people can self-administer (i.e. over the counter products), this research focuses on chelation therapy provided by physicians in Canada for non-standard of care applications.[41] The next section of this chapter presents highlights of this form of chelation therapy's history in Canada.

5.1.2 Unproven applications of chelation therapy in Canada

Public interest in chelation therapy, particularly as a treatment for cardiovascular conditions, grew in prominence in Canada in the late 1980s and 1990s. Numerous media stories presented positive anecdotal reports of individual treatment success,[42] and as discussed in more detail in the next section, there were strong political lobby efforts to expand access. In the late 1980s, the Government of Ontario and the College of Physicians and Surgeons of Ontario prohibited provision of chelation therapy for cardiovascular conditions.[43] Conversely, British Columbia initially took a more permissive approach, and there are reports of Canadians travelling to British Columbia from other provinces for chelation therapy.[44] Other news articles dating back to the 1980s highlight similar stories of individuals travelling to the US for chelation treatment.[45]

More chelation therapy clinics opened in Canada throughout the 1990s, enabled by legislative reforms (discussed in more detail below) that expanded physicians' freedom to provide alternative therapies. A discussion in the Alberta Legislative Assembly reflected that by 1994, there were at least four chelation therapy clinics in Alberta with an estimated 12,000 people waiting for treatment,[46] and that by 1998, there were seven physicians approved to provide CAM in Alberta, including chelation therapy.[47] As of May 1998, the Saskatchewan Minister of Health indicated there were nine chelation therapy clinics operating in Saskatchewan by physicians licensed to practice chelation therapy.[48] These treatments, each of which typically involved a course of 25-30 intravenous administration sessions at $100 each, were not covered by provincial health insurance.[49] An article in *MacLean's* from 1999 suggested there were by

[41] Although outside the scope of this analysis, chelation therapy is also provided by other health care professionals, including providers of complementary and alternative medicine such as naturopaths, with related but distinct implications for regulation and governance. See e.g. Blake Murdoch, Robyn Hyde-Lay & Timothy Caulfield, "Commentary: An Examination of the Public Justifications for the Expansion of Canadian Naturopaths' Scope of Practice" (2011) 19 Health LJ 215; see also Laura Eggertson, "The new rules of naturopathy" (2012) 184:14 CMAJ E743.

[42] See e.g. Barbara Turbull, "Shooting past bad blood; Blood therapy could be non-surgical answer for clogged arteries" *Toronto Star* (4 May 2007) E5; see also Eugene Perry, "Success Story; Chelation testimony" *MacLean's* (2 August 1999) 4; see also Robert Walker, "Artery therapy blocked by ban in most provinces; Calgary patient swears by chemical treatment" *Edmonton Journal* (28 November 1991) B9.

[43] Janice Mawhinney, "Controversial chelation has devoted believers; Infusions provide some with alternative to open heart surgery" *Toronto Star* (26 February 1999) A1.

[44] See e.g. Robert Walker, "Artery therapy ban drives patient west" *Calgary Herald* (25 November 1991) B1.

[45] Edmonton Journal, "Canadians flock to U.S. clinic for therapy" *The Edmonton Journal* (11 June 1989) B6.

[46] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky).

[47] Alberta, *Journals of the Legislative Assembly*, 24-2 (12 February 1998) at 348-349 (Hon. Mr. Magnus & Hon. Mr. Jonson).

[48] Saskatchewan, *Journals of the Legislative Assembly*, 23-3 (25 May 1998) at 1350 (Hon. Mr. Calvert).

[49] Anon (1997) 157:6 CMAJ 752.

then approximately 50 physicians in Canada offering chelation therapy for coronary artery disease.[50]

One study involving patients who had coronary angiography in Alberta between 1995 and 1996 found that 8% of respondents either were using or had also used chelation therapy.[51] A survey of 360 patients who received coronary angioplasty in Alberta between 1998 and 2000 showed 96 had also used chelation therapy. In addition to the frequency of use of chelation therapy, this research also provides some insight into people's motivations. Of the individuals who pursued chelation therapy, "20.8% believed that chelation therapy could cure heart disease, 44.2% believed that it could relieve symptoms, 16.7% believed that it could have side effects, and 58.4% believed that it could increase quality of life". Approximately 50% used chelation therapy to avoid heart surgery.[52] This study also found that a majority of patients looked to physicians to help them understand the benefits and risks of chelation therapy. In brief, chelation therapy was often viewed as a non-invasive and safe option, with few side effects.[53] Another survey explored what factored into people's decisions regarding chelation therapy. It found that the most important factors in that decision included:

> previous experience with or learning about chelation therapy, openness to alternative treatments, satisfaction with current level of (traditional) care, physician opinion regarding chelation therapy, costs associated with chelation therapy, perceived access to chelation therapy provider, current state of health (good or bad), and wanting to do 'all one can' for heart health.[54]

Much of the history surrounding access to chelation therapy in Canada has been closely linked with that of access to CAM. Ipsos Reid surveys from 1997, 2006, and 2016 suggested that over 75% of Canadians had tried at least one form of CAM, although chelation was among the least tried CAM therapies by Canadians in all three surveys.[55]

As discussed in the sections that follow, there was strong support for expanded access to chelation therapy among advocates and in some provincial legislative assemblies through the 1990s. Much of this support reflected broad enthusiasm for a wide range of potential benefits and applications of chelation therapy.[56]

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[50] Susan Oh, "An alternative to Bypass surgery?" *MacLeans's* (12 July 1999) 112:28, 50.
[51] Hude Quan et al, "Use of chelation therapy after coronary angiography" (2001) 111 American J Medine 686.
[52] Hude Quan et al, "Opinions on chelation therapy in patients undergoing coronary angiography: Cross-sectional survey" (2007) 23:8 Canadian J Cardiology 635 at 635.
[53] *Ibid* at 637.
[54] K.M. King-Shier, "Understanding coronary artery disease patients' decisions regarding the use of chelation therapy for coronary artery disease: Descriptive decision modeling" (2012) 49 Intl J Nursing Studies 1074. This survey included 167 patients, 27 of whom where current users of chelation therapy, 72 were previous users, and 68 had never used chelation therapy.
[55] Nadeem Esmail, "Complementary and Alternative Medicine: Use and Public Attitudes, 1997, 2006, and 2016" (April 2017), *The Fraser Institute,* online (pdf): <www.fraserinstitute.org/sites/default/files/complementary-and-alternative-medicine-2017.pdf>.
[56] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky).

However, the growth of the Canadian market for chelation therapy has not been uncontroversial, and there have been high-profile debates within the medical profession.[57] The "chelation debate" continued in Canada through the 2000s.[58] By the late 2010s, public discourse and policy debates started to reflect more critical perspectives. In 2019, a British Columbia MLA made the following comment, which stands in sharp contrast to the above earlier framing of chelation therapy: "I'm not speaking about pseudoscience therapies like chelation".[59] Nonetheless, and notwithstanding the lack of evidence regarding effectiveness and its potential risks, there have been reports of chelation therapy being used in Canada as a treatment for autism as recently as 2018,[60] and at the time of writing there were still clinics offering forms of chelation therapy for cardiovascular disorders.[61] For example, one clinic offers "Detoxifying therapies", and explains: "After testing for heavy metals, chelating agents remove lead, mercury, arsenic, aluminum and cadmium, safely and effectively from the body when specific protocols are followed. Research shows chelation therapy can be beneficial and safe for patients with heart disease".[62] The following sections will explore regulation and governance of access to chelation therapy in Canada, recognizing that it is still an evolving situation.

5.2 Regulatory and governance analysis

Following the conceptual framework outlined in Chapter 2, my regulation and governance analysis will proceed in four parts. I will address actors and instruments, clarity of purpose, legitimacy, and responsiveness and adaptability.

5.2.1 Actors and instruments

For this analysis, governance actors are bodies, institutions, or identifiable individuals with influence over access to chelation therapy. Regulatory actors are a subcategory of governance actors and include the state as well as bodies acting under direct state authority. Over the long history of chelation therapy in Canada, a variety of regulatory and governance actors have exerted influence over access to this intervention, using different forms of instruments. The most prominent actors have been governments, medical regulatory and professional bodies, and advocacy groups. The courts have also played an important role by interpreting legislation relevant to access issues, and by considering related questions of

[57] Mark Lowey, "Bad Medicine? Chelation therapy raises questions about alternative treatments" *Calgary Herald* (3 September 1994) B6; see also Joan Breckenridge & Doug Saunders, "Bitter medicine There's a nasty turf war underway between orthodox treatments and the growing armamentarium of unproved therapies. The old guard says it just wants to protect patients from quacks. The newcomers say the medical establishment is motivated by fear, ignorance and territoriality" *The Globe and Mail* (3 June 1995) D1.

[58] See e.g. Martin Mittelstaedt, "The chelation debate" *The Globe and Mail* (27 August 2002) R5.

[59] British Columbia, *Journals of the Legislative Assembly*, 41-4, No 21 (22 May 2019) at 9:35 (Hon. V. Ly).

[60] See e.g. *A.B.K. v. J.M.G*., 2019 CanLII 115445 (ON HPARB); see also Nicole Ireland, "Treatment to remove metals from children with autism unproven and risky, but no clear regulations" *CBC News* (30 August 2018), online: <www.cbc.ca/news/health/autism-chelation-therapy-unproven-and-dangerous-1.4803423>.

[61] See e.g. SOHO Integrative Medicine, "Chelation Therapy" (last visited 27 May 2022), online: <sohointegrativemedicine.com/chelation-therapy/>. This clinic provides an Ontario address for its Canadian location, with other locations in the US.

[62] Markham Integrative Medicine, "Services; Integrating Conventional and Complementary Medicine" (last visited 27 May 2022), online: <integrative-medicine.ca/services/>.

evidence. This section presents examples of influential actors and the varied instruments used to influence access to chelation therapy provided by physicians in Canada.[63]

Instruments (i.e. modes of regulation or governance) are the tools or strategies used to exert influence (i.e. to steer conduct), such as information, funding, and in the case of the state, coercive measures including legislation. As discussed in Chapter 2, leading theories of regulation including Braithwaite's concept of "responsive regulation",[64] and Black and Baldwin's work on "really responsive regulation",[65] identify regulatory instruments with varied levels of coerciveness. They suggest that information-based strategies are among the least coercive regulatory instruments available and are often a good place to start.

Information-based approaches have been used by regulatory and governance actors including medical organizations, research bodies, and governments, generally to warn against unproven applications of chelation therapy, including for heart disease. As early as 1986, the Canadian Cardiovascular Society reportedly mailed a warning against chelation therapy for heart disease to medical associations and health ministries.[66] More recently, in 2014 it published Guidelines for the Diagnosis and Management of Stable Ischemic Heart Disease, which recommended against chelation therapy.[67] The Heart and Stroke Foundation has made similar cautionary statements regarding the expense of chelation therapy for artery disease and its risks, including convulsions, abnormal heart rhythms, and kidney damage.[68] The Institute for Clinical Evaluative Sciences in Ontario, a not-for-profit research institute that seeks to inform health care and policy decisions, provided guidance dating to the late 1990s to caution that the evidence available at that time did not support use of EDTA chelation therapy to treat coronary artery plaques.[69]

Different medical organizations have focused on other unproven applications of chelation therapy. In 2010, the Canadian Medical Association Journal, a widely read publication for Canadian physicians, published a brief information update titled "Chelation cures 'dangerously misleading'".[70] This update discussed the United States Food and Drug Administration (FDA) warnings issued to companies marketing "chelation 'miracle cures' to treat everything from autism to heart conditions", and noted that there are "serious safety concerns" with chelation

[63] Access via online purchases of OTC applications is beyond the scope of this study, as are considerations of facilities regulations. See e.g. Dan Lett, "Private health clinics remain unregulated in most of Canada" (2008) 178:8 CMAJ 986.
[64] John Braithwaite, "Types of responsiveness" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 117.
[65] Julia Black and Robert Baldwin, "Really Responsive Risk-Based Regulation" (2010) 32 L & Policy 181.
[66] Marilyn Dunlop, "New heart therapy stirs controversy" *Toronto Star* (9 December 1986) B1.
[67] G.B. John Mancini et al, "Canadian Cardiovascular Society Guidelines for the Diagnosis and Management of Stable Ischemic Heart Disease" (2014) 30 Canadian J Cardiology 837 at 842. This publication was a consensus statement from a panel of experts on behalf of the Canadian Cardiovascular Society (CCS). The CCS identifies itself as the "national voice for cardiovascular physicians and scientists in Canada", and as representing more than 2,000 professionals in the field. See Canadian Cardiovascular Society, "About us" (last visited 15 June 2022), online: <ccs.ca/about/>.
[68] Marilyn Dunlop, "Bone fracture risk higher in women smokers: Study" *Toronto Star* (26 February 1994) K2.
[69] Murray Oliver, "MDs remain sceptical as chelation therapy goes mainstream in Saskatchewan" (1997) 157 CMAJ 750 at 753.
[70] Lauren Vogel, "Chelation cures 'dangerously misleading'" (2010) 182:17 CMAJ E756 at E756.

therapy including "dehydration, kidney failure and death".[71] In 2019, the Canadian Paediatric Society published a Position Statement regarding the post-diagnostic management and follow-up care for autism spectrum disorder, in which it identified chelation therapy as risky and ineffective.[72]

Alberta Health Services (AHS) was a notable actor in this case study for its use of information-based tools on its government-sponsored, public facing websites. For example, it published a public FAQ document regarding chelation therapy where it explained chelation therapy and provided cautions regarding types of medical conditions for which chelation therapy has not been shown to be useful, including autism, cancer, heart disease, Parkinson's disease, and multiple sclerosis.[73] This document recommended against the use of any non-prescription oral or suppository forms of chelators, with an emphasis on the risks for children.[74] MyHealthAlberta also produced an information page on chelation therapy which explained how it works and stated that "[e]xcept as a treatment for lead poisoning, chelation therapy is controversial and unproved".[75] Although not a distinct regulatory or governance actor, media sources also disseminated information-based warnings about chelation therapy.[76]

Funding is another influential access-related instrument often, though not exclusively, used by government.[77] For example, provincial and territorial governments can support individuals in accessing a medical intervention by including it in their publicly funded healthcare programs.[78] I found some limited discussion in political forums regarding public funding for research into the safety and efficacy of chelation therapy for heart disease. For example, in 1994 there was a motion passed in the Alberta Legislative Assembly directing the Heritage Savings Trust Fund Committee to encourage the Minister of Health to use its trust fund to investigate the efficacy of chelation therapy as a treatment for atherosclerosis.[79] However, it does not appear that public funding has been used to any large extent to facilitate access to chelation therapy in Canada.

Conversely, access to unproven applications of chelation therapy has more commonly been limited by provinces and territories withholding public funding for it. For example, PEI's *Autism Funding Guidelines* list chelation as one of several "Non-Evidence Based Practices for

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[71] *Ibid*.
[72] Canadian Paediatric Society, "Position Statement: Post-diagnostic management and follow-up care for autism spectrum disorder" (24 October 2019, updated 2 February 2021), online: < www.cps.ca/documents/position/asd-post-diagnostic-management>. Hyperbaric oxygen therapy and secretin were other interventions placed in this same category.
[73] Alberta Health Services, *supra* note 1.
[74] *Ibid*. Identified risks include loss of important minerals for growth.
[75] Government of Alberta, "Chelation Therapy", *supra* note 10.
[76] See e.g. Chris Zdeb, "Misinformation is a killer" *Saskatoon Star Phoenix* (1 March 2003) E3.
[77] Hood and Margetts use the term "treasury" to describe this government power. See Christopher Hood & Helen Margetts, *The Tools of Government in the Digital Age* (New York: Palgrave Macmillan, 2007).
[78] Many Canadians also have private health insurance, commonly provided as an employment benefit, which provides some support for services that are not covered in the public system such as many dental, optometrist, pharmaceutical, and physiotherapist treatments, among other products and services. I did not find data to suggest that private health insurance has a played a notable role in facilitating access to chelation therapy in Canada, or to the other unproven medical interventions studied in this project, but that may be an area worthy of exploration in future research.
[79] Alberta, *Journals of the Legislative Assembly*, 23-2 (25 January 1994) at 193 (Hon. Mr. Mitchell).

Individuals with ASD", which are not eligible for funding.[80] Provincial or territorial decisions not to fund chelation therapy have been linked to insufficient evidence and lack of endorsement by the medical community. As an illustration, there was discussion before the Committee of Finance in Saskatchewan in 1998 about whether chelation therapy would be funded provincially, given reports of positive patient experiences. Then Minister of Health, the Honourable Mr. Calvert's response was that it would not be covered without endorsement by the College of Physicians and Surgeons of Saskatchewan.[81] In response to an update sought in 2013, the Deputy Minister of Health advised that there had been no movement on the file in the past five or six years, given remaining "issues around medical evidence".[82]

Along with governments, medical professional regulatory bodies including provincial colleges of physicians and surgeons are important actors in regulation and governance of medical interventions. They could be considered regulatory actors because they act under delegated provincial government authority, and as part of the broader governance framework because they also operate with a high degree of autonomy from government in various capacities. The colleges of physicians and surgeons have a range of regulatory and governance instruments at their disposal, including information (e.g. advisories to members), professional guidelines or practice standards, and the professional discipline process. Over the history of chelation therapy use in Canada, colleges have employed different instruments to influence or direct the conduct of regulated physicians.

One example of an information-based approach used by the College of Physicians and Surgeons of Alberta is a 2013 issue of its newsletter, *The Messenger*, which addressed physicians' approaches to complementary and alternative medicine.[83] It gave chelation therapy as one example of a CAM, which it indicated includes "any therapy not supported by scientific studies published in orthodox medical literature. Without scientific evidence, there are unanswered questions about the safety and effectiveness of these therapies". This article reminded physicians that they cannot provide CAM if they feel it will endanger a patient's health and advised they must consider both the risk of the intervention as well as of foregoing conventional care. In another information-based strategy, the College of Physicians and Surgeons of British Columbia included a case summary from a professional disciplinary decision regarding provision of chelation in the January/February 2015 issue of the newsletter, *The College Connector*. The Inquiry Committee determined that the physician had provided chelation therapy without adequately investigating or treating the patient for their symptomatic ischemic heart disease, and thus failed to meet the expected standards for medical care of patients receiving therapy characterized as complementary or alternative. The following excerpt from *The College Connector* summary reflects important guidance to College of Physicians and Surgeons of British Columbia's members regarding its position with respect to physicians' obligations when providing CAM, including chelation therapy:

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[80] Prince Edward Island, "Autism Funding Guidelines" (July 2014), online (pdf): <www.princeedwardisland.ca/sites/default/files/forms/eelc_autism_funding_application_and_guidelines.pdf> at 32.
[81] Saskatchewan, *Journals of the Legislative Assembly*, 23-3 (25 May 1998) at 1349-1350 (Hon. Mr. Toth & the Hon. Mr. Calvert).
[82] Saskatchewan, *Journals of the Legislative Assembly*, Standing Committee on Human Services, 27, no 19 (30 April 2013) at 443 (Hon. Mr. Hendricks).
[83] College of Physicians and Surgeons of Alberta, "Complementary & Alternative Medicine" (6 February 2013), online: *The Messenger* <www.cpsa.ca/ays-complementary-alternative-medicine/?highlight=chelation>.

> Many physicians are naturally frustrated by the persistence of unscientific treatments and have formed the mistaken belief that, given the statutory protection set out above, there are no rules by which the College can hold physicians employing these methods accountable when unsuspecting patients are placed at risk or harmed. While it is true that the Act values freedom of choice for patients, the expectations of the College are concisely set out in a professional guideline titled Complementary and Alternative Therapies. Key points include requirements that physicians must:
>
> • carry out appropriate and conventional examinations and investigations in order to establish a diagnosis and basis for treatment
>
> • employ a rigorous medical approach before offering any unorthodox therapy
>
> • not expose the patient to any degree of risk from a complementary or alternative therapy of no proven benefit.
>
> The College is legally prohibited from investigating physicians solely for their use of unconventional therapies, but it can and does hold such physicians to expected standards in their medical management of the conditions they encounter. For every patient, standard medical assessments, diagnoses, differential diagnoses, and referrals are required. Patients have a right to refuse effective and proven therapies, but these must be explained and offered in accordance with practice standards.[84]

Examples of physicians' practice standards with respect to provision of CAM and chelation therapy specifically will be discussed below.

Professional standards and guidelines are a more coercive instrument that medical regulatory bodies can use to control the conditions under which access to medical interventions is provided. There are some chelation-specific professional guidelines and practice standards in Canada, and these have evolved over time to be more permissive of expanded access.[85] In 1991, the British Columbia College of Physicians and Surgeons passed a resolution that noted the "controversial nature, reported potential hazards and the potential for entrepreneurial exploitation" associated with chelation therapy and determined that it was "important to evaluate the circumstances in the case of each practitioner reported to be providing chelation therapy".[86] It followed this resolution with another in 1992, in which it endorsed chelation therapy with EDTA only for conditions as approved by the Health Protection Branch and Health & Welfare Canada

[84] College of Physicians and Surgeons of British Columbia, "Cases and recommendations of the Inquiry Committee" (January/February 2015) 3:1 *College Connector* 10 at 10.

[85] I found references to the Yukon Medical Council developing a chelation-specific position statement as early as 1996 but was not able to obtain a copy of it. Yukon, *Journals of the Legislative Assembly*, 28-2 (18 April 1996) (Hon. Mr. Fisher); see also Robert Crouch et al, "Complementary/Alternative Health Care and HIV/AIDS; Legal, Ethical & Policy Issues in Regulation", (2001) online (pdf*): Canadian HIV/AIDS Legal Network* <www.hivlegalnetwork.ca/site/wp-content/uploads/2013/04/Complimentary+Alternative+Healthcare+-+ENG.pdf> at 80.

[86] *College of Physicians and Surgeons of British Columbia v. Barber (B.C.C.A.)*, [1993] B.C.J. No. 2531, 87 BCLR (2d) 362 at para 13.

(lead poisoning) or in an approved investigational setting, and required any physician providing EDTA chelation therapy in other circumstances to be investigated by the college.[87]

Whether the Council had the power to make these resolutions was tested in *Strauts v. College of Physicians & Surgeons (British Columbia)*[88]. Dr. Strauts was a physician in British Columbia and director of the Canadian Association of Chelating Physicians who was treating patients with chelation therapy. The College of Physicians and Surgeons of British Columbia wanted to investigate his records pursuant to the 1991 resolutions, and Dr. Strauts sought to have the two resolutions set aside. The British Columbia Court of Appeal affirmed the Superior Court's holding that the Council had the power to make the resolutions by virtue of its authority under the *Medical Practitioners Act*[89]. In so finding, the court reflected on the broad mandate the legislation gave the Council to make rules regarding the professional conduct of members engaged in the practice of medicine, and on the college's legislative mandate to act in the public interest.[90]

The College of Physicians and Surgeons of Alberta has a Guideline for Provision of Intravenous EDTA Chelation as a Complementary and Alternative Medicine.[91] First released in 1999 and updated in 2010, this Guideline applies only to the intravenous administration of EDTA. It relies on the protocol for chelation therapy of the American College for Advancement in Medicine (ACAM), and states that "[a]lthough the college does not approve therapies themselves, the development of a standardized approach based on published research or on expert experience is desirable for some therapies".[92] To be eligible to provide chelation therapy in Alberta under this Guideline, physicians must be licensed to practice medicine, and have a certificate of competence in chelation therapy from the American College for Advancement in Medicine, evidence of continuing education in chelation therapy, an active practice in chelation therapy, and a current certification in cardiopulmonary resuscitation. The Guideline also includes requirements regarding staff, contraindications, patient assessment, required laboratory investigations, equipment, documentation, and quality improvement.

The College of Physicians and Surgeons of Saskatchewan has had a chelation-specific bylaw since 1997.[93] The original bylaw applied only to chelation therapy for indications other than heavy metal poisoning. Its opening clause confirmed that "[w]hile the College of Physicians and Surgeons is not convinced of the efficacy of chelation therapy, and does not endorse its use for any purpose other than heavy metal poisoning, it recognizes that there is public demand for

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[87] *Ibid* at para 18.
[88] (1996), 42 Admin. L.R. (2d) 219, 1996 CanLII 8471 (BC SC), aff'd *Strauts v. The College of Physicians and Surgeons of British Columbia*, (1997), 47 Admin. L.R. (2d) 79, 36 BCLR (3d) 106, 1997 CanLII 3188 (BCCA) [*Strauts*].
[89] RSBC 1979, c 254.
[90] *Strauts, supra* note 88 at paras 20-22.
[91] College of Physicians and Surgeons of Alberta, "Provision of Intravenous EDTA Chelation as a Complementary and Alternative Medicine" (last modified August 2010), online: <docplayer.net/10150227-Provision-of-intravenous-edta-chelation-as-a-complementary-and-alternative-medicine.html>. This 2010 publication updated the previous 1998 version.
[92] *Ibid*.
[93] This bylaw was passed pursuant to the authority granted by the *Medical Profession Act 1981*, SS 1980-81, c M-10.1.

safe access to this treatment".[94] The Bylaw established requirements for charting practices, informed consent, pre-procedure testing requirements, exclusion criteria, treatment protocols, and follow-up procedures, among other safeguards including practice review provisions. It also included a provision stating that "[n]o physician shall, by any method, state or imply that chelation therapy has been approved by the College of Physicians and Surgeons or that any particular physician has been endorsed by the College to perform chelation therapy".[95] Practising chelation therapy otherwise than in accordance with this bylaw was established as "unbecoming, improper, unprofessional or discreditable conduct for a physician",[96] for which physicians may be subject to professional discipline. The bylaw concluded with this provision:

> 18 Chelation therapy is an unproven therapy with an unproven record of safety and efficacy. The Council may review the available information from time to time and may change the standards and protocols which apply to the practice of chelation therapy and may prohibit the practice of chelation therapy if the available information indicates to the Council that this would be a prudent action.

This bylaw was reportedly opposed by some Saskatchewan physicians.[97] It was repealed and replaced with an updated version in 2004 that included provisions clarifying that the costs of practice inspections would be borne by the physician who was subject to the inspection.[98] All of the CPSS bylaws were subsequently repealed and replaced with a consolidated version which incorporated the previous chelation bylaw in its entirety.[99]

In some provinces and territories, expanded access to chelation therapy came by way of legislative amendments that gave physicians greater latitude to provide CAMs. Legislation is perhaps the most familiar instrument in governments' regulatory toolboxes, and potentially one of the most coercive. In Alberta, Ontario, and British Columbia, these amendments began as private member's bills.[100] These provisions have been referred to as "negative proof" provisions,[101] because they permit physicians to provide CAM (including chelation therapy) as long as it does not present greater risk than conventional standard of care treatment. For example, Bill 339 involved the following amendment to Alberta's *Medical Profession Act*:

> (3) Notwithstanding subsection (2), a matter, conduct or thing shall not, in the absence of demonstrable harm to the patient, be judged to be unbecoming conduct solely on

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[94] *The Medical Profession Act, 1981, Bylaw 52 – College of Physicians and Surgeons of Saskatchewan Standards for Performance of Chelation Therapy*, (1997) S Gaz I, 93:7 at 128 [*Bylaw 52*]. The bylaw was revised with minor updates in 2000. See *The Medical Profession Act, 1981, Bylaw 52 – College of Physicians and Surgeons of Saskatchewan Standards for Performance of Chelation Therapy*, (2000) S Gaz I, 96:38 at 1171.
[95] *Bylaw 52*, *supra* note 94 at s 12.
[96] *Ibid*, at s 17.
[97] Oliver, *supra* note 69.
[98] *The Medical Profession Act, 1981, Bylaw 52 – College of Physicians and Surgeons of Saskatchewan Standards for Performance of Chelation Therapy* (25 June 2004) S Gaz I, 100:26 at 861.
[99] This approach is still in place at the time of writing. Saskatchewan College of Physicians and Surgeons, *Regulatory Bylaws – for medical practice in Saskatchewan* (October 2021), online (pdf): <www.cps.sk.ca/iMIS/Documents/Legislation/Legislation/Regulatory%20Bylaws.pdf> at s 22.2.
[100] Ann Silversides, "More provinces protecting MDs who practise alternative medicine" (2002) 166:3 CMAJ 367 at 367.
[101] Nola Reis & Katherine Fisher, "The Increasing Involvement of Physicians in Complementary and Alternative Medicine: Considerations of Professional Regulation and Patient Safety" (2013) 39 Queen's LJ 273 at para 17.

> the grounds that the matter, conduct or thing arises from a practice of chelation therapy.[102]

Bill 339 and then its later version Bill 209 were debated from 1994 until 1996. Much of the legislative discussion surrounding Bills 339 and 209 focused on the desire to protect physicians who wished to provide chelation therapy, or other non-standard treatments, from professional discipline. For example, one Alberta MLA made the following remarks:

> I'm not prepared to advocate that chelation therapy is a treatment for everything I have heard it will benefit, but I am committed to seeing it gain legitimacy so that private chelation clinics can be fully accessible and the doctors can administer this treatment under established guidelines without fear of disciplinary action from the college.[103]

The appropriateness of chelation therapy for heart disease and obesity was a matter of debate in Ontario in the late 1980s at which time, based on the recommendation of the College of Physicians and Surgeons of Ontario, the province amended the *Health Disciplines Act* to clarify it was unacceptable.[104] However, as in other provinces and territories, by the late 1990s there was considerably more support in Ontario for CAM options. Bill 2, the *Medicine Amendment Act, 1999* was proposed by MLA Monte Kwinter and was subsequently referred to as the "Kwinter Bill".[105] The sole section in the Kwinter Bill amended the *Medicine Act*[106], by adding this provision:

> 5.1 A member shall not be found guilty of professional misconduct or of incompetence under section 51 or 52 of the Health Professions Procedural Code solely on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice unless there is evidence that proves that the therapy poses a greater risk to a patient's health than the traditional or prevailing practice.[107]

A similar amendment was first proposed in British Columbia in 2000,[108] and again in 2001 with Bill M202 – 2001, *The Medical Practitioners Act Amendment Act, 2001*.[109] Manitoba's *Medical*

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[102] Bill 339, *Medical Profession Amendment Act, 1993*, 4th Sess, 22nd Leg, Alberta, at s 2. A later version of this Bill was introduced as Bill 209, *Medical Profession Amendment Act, 1996*, 4th Sess, 23rd Leg, Alberta. Bill 209 moved from a focus on chelation therapy specifically to therapies that are "non-traditional" or which "departs from the prevailing medical practices" (at s. 2).

[103] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1459 (Hon. Mr. Brassard).

[104] See Brad Evenson, "Two treatments deemed unacceptable" The Ottawa Citizen (2 August 1987) A13.

[105] Theresa Danyluk, "Prescription in the Public Interest? Bill 207, The Medical Amendment Act" (2008) (2008) 5 Man LJ 197 at 205.

[106] 1999, SO 1991, c 30.

[107] *Bill 2, Medicine Amendment Act, 1999*, 3rd Sess, 36th Leg, Ontario, 1999 (first reading 26 April 1999), online: < www.ola.org/en/legislative-business/bills/parliament-36/session-3/bill-2>.

[108] British Columbia, *Journals of the Legislative Assembly*, 36-4, vol 20, No 4 (6 July 2000) at 17152 (Hon. S. Orcherton).

[109] British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 6 (9 April 2001) at 17402 (Hon. S. Orcherton). For text of the Bill, see online: <https://www.bclaws.gov.bc.ca/civix/document/id/lc/billsprevious/36th5th:mem202-2>.

Act[110], amended in 2005 by Bill 207, *The Medical Amendment Act*[111], includes the following provision:

> Despite section 36 and Parts VIII to X, a member shall not be found guilty of professional misconduct or of incompetence solely on the basis that the member practises a therapy that is non-traditional or departs from the prevailing medical practice, unless it can be demonstrated that the therapy poses a greater risk to a patient's health or safety than the traditional or prevailing practice.[112]

British Columbia's *Medical Practitioners Act* was replaced by the *Health Professions Act* in 2009, which provides that "An investigating committee may not be appointed under subsection (1) solely on the grounds that a registrant practises complementary medicine or uses non-traditional therapies".[113]

Even where legislative reforms broadened the scope for CAM in general, chelation therapy was often central to debates. For example, although Manitoba's legislation noted above is not specific to chelation therapy, interviews with involved parties at the time pointed to the role of lobbying by constituents in the Bill's sponsoring member's constituency for legislation that would facilitate access to chelation therapy.[114] Manitoba's *Medical Act* was later replaced with *The Regulated Health Professions Act.*[115] The current version of this legislation retains the wording of the foregoing provision regarding "non-traditional therapies".[116] As discussed in the sections that follow, it appears that some of these legislative developments were initially opposed by the colleges of physicians and surgeons. For example, the College of Physicians and Surgeons of Ontario reportedly opposed the amendment outlined above until the word "solely" was added (i.e. "A member shall not be found guilty of professional misconduct or of incompetence … **solely** on the basis that the member practises a therapy that is non-traditional or that departs from the prevailing medical practice[117]), to ensure the college retained jurisdiction to regulate its members.[118]

Much of this legislative activity appears to have been promoted by advocacy organizations that have been influential actors with respect to access to chelation therapy in Canada. Chelation therapy has had strong advocacy support dating back to at least the 1980s, with seemingly well-organized political lobbying. For example, British Columbia Hansard records from 1987 detail a lobby effort where one MLA received "letters by the hundreds" from people wanting provincial funding for chelation therapy.[119] An Alberta MLA referenced having

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[110] CCSM c M90.
[111] SM 2005, c 45.
[112] *The Medical Amendment Act*, SM 2005, c 45, at s 36.1. This was the sole provision included in this amendment.
[113] *Health Professions Act,* RSBC 1996, c 183, at s 25.2(2).
[114] Danyluk, *supra* note 105 at 205.
[115] CCSM c. R117.
[116] *The Regulated Health Professions Act,* CCSM c. R117 at s 185.
[117] *The Medical Amendment Act*, SM 2005, c 45 at s 36.1, emphasis added.
[118] Silversides, *supra* note 100 at 367.
[119] British Columbia, *Journals of the Legislative Assembly*, 34-1 (8 December 1987) at 2895 (Hon. Mr. Dueck). See also British Columbia, *Journals of the Legislative Assembly*, 35-1, vol 5, No 9 (29 June 1992) at 3231 (Hon. E. Cull). The members again referenced having received "many letters" seeking funding for chelation therapy. See also British Columbia, *Journals of the Legislative Assembly*, vol 5, No 10 (27 May 1997) at 3704 (S. Hawkins and Hon. J. MacPhail).

been lobbied for access to chelation as early as 1989, at which time he indicated he was skeptical, as was "a program on CBC", "some newspapers articles" and the College of Physicians and Surgeons of Alberta.[120] By 1991, a media article from Alberta suggested that chelation therapy had "replaced abortion as the special-interest topic of choice at public meetings with politicians".[121] In 1994, an Alberta MLA observed the "strong grassroots lobby for chelation therapy",[122] and by 1997, a Saskatchewan MLA observed that hundreds of Saskatchewan residents had testified to having benefitted from chelation therapy out of province, and wanted to access it in Saskatchewan.[123]

Chelation associations played a key role in the political lobbying in favour of expanding access to chelation therapy, particularly for heart disease. The Alberta chelation association was incorporated in 1991 and reportedly had over 3,000 members by 1994.[124] Hansard records reflect that the EDTA Chelation Association of Alberta appeared at the legislative assembly on multiple occasions in the 1990s to lobby for access.[125] The EDTA Chelation Association of Saskatchewan engaged in similar advocacy through the late 1990s – 2000s, in support of legislative amendments to the *Medical Practitioners Act* that would permit expanded access to CAM including chelation therapy.[126] The British Columbia EDTA Chelation Association appeared before the Special Committee to Review the Freedom of Information and Protection of Privacy Act in 1998, seeking access to historical research records and to draw attention to the demand for chelation therapy across the province.[127] In commenting on amendments to British Columbia's legislation (discussed further below), one British Columbia MLA acknowledged and thanked various advocacy groups including the Citizens Supporting Complementary Medicine, the Association of Complementary Physicians of British Columbia, and members of the Chelation Association of British Columbia who "helped so much in pushing this initiative forward".[128]

Hansard records from Alberta, Saskatchewan, and the Yukon also contain references to petitions being presented to the legislative assemblies in favour of expanded access in different forms. For example, discussion in the Alberta assembly in 1996 references three different petitions, with 25,000, 2,500, and 3,115 names having been presented.[129] A petition tabled in the Yukon legislature in 1996 sought government approval for use of chelation therapy by registered

[120] Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1361 (Hon. Mr. Wickman).
[121] Mark Lisac, "Are Albertans finally waking up?" *Edmonton Journal* (12 November 1991) A12.
[122] Alberta, *Journals of the Legislative* Assembly, 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky).
[123] Saskatchewan, *Journals of the Legislative Assembly*, 23-2 (17 March 1997) at 240 (Mr. Kowalsky).
[124] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1459 (Hon. Mr. Brassard).
[125] Alberta, *Journals of the Legislative Assembly*, 22-4 (2 February 1993) at 2035 (Hon. Mr. Cherry & Hon. Mrs. McClellan). Minister of Health McClellan was repeatedly called to respond to questions in 1993 and 1994 about access to chelation therapy. See also Alberta, *Journals of the Legislative Assembly*, 22-4 (17 May 1993) at 2802 (Hon. Mrs. McClellan). The latter record discusses the chelation association making a presentation to the Standing Committee on Community Services. See also Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1348 (Hon. Mr. Kirkland). See also Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 858 (Hon. Mr. Langevin). Mr. Langevin welcomed members of the EDTA Chelation Association of Alberta.
[126] Anne Kyle, "Changes urged in medical legislation" *Leader Post* (24 August 2000) A5.
[127] British Columbia Legislative Assembly, Special Committee to Review the Freedom of Information and Protection of Privacy Act, 36-2 (4 February 1998) at 5:45 (J. Macpherson).
[128] British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 6 (9 April 2001) at 17402 (Hon. S. Orcherton).
[129] Alberta, *Journals of the Legislative Assembly*, 23-4 (16 April 1996) at 1137 (Hon. Mr. Brassard).

physicians,[130] and a petition presented in Saskatchewan in 1999 sought provincial funding for chelation therapy.[131] As discussed in the following section, these different forms of advocacy appear to have been a driver of many choice-based narratives that underpinned important regulatory and governance responses to chelation therapy in Canada.

Finally, courts and tribunals are other important governance actors that have exerted influence over access to chelation therapy in Canada. Three notable areas of influence stood out in the case study data, including funding-related claims, family law litigation, and professional discipline. Although the case law is limited, appeals from denials of provincial health insurance coverage for chelation therapy have generally been unsuccessful. For example, in *SM v. The General Manager, The Ontario Health Insurance Plan*[132], the General Manager of the Ontario Health Insurance Plan denied the Appellant's request for payment for chelation therapy on the grounds that it was not an insured service because it was not provided in a hospital setting under the supervision of a licensed physician.[133] In another decision, the Appellant had paid approximately $100,000 for a suite of treatments including chelation therapy to treat chronic fatigue syndrome and Lyme disease.[134] The Ontario Health Services Appeal and Review Board held that the treatments were not insured services. The Appellant had not filed any evidence to suggest that the services he received were generally accepted by the medical profession in Ontario as appropriate for someone in her medical circumstances, which is one of the legislative criteria for out-of-country services to be deemed to be insured services.

Conversely, in *Melnychuk v The Queen*[135], the Canada Revenue Agency had rejected the Appellant's medical expense claim under the Income Tax Act for vitamin, herb, and metal supplements he had purchased from a health food store or a chelation clinic as part of chelation therapy treatments for heart disease. The Tax Court of Canada dismissed the appeal because the Income Tax Act limits claims to purchases "recorded by a pharmacist". However, the court's obiter is notable because it suggests acceptance of chelation therapy as an acceptable and established treatment for heart disease, notwithstanding the previously noted medical and scientific controversy on this question, as well as acceptance of CAM options more broadly:

> Chelation therapy is a College of Physicians and Surgeons authorized therapy that removes heavy metals from a patient's body.[136]
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> …
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> In this case, the vitamins were prescribed by a distinguished medical doctor, highly qualified in the field of chelation. His treatment of the Appellant has been successful to date, preventing a second bypass operation. The Appellant purchased the specially

[130] Yukon, *Journals of the Legislative Assembly*, 29-1 (10 April 1997) (Hon. Mr. Jenkins).
[131] Saskatchewan, *Journals of the Legislative Assembly*, 23-4 (16 March 1999) at 7 (Hon. Ms. Draude).
[132] 2004 CanLII 69741 (ON HSARB).
[133] *SM v. The General Manager, The Ontario Health Insurance Plan*, 2004 CanLII 69741 (ON HSARB).
[134] *T.M. v. The General Manager, The Ontario Health Insurance Plan*, 2012 CanLII 81327 (ON HSARB) at para 3.
[135] 2002 CanLII 881 (TCC).
[136] *Melnychuk v. The Queen*, 2002 CanLII 881 (TCC) at para 3.

> designated drugs or vitamins through Dr. Wiancko's clinic. The clinic is recognized with approval by his peers, the Medical Association of Alberta.[137]
>
> …
>
> The Appellant is a very good example of a person who has used alternative methods successfully. I am sorry that I cannot give him relief, but I do commend him for his courage in coming to Court.[138]

Issues related to access to chelation therapy have also arisen in custody and child support cases. For example, in *R.K.K. v. B.M.M.*[139], one of the issues in an interim custody dispute was the authority to make medical decisions for a 6-year-old child with autism spectrum disorder. The child's mother wanted to pursue vitamin B-12 shots, chelation therapy, and parasite medications. The father objected on the basis that chelation therapy is controversial and carries risks, and that there was no evidence the child had high mercury levels warranting this treatment.[140] The court determined "there is some danger in moving too quickly and confidently with a given treatment, before a comprehensive assessment of the pros and cons".[141] Ultimately, the court held that there was "a legitimate difference of opinion between the mother and father over the best medical treatment" for the child and held that pending the final disposition at trial, major medical decisions regarding the child's autism treatments should be made jointly by the parents, with the court as the ultimate arbiter should they fail to come to a resolution.[142]

In *Ruffolo v. David*[143], the court considered claims for health-related and extraordinary expenses pursuant to Ontario's Child Support Guidelines, including chelation therapy to treat a child of the marriage who had been diagnosed with autism. The court dismissed these claims on the grounds that "the expense is not necessary, or because of lack of evidence that the expense is necessary".[144] In so finding, the court noted that it could not take any position about the treatments themselves and whether they are harmful or helpful. Healey J. observed that would be a different proceeding, and any such evaluation would require "reliable and persuasive medical evidence", going beyond "articles taken from the internet and newspapers".[145] The courts' treatment of chelation therapy in these decisions is noteworthy for the emphasis they placed on the need for full consideration of relevant evidence.

Professional disciplinary approaches to provision of chelation therapy have emphasized that physicians providing chelation therapy in Canada must comply with the relevant standards of care for CAM. In *Ontario (College of Physicians and Surgeons of Ontario) v. Wojcicki*[146], Dr. Wojcicki was alleged to have committed an act of professional misconduct and to have been incompetent as defined by subsection 52(1) of the *Health Professions Procedural Code* (the "Code"), which is Schedule 2 to the *Regulated Health Professions Act, 1991*. Part of the charge

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[137] *Ibid* at para 10.
[138] *Ibid* at para 13.
[139] [2009] Y.J. No. 54, 2009 YKSC 33.
[140] *R.K.K. v. B.M.M.*, 2009 YKSC 33 at paras 41-42.
[141] *Ibid* at paras 51-52.
[142] *Ibid* at para 48
[143] 2012 ONSC 5693 (CanLII).
[144] *Ibid* at para 31.
[145] *Ibid* at para 23.
[146] 2016 ONCPSD 9 (CanLII).

related to Dr. Wojcicki's recommendations that patients with atherosclerosis undergo chelation therapy. The Discipline Committee of the College of Physicians and Surgeons of Ontario determined that he had not complied with the College of Physicians and Surgeons of Ontario's *Complementary and Alternative Medicine Policy* and had not met the standard of practice.[147]

Similarly, in *R.N., MD v. M.B.*[148], the physician had treated a patient with intravenous chelation therapy to treat what he felt was a "dysfunction of the nervous system" and possible hypersensitivity to metals related to "a multiple chemical sensitivity syndrome".[149] The Inquiries, Complaints and Reports Committee (ICRC) of the College of Physicians and Surgeons of Ontario found that the physician's practice was inconsistent with the CAM Policy in several respects. The details of these findings are worth reviewing in full because of the insight they provide into the requirements for physicians who provide chelation therapy for non-standard applications in Ontario:

> Physicians providing CAM must reach a conventional diagnosis when assessing a patient. The Committee was not satisfied that the Applicant had done this with the patient given that "dysfunction of the nervous system" or "multiple chemical sensitivity syndrome" do not qualify as a conventional diagnosis...if physicians reach a CAM diagnosis, it must be informed by evidence and science. The Committee saw no evidence or science in the patient's case to make a diagnosis of toxic interference/metal hypersensitivity. While the Applicant advised that he uses heavy metal testing only as a guide, the Committee found no support for such testing in the medical literature; any CAM therapeutic option that is recommended by a physician must be informed by evidence and science. The Applicant provided the Committee with the Trial to Assess Chelation Therapy (TACT trial) article from the Journal of the American Medical Association which suggested that this therapy had moderate benefits for patients with myocardial infarction, but the Committee noted that the results were not enough to support the routine use in the patient group studied which, as a group, differed from the patient's type; regarding informed consent, physicians are expected to convey the extent to which the CAM diagnosis reached is supported by the conventional medical community. The Committee found no evidence in the record that the Applicant conveyed to the patient that his diagnosis of "toxic interference" is not generally supported by the conventional medical community; physicians must convey whether the therapeutic option is supported by the conventional medical community. The Committee determined that chelation therapy for a patient of her type is not supported and there is no evidence of that discussion in her medical record; physicians must convey a description of how the CAM therapeutic option compares to conventional medical interventions that would be offered to treat the same symptoms or condition. Again, the Committee found no evidence in the record of such discussion between the Applicant and the patient. In addition, the Applicant did not document the patient's consent process: she signed a generic consent

[147] *Ibid* at 4. It is notable that Dr. Wojcicki's own expert in CAM came to the same conclusion.
[148] 2019 CanLII 31648 (ON HPARB).
[149] *Ibid* at para 4. The complaint in this case was made by the patient's partner. The patient was satisfied with the treatment received.

> form, but it did not discuss what the conventional medical community thinks or would offer as conventional treatment.[150]

The Ontario Health Professions Appeal and Review Board (ON HPARB) found the ICRC's conclusions were supported by the record and were reasonable.[151] It confirmed the ICRC's decision to require the physician to appear before the college to be cautioned regarding improper consent, documentation, and examination of a patient and failing to follow the college's CAM Policy, and to require a specified continuing education or remediation program.[152]

However, the outcome in *King v. Gannage*[153] was different. Dr. Gannage is an Ontario physician who provides CAM as part of his practice, including chelation therapy for children with autism. Though not a patient of Dr. Gannage, King brought a complaint to the College of Physicians and Surgeons of Ontario and provided various sources of information including FDA warnings about chelation therapy, but no information regarding any patient harms. The ICRC considered her complaint and decided to take no further steps.[154] The ON HPARB dismissed King's requested review of that decision, finding the ICRC's investigation was adequate and its decision had been reasonable. King then applied to the Ontario Court of Appeal for judicial review. The court held that the ON HPARB's decision was reasonable and dismissed the application for judicial review. In considering the reasonableness of the ON HPARB's decision, the court looked to s. 5.1 of the *Medicine Act, 1991*[155], which permits the use of non-traditional therapies by physicians, as well as the college's CAM Policy, which sets out requirements for provision of CAM including obtaining informed consent, and:

> Any CAM therapeutic option that is recommended by physicians must be informed by evidence and science, and it must:
> - Have a logical connection to the diagnosis reached;
> - Have a reasonable expectation of remedying or alleviating the patient's health condition or symptoms; and
> - Possess a favourable risk/benefit ratio based on: the merits of the option, the potential interactions with other treatments the patient is receiving, the conventional therapeutic options available, and other considerations the physician deems relevant.
>
> Physicians must never recommend therapeutic options that have been proven to be ineffective through scientific study.[156]

The court determined that the applicant was essentially seeking a finding that chelation therapy for children with autism is not acceptable, which the court held is not the role of the ICRC.[157] The court further held that even though the ON HPARB had acknowledged that there is debate about chelation therapy to treat autism, with inconclusive evidence, its decision to dismiss the

[150] *Ibid* at para 48.
[151] *Ibid* at para 52.
[152] *Ibid* at para 1.
[153] 2020 ONSC 7967 [*King*].
[154] *Ibid* at paras 1-2.
[155] SO1991, c. 30.
[156] *King*, *supra* note 153 at paras 11-13.
[157] *Ibid* at paras 27-29.

request for review was not unreasonable given its corresponding conclusion "that science does not show that the use of chelation therapy is ineffective".[158] To some extent, this decision illustrates the latitude that is provided to physicians who provide chelation therapy and other CAM options, as well as the limits of professional discipline in addressing questions about the appropriateness of specific treatments in the absence of individual patient complaints regarding harms suffered. It also prompted discussion in media articles regarding the public interest mandate of the colleges of physicians and surgeons, an issue which is discussed in Section 5.3.

My data collection did not capture tort cases where negligence was alleged in relation to administration of chelation therapy. However, there are long-standing questions regarding what standard of care applies to provision of CAM in general, including obligations around informed consent.[159] One line of argument is that the same legal standards should apply to physicians' provision of CAM as apply to conventional therapies.[160] As is also discussed in the final section of this chapter, the sufficiency of evidence is likely centrally important to this issue. I will revisit these varied regulatory and governance actors and the instruments they have used to influence access to chelation therapy in Canada in the following sections, through the lenses of purpose, legitimacy, and responsiveness or adaptability.

5.2.2 Clarity of purpose

As discussed in Chapter 2, there is no real consensus regarding the identifying features of "good" regulation and "good" governance.[161] However, exploring the extent to which there is clarity of purpose is a useful starting point to considering the effectiveness of regulation and governance.[162] Identifying and understanding the goals or objectives underpinning regulation and governance is an important aspect of evaluating the fit and effectiveness of instruments used.[163] Brownsword's definition of regulatory effectiveness includes assessing "whether, and how well, a regulatory intervention is serving its intended purpose".[164] Part of understanding goals or purposes involves identifying the priorities or imperatives driving the regulatory or governance agenda, as well as relevant constraints.

In this research, I relied on publicly available information to gain insight into these features. Where there are multiple and diverse actors, it is not always possible to identify one (or

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[158] *Ibid* at para 50.

[159] For early work on this topic, see Colin Feasby, "Determining Standard of Care in Alternative Contexts" (1997) 5 Health LJ 45. See also Timothy Caulfield & Colin Feasby, "Potions, Promises and Paradoxes: Complementary Medicine and Alternative Medicine and Malpractice Law in Canada" (2001) 9 Health LJ 183.

[160] Caulfield, *supra* note 23 at 4.

[161] See Chapter 2, Sections 2.1.3 and 2.2.2, *above*, for a review of this literature.

[162] See e.g., Karen Yeung, "Towards an Understanding of Regulation by Design" in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 79 at 91. Yeung proposes an approach to evaluation of regulation that considers its underlying policy goal and whether it was achieved. See also Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 11. Brownsword similarly looks to whether regulation achieves its intended purpose when considering its effectiveness.

[163] Michael Howlett & Jeremy Rayner, "Design Principles for Policy Mixes: Cohesion and Coherence in 'New Governance Arrangements', (2007) 26:4 Policy & Society 1. Howlett and Rayner use a matrix approach to provide insight into how instrument mixes can be characterized as consistent or inconsistent, and policy goals as coherent or incoherent. See also Chapter 2, Section 2.2.2., *above.*

[164] Brownsword, *supra* note 162 at 11.

more) shared goals or objectives. As reviewed above, multiple actors have engaged in the regulation and governance of access to chelation therapy in Canada over the past several decades, in many cases with different apparent priorities. Protection and promotion of health was a strong theme underlying much of the regulatory and governance activity relating to access to unproven applications of chelation therapy, both in aid of increasing access and restricting it. I identified three sub-goals within this broader imperative including: (i) facilitating individual choice, (ii) mitigating risk to patients, and (iii) making evidence-based decisions. Additional goals that appear to have motivated some government actors included cost savings imperatives and political interest in taking a leadership role in this area of health and wellness.

The desire to facilitate individual choice about healthcare options was particularly prominent in political forums. It was sometimes coupled with the idea of personal responsibility, and often directly linked with efforts to expand access to CAM in general. For example, in the Alberta Legislative Assembly debates regarding Bill 209 (the amendment to Alberta's *Medical Profession Act* which established that providing chelation and other non-traditional therapies would not be the sole ground for unbecoming conduct, in the absence of patient harm), the Honourable Mrs. Burgener made the following argument: "Mr. Speaker, I think today what is most appropriate, as has been mentioned, is that the focus is now on choice and options and wellness, having citizens in this province have the opportunity to take some of the responsibility and initiative of their own health needs personally".[165] Another Alberta MLA relayed a story in the Assembly about an individual whose mother had pursued chelation therapy with positive results, notwithstanding potential risks. He used that story to make the following argument in support of Bill 209:

> Mr. Speaker, that's the key: the word "choice." Throughout life we're always faced with that question of choice. People choose to smoke. It's their choice if they want to smoke. Despite the warnings and the danger that smoking could cause, people take that risk because they get some enjoyment, some benefit out of it. Others choose to eat foods that are not recommended. That's a choice they make. Mr. Speaker, when we have people that want to make the choice to get a treatment even though there are those that may claim there is an element of risk, they make that choice because they figure it's going to benefit them in terms of the number of years they have left and they want to make the most out of them. Mr. Speaker, in respect for choice, that all of us seem to respect so much in this House, really there is no hesitation to support Bill 209. Bill 209 doesn't ask for Alberta health care or Blue Cross to cover the cost of the treatment. It simply legitimizes what people at one time had to go to B.C. or the United States for.[166]

As these quotations illustrate, the idea of freedom of choice featured prominently in the 1990s debates about expanding access to chelation therapy (and CAM more broadly) by way of legislation, and often had undertones of autonomy-based rationales.[167] For example, one Alberta

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[165] Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1362 (Hon. Mrs. Burgener). See also Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 867 (Hon. Mr. Langevin).
[166] Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1361 (Hon. Mr. Wickman).
[167] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 875 (Hon. Mr. Langevin). This example is of statements made in support of Bill 209 in Alberta. The Hon. Mr. Langevin situated the freedom of choice in medical treatments within the context of Alberta's democratic system that also provides freedom of choice in elections, movement, education, assembly, and religion.

MLA argued that "[p]atients must have access to the necessary factual information and be free to choose the medicine and the medical practitioner of their choice".[168] An MLA in British Columbia made similar statements in support of the *Medical Practitioners Act Amendment Act 2000*:

> People must be made to make their own decisions. People want to be accountable for their own bodies; they want to be accountable for their own health. But they have to have the tools to do that with, so all parties in this province should be supporting this bill. They should be unanimously supporting this bill, because this bill is about that very fundamental right of the individual to look after their own body, their own self, their health. I would encourage the opposition members to support this bill, because this bill is about freedom of choice for patients.[169]

Though discussions about choice often focused primarily on patients, there were related rationales advanced about giving physicians the ability to choose how to best treat their patients, including via CAM options.[170] Rights-based language was also sometimes used to explain or justify access imperatives. For example:

> Out of some 2 million people who have been chelated in the United States and Canada thus far, there has not been one known death from chelation therapy. Mr. Speaker, patients have the right to demand the right to choose the type of therapy they want and not what's being forced on them. This way they will be taking responsibility for their own health. Yes, patients do have some rights. They have the right to be treated as an equal human being, with their problems being taken seriously. They have the right to an explanation on their health care. They have a right to know choices of treatment that are available to them and their possible side effects. They have a right to choose natural or complementary therapies and not to be ridiculed for their choice.[171]

Rights language was also used in other public forums, including news media. By way of example, one media article quoted individuals seeking to access chelation therapy in Alberta as stating: "It's one of our rights. It's like a religious right".[172] These types of rights claims were non-specific, in that the bases or grounds of the supposed rights were not identified.

The desire to control and minimize risk to patients was another imperative that appears to have underpinned the activities of regulatory and governance actors, including political actors and colleges of physicians and surgeons. Perhaps in part due to the strength and prominence of choice and individual freedom-based rationales in favour of increased access to chelation therapy, concerns about risk appeared to be often tied to efforts to control access rather than to

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[168] Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 867 (Hon. Mr. Langevin). Similar sentiments regarding patients' "freedom to choose" were expressed by other members of the Assembly in support of Bill 209. See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 868 (Hon. Mr. Van Binsbergen).

[169] British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 17 (3 April 2001) at 17628-17629 (E. Walsh). See also British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 17 (3 April 2001) at 17627 (Hon. E. Walsh). In the latter example, E. Walsh framed the Bill as "progressive".

[170] See e.g. British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 6 (9 April 2001) at 17402 (Hon. S. Orcherton).

[171] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky).

[172] Lowey, *supra* note 57.

restrict it. In other words, risk mitigation seemed to underpin regulatory and governance compromises.

For example, in several provinces including Alberta, Saskatchewan, and Ontario, the colleges of physicians and surgeons initially opposed legislative efforts to facilitate broader access to CAM, but ultimately acceded to them. In Saskatchewan, then Registrar of the College of Physicians and Surgeons of Saskatchewan (CPSS), Dr. Dennis Kendel, emphasized that the new chelation bylaw did not mean the CPSS had endorsed chelation therapy, but rather that it was establishing specific protocols under which it could be provided safely by a licensed physician. He also reportedly noted that it would be safer for chelation therapy to be provided under the regulatory oversight of the college, rather than in unregulated clinics.[173] A similar argument was made in the Alberta Legislative Assembly:

> Mr. Speaker, as long as EDTA is administered by physicians trained in the procedure, safety will be assured. I would counter by saying that, if anything, chelation therapy has more potential to be hazardous in these outlawed clinics. If legitimatization occurs, then the entire process will be opened up so that chelation can be scrutinized and regulated in accordance with the mandate of the college.[174]

An interesting nuance I observed in some of these debates was the idea that chelation therapy and other CAMs should not be held to a higher standard than other areas of medicine when it comes to risk, given that there are many areas of conventional medicine that carry risk.[175] For example, one Alberta MLA who supported the proposed amendments in Bill 209 emphasized the importance of making "absolutely certain that the college was going to be held responsible and not impose some double standard on those physicians that are practising complementary medicine, even though they're not posing any greater risk to the patient than the prevailing treatment or disease itself".[176]

Discussions about risk relate closely to the third sub-theme under the umbrella of objectives seeking to protect and promote health, which is the imperative to make evidence-informed decisions regarding access to chelation therapy. For example, an Alberta MLA made the following argument in favour of using provincial funding to research chelation therapy as a treatment for atherosclerosis:

> I think we're all aware of this intense public concern on the part of many people who feel that chelation therapy has enhanced their quality of life significantly. The problem has been that this therapy has not received formal recognition by the College of Physicians and Surgeons, and it is on that basis that the government has excluded it from support through its health care funding system. Given that there is this impasse -- on the one side some health care professionals and certainly the group that could make that decision, on the other side a general concern amongst the public -- I felt that the heritage trust fund might be able to assist in resolving this impasse by funding from

[173] Oliver, *supra* note 69 at 751.
[174] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1461 (Hon. Mr. Sohal).
[175] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1358-1359 (Hon. Mrs. Abdurahman).
[176] Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1358 (Hon. Mr. Brassard).

> an objective point of view a chelation therapy study which would give us the kind of information upon which a decision could be based.[177]

As part of a discussion around provincial funding, then Saskatchewan Minister of Health, the Honourable Mr. Calvert similarly acknowledged that there were personal testimonies of success, and emphasized interest in a "credible, scientific, research project around the benefits of chelation".[178] In British Columbia, the Honourable Mr. Dueck indicated that chelation therapy would not be publicly funded until it was "proven medically".[179] Indeed, an interesting pattern emerged in both this and the liberation therapy case study (Chapter 6). In early debates about access to these interventions, provincial ministers of health often spoke on behalf of their governments to emphasize the importance of research and evidence, and of supporting research to generate evidence, in response to urgings from members of the opposition to facilitate access to the intervention. The following exchange from Alberta is as an illustrative example:

> MR. HLADY: Thank you, Mr. Speaker. My question is to the Minister of Health. Madam Minister, many Albertans believe that EDTA chelation therapy is the only effective way to deal with their coronary artery disease. Why is the provincial government restricting its use in the province, while it is being used in other jurisdictions?
>
> MRS. McCLELLAN: The province is not restricting the use of chelation therapy. It is used as an accepted treatment in this province for the removal of heavy metals. It is, however, not a recognized treatment for coronary artery disease. Mr. Speaker, this is not the province's doing. The drug, EDTA, is not licensed by Health Canada, and for use in this province it must be licensed by Health Canada. So its use has to apply. It also, Mr. Speaker, has not been accepted by the College of Physicians and Surgeons in this province as an accepted treatment for coronary artery disease. I think we still believe that we should depend on the medical community, on the expertise from that community to ensure that only scientifically proven treatments are utilized. …
>
> This is a difficulty because a lot of the information that we have on this is anecdotal and testimonial, so we need some scientific information. I have discussed this matter with the College of Physicians and Surgeons, and they have met and will be discussing this further with the University of Alberta. I believe we will be able to embark upon a research study into the use of this therapy in this province some time in the near future, Mr. Speaker.[180]

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[177] Alberta, *Journals of the Legislative Assembly*, 23-2 (1 February 1994) at 212 (moved by Hon. Mr. Mitchell); see also Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1462 (Hon. Mr. Sapers), where a similar argument was made regarding the need for a "true scientific test, a trial in a carefully monitored way, so that the benefits of chelation can be determined".

[178] Saskatchewan, *Journals of the Legislative Assembly*, 23-3 (25 May 1998) at 1349-1350 (Mr. Toth & the Hon. Mr. Calvert) [*sic*]. See also Alberta, *Journals of the Legislative Assembly*, 23-2 (24 January 1994) at 165 (Hon. Dr. Spence). Dr. Spence argued for the need for blinded research to determine whether chelation therapy works before it receives public funding.

[179] British Columbia, *Journals of the Legislative Assembly*, 34-1 (8 December 1987) at 2895 (Hon. Mr. Dueck).

[180] Alberta, *Journals of the Legislative Assembly*, 23-2 (27 October 1994) at 2642 (Hon. Mrs. McClellan).

Then Minister of Health in British Columbia emphasized a similar evidence-based approach in response to arguments for access based on anecdote: "Yes, I too get a lot of information from meetings around the issue of chelation therapy, and I very much respect the people who lobby me on this. So my comments that I'm about to give to the House are really based on what health care professionals advise me of, because I, of course, would not make a decision around this or even offer any advice that wasn't evidence-based".[181]

The potential for cost-savings was a rationale used in favour of the 1990s legislative amendments in British Columbia and Alberta that expanded CAM options, and chelation therapy specifically.[182] The argument was that EDTA chelation therapy could serve as a much less expensive alternative to bypass surgery and balloon angioplasty. One Alberta MLA suggested that the colleges of physicians and surgeons "have a vested interest in high-cost surgical solutions to cardiac problems", and that chelation therapy "could save us millions of dollars".[183] Similar cost-savings imperatives were raised in the British Columbia legislature: "If there is an opportunity through this to decrease the cost of heart surgery or to have an alternative to some procedures, it is obviously something that the ministry should be advocating to the federal government".[184] The cost-savings angle also arose during federal parliamentary discussions. In the context of debates in 2002 about healthcare, including the release of the Kirby report and the forthcoming Romanow report, one Member of Parliament (MP) noted the high costs of treating cardiovascular disease and suggested that government should be considering alternatives such as chelation therapy.[185] The cost-savings advantage of chelation therapy over bypass surgery and pharmaceutical options was also highlighted in media coverage. For example, an article from 1994 outlined the purported cost savings of chelation therapy:

> Chelation advocates argue that it`s safe, effective and inexpensive an alternative to drugs and surgery. And in these times when government health-care dollars are dwindling rapidly, it is just one of the many alternative therapies which could save the system money. For example, in Alberta, routine bypass surgery with an average recovery hospital stay of seven days costs about $17,500, says Alberta Health spokesman Gordon Turtle. On top of that, a surgeon would receive $1,310 and an anesthesiologist $455. Chelation therapy costs about $100 per treatment anywhere in Canada. Most people see a benefit after eight to 15 initial treatments and average a total of 20 to 30 treatments, says Wilson. That`s, at most, $3,000.[186]

Economic arguments levied in favour of expanding access to CAMs, including chelation therapy to treat heart disease, were sometimes linked to broader political interests in being recognized for leadership in this important area of health and wellness. For example, when discussing chelation therapy as a less invasive alternative to surgical options such as bypass operations, one Alberta MLA discussed their government's pledge "to break new ground in the area of health care so that we can find more effective and cost-efficient ways of dealing with the

[181] British Columbia, *Journals of the Legislative Assembly*, vol 5, No 10 (27 May 1997) at 3704 (Hon. J. MacPhail).
[182] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1458 (Hon. Mr. Brassard).
[183] Alberta, *Journals of the Legislative Assembly*, 22-4 (17 May 1993) at 2802 (Hon. Mrs. McClellan & Hon. Mr. Payne).
[184] British Columbia, *Journals of the Legislative Assembly*, 35-1, vol 5, No 9 (29 June 1992) at 3231 (Hon. E. Cull).
[185] *House of Commons Debates*, 37-2, vol 138, No 18 (30 October 2002) at 5:15 (James Lunney); see also House of Commons, *Standing Committee on Health*, 37-2 (10 February 2003) where Mr. Lunney made similar arguments.
[186] Mario Toneguzzi, "Arterial Therapy Advocates Stress Prevention" *Calgary Herald* (16 January 1994) B2.

well-being of our citizens".[187] In arguing for public funding of research into chelation therapy, another MLA suggested that "EDTA chelation could be a pioneer project in our pursuit of a wellness-based model of medicine".[188] Similar sentiments appeared in the Saskatchewan Legislative Assembly where, for example, one MLA observed that "[a] great many of my constituents are extremely pleased that Saskatchewan is once again showing leadership with the introduction of the first legal chelation clinics in the country …The health of Saskatchewan people is our top priority. Chelation treatment is just one more step".[189] Political support is one element of governments' legitimacy. Other relevant considerations involved in decision-making and implementation processes that support or detract from the lawfulness and credibility of regulation and governance actors and their activities will be discussed in the next section.

5.2.3 Legitimacy

The strength of regulation and governance depends to some extent on the support or "buy-in" of affected stakeholders. For the subjects or targets of regulation and governance, this support can take the shape of compliance with rules, standards, or processes – understanding "compliance" here narrowly as adherence to regulatory and governance instruments that are intended to direct behaviour – and acceptance of the legitimacy of authority.[190] For non-government regulatory and governance actors, such as delegated actors like the colleges of physicians and surgeons, this support may involve maintaining the confidence of government to exercise appropriate oversight in a field. Without such confidence, governments may exercise their authority to legislate and assume greater control over the area.[191] Governments also require sufficient public confidence to maintain their electoral mandate. As outlined in my Conceptual Framework (Chapter 2, Table 1), other important aspects of legitimacy relate to decision-making and implementation processes such as fairness, transparency, conflicts of interest, collaboration, and engagement, as well as influences on decision-making, including questions of expertise, evidence, political priorities, and advocacy.

In this case study data, there were examples of procedural elements that arguably strengthened the legitimacy of regulatory and governance responses to chelation therapy, including coordination or delineation of roles and responsibilities, and evidence-based decision-making. However, the data also pointed to several important threats to legitimacy, including political pressure, reliance on unsubstantiated sources of information, and credibility issues

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[187] Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1461 (Hon. Mr. Sohal).
[188] *Ibid*.
[189] Saskatchewan, *Journals of the Legislative Assembly*, 23-2 (11 March 1997) at 103 (Hon. Mr. Jess). See also Saskatchewan, *Journals of the Legislative Assembly*, 23-2 (17 March 1997) at 240 (Hon. Mr. Kowalsky) for a similar theme.
[190] See John McMillan & Jeanne Snelling, "Equality: Old Debates, New Technologies" in Roger Brownsword, Eloise Scotford & Karen Yeung, eds, *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) 69. As noted earlier in Chapter 3, Section 3.3, and Chapter 4, Section 4.1, this approach reflects a narrow conception of compliance.
[191] For a discussion of the role of the state in metagovernance, see Anders Esmark, "Systems Theory" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 91 at 95; see also Peter Grabosky, "Meta-regulation" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 149; see also Paul Hirst, "Democracy and Governance" in Jon Pierre, ed, *Debating Governance: Authority, Steering, and Democracy* (Oxford: Oxford University Press, 2000) 13; see also Bob Jessop, "Metagovernance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 106 at 116.

triggered by real or perceived conflicts of interest. Each of these features is discussed in turn below. As noted earlier, this case study spans several decades. This analysis focuses on key events and notable shifts over that time and reflects a 'big picture' perspective.

In terms of procedural strengths, there were instances of coordination between key regulatory and governance actors on the question of access to chelation therapy, where actors' different roles and responsibilities were emphasized along with the importance of respecting boundaries of jurisdiction and expertise. For example, in the 1992 debates in the British Columbia Legislative Assembly regarding whether the province should pursue chelation therapy as an alternative to heart surgery, the Minister of Health's response focused on the "division of labour" between the provinces and federal government, and emphasized that the federal government had the resources and processes to investigate and approve new technologies and medical procedures.[192] In subsequent discussions on this topic in 1997, Minister of Health the Honourable J. MacPhail stressed that it was the federal government, via the department known then as Health and Welfare Canada, that had authority to approve EDTA as a treatment for coronary atherosclerosis, and that British Columbia would not provide provincial funding until it was approved for that use.[193] In these same remarks, the Minister also indicated that the provincial government had asked the College of Physicians and Surgeons of British Columbia to "deal with this issue", referring to lobbying for access to this application of chelation therapy.[194] However, there were few examples of this type of recognition of the different roles for federal, provincial, and territorial governments and for medical regulators in my data, particularly in political forums. To the contrary, as is discussed below, several provincial and territorial governments used their legislative authority to advance access to chelation therapy (and other forms of CAM) notwithstanding lack of support from medical regulatory bodies.

Today, it is common to find an emphasis on 'evidence-informed decision-making' in political and health spheres, and the data reflect a similar emphasis in some of the historical discussions regarding access to chelation therapy. For example, the following quote from a Health Canada representative in 1993 emphasized the importance of evidence to its decision-making processes:

> Health Canada confirms it has banned the import of EDTA into Canada since May. It denies any vendetta against chelation therapy advocates, and says it is not acting at the request of the medical establishment or anyone else. 'Our position is that the safety and effectiveness of EDTA as used in chelation therapy for the treatment of (heart disease) is scientifically unproven,' said Dennis Shelley, chief of drug and environmental health inspection division, western region, for Health Canada`s health protection branch.[195]

However, some of the political debates in provincial legislative assemblies raise questions about decision-making processes, including the influence of unsubstantiated sources of information and the role of political pressure. Hansard records from several provinces including British

[192] British Columbia, *Journals of the Legislative Assembly*, 35-1, vol 5, No 9 (29 June 1992) at 3231 (Hon. E. Cull).
[193] British Columbia, *Journals of the Legislative Assembly*, 36-2, vol 5, No 10 (27 May 1997) at 3704 (Hon. J. MacPhail).
[194] British Columbia, *Journals of the Legislative Assembly*, 36-2, vol 5, No 10 (27 May 1997) at 3704 (Hon. J. MacPhail).
[195] Robert Walker, "Doctors under investigation" *Calgary Herald* (2 September 1993) B1.

Columbia, Alberta, and Saskatchewan, suggest that political decisions were influenced by anecdote and unsubstantiated claims relating to safety and efficacy of both chelation therapy specifically, and CAM interventions more broadly.[196] The following quote from Alberta in 1994 serves as an example of representations of the current state of the science being presented in political decision-making forums without substantiation or nuance:

> EDTA chelation is also beneficial in treating strokes, neurodegenerative disease, arthritis, high blood pressure reduction, diabetes, cataracts, allergies, Alzheimer's disease, et cetera, et cetera. It works because it removes toxic heavy metals such as lead and mercury. Proponents of EDTA chelation therapy claim that cholesterol is not the cause of hardening of the arteries; it's caused by free radical pathology. Chelation treats the whole circulatory system, not only an inch and a half or so of artery that is replaced by very painful bypass surgery. Many legs of senior citizens have been saved from amputation because of poor circulation through chelation therapy. Ongoing studies are also indicating that chelation seems to be beneficial in the prevention of cancer. Chelation is not a placebo. It is a proven therapy with glowing examples of people that have been restored to health.[197]

When offering support for Bill 209 in Alberta, one MLA made the following remarks which illustrate the perceived power of anecdote and its links to political advocacy:

> I think everybody in this Assembly, be they in the gallery or on the floor, would indicate that word of mouth is probably the best means of advertising and the one that would bring us to trusting the purchaser of some sort of service. These members, who are the best salesmen for this particular treatment called chelation, are here today. They're living proof. Their testimony is that this is a very, very acceptable and worthwhile aspect. Certainly I will support the Bill so that in fact they may continue to receive that, and I would say that I'm an ardent supporter of it.[198]

Indeed, advocacy in the form of political pressure appears to have played a powerful role in driving legislative reform through the 1990s to broaden accessibility to CAM interventions and chelation therapy, which was often used as a 'poster child' for a broader class of non-standard CAM interventions.[199]

At least initially, it appears these reforms to expand access were not universally supported by the different colleges of physicians and surgeons in Canada. Some of the discourse from these debates reflects a challenge to the legitimacy of the colleges of physicians and surgeons that appears to have escalated as pressure increased on governments to expand access to CAM and to chelation therapy specifically. In the earlier debates about access to chelation therapy and

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[196] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1363 (Hon. Mr. Lund); Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 868 (Hon. Mrs. Black).

[197] Alberta, *Journals of the Legislative Assembly* 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky). See also British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 17 (3 April 2001) at 17627 (Hon. E. Walsh). This second example addresses CAM, suggesting "these therapies are virtually free from the side effects, as I said earlier, of prescription drugs".

[198] Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1363 (Hon. Mr. Kirkland).

[199] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (24 April 1996) at 1363 (Hon. Mr. Lund); see also Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 868 (Hon. Mrs. Black); see also Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 868 (Hon. Mr. Van Binsbergen).

expanded CAM options, some colleges maintained a degree of deference from other regulatory and governance actors, and a relatively well protected sphere of decision-making authority regarding oversight of medical practice. For example, comments from some courts in the jurisprudence reviewed above emphasized that the colleges of physicians and surgeons have a broad mandate to make rules regarding treatment provided by their members, and that this mandate flows from their obligation to protect the public interest.[200]

The colleges' authority to govern the practice of medicine was also a theme in some legislative discussions regarding questions of funding and approval for chelation therapy. For example, the question of provincial funding for chelation therapy was raised in 1996 in the Yukon legislative assembly. The Minister of Health emphasized that the province followed the medical regulatory body and Canada Health Insurance in its decisions regarding funded treatments.[201] In the following year, when responding to a petition that asked the government to approve the use of chelation therapy by registered physicians in Yukon, the Honourable Mr. Sloan gave the following response: "there is no Yukon legislation that prohibits a physician from providing a service not covered under the health care insurance plan and charging that patient directly. But, I can say that a physician who does provide this service does so contrary to the advice of the Yukon Medical Council and therefore it would have to be resolved with them".[202] Similar discussions took place in the Alberta Legislative Assembly in the early 1990s. For example, in response to a question about why chelation therapy was not available in the province, the Minister responded that:

> the issue of chelation therapy is not a simple one. However, I think it is important that we clarify Alberta Health's position on this. The drug EDTA is not approved by Health and Welfare Canada for use in Canada. Chelation therapy is approved for certain use in Alberta; that is, the indications. Also, the College of Physicians and Surgeons is the body that designates medical procedures in this province, not the Legislature or the minister.[203]

As the debates about chelation therapy and CAM evolved, a combination of political advocacy and growing discord within the medical community, where a vocal minority of physicians were interested in providing chelation therapy and other forms of CAM,[204] appears to have shifted this narrative. Hansard records, particularly from Alberta but also to some extent Saskatchewan and British Columbia, contain multiple critiques of the colleges that challenged their legitimacy as regulators, including allegations of bias, and assertions that they were inappropriately seeking to restrict patient choice and access to desired treatments.[205] The following quote from the British Columbia Hansard is illustrative of this narrative:

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[200] See e.g. *Strauts, supra* note 88; see also *Vrabec v. College of Physicians and Surgeons of B.C.*, 2009 BCSC 675 (CanLII) at para 126.
[201] Yukon, *Journals of the Legislative Assembly*, 28-2 (18 April 1996) (Hon. Mr. Fisher).
[202] Yukon, *Journals of the Legislative Assembly*, 29-1 (6 May 1997) (Hon. Mr. Sloan); see also Yukon, *Journals of the Legislative Assembly*, 29-1 (10 April 1997) (Hon. Mr. Jenkins).
[203] Alberta, *Journals of the Legislative Assembly*, 22-4 (2 February 1993) at 2035-2036.
[204] Colby Cosh, "Elation about chelation: the Alberta legislature may tell doctors to stop blocking popular 'alternative' therapies" (1996) 23:19 Alberta Report 13.
[205] See e.g. British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 17 (3 April 2001) at 17627 (Hon. E. Walsh). See also Alberta, *Journals of the Legislative Assembly*, 24-2 (28 April 1998) at 1792 (Hon. Ms.

> Across Canada, a long history of interference by the College of Physicians and Surgeons exists with the public's right to choose medical doctors who incorporate complementary or alternative therapies in their practices -- a combination of the best of conventional western medicines and the best of alternative medicines. Complementary medicines include therapies such as environmental medicine, acupuncture, homeopathy, botanicals, orthomolecular medicine, vitamins and minerals and chelation therapy. This bill allows physicians to use their own judgment in the interests of their patients to diagnose and treat patients using complementary therapies. This bill also protects physicians who practise complementary medical therapies from harassment by the College of Physicians and Surgeons.[206]

Similar themes were reflected in media coverage from this same period, when the credibility of the colleges was questioned on several grounds.[207] Some publications framed the colleges as being slow to adapt. For example, the President of the Calgary chapter of the EDTA Chelation Association of Alberta was quoted as suggesting: "The only complaint I would have against the medical profession in Canada is that they're very, very slow to accept anything other than the traditional medicines of the past. We do have to look at some of these newer ideas".[208] Another article quoted a British Columbia physician who was identified as providing chelation therapy for cardiovascular disease, among other alternative therapies: "'Everything I do is supported with scientific literature,' stresses Cline who adds most such therapies are commonplace in Europe. There are 16 mercury detox centres in West Germany alone. 'People here in North America are very slow to catch on'".[209] Other public critiques reflected a conspiracy narrative, suggesting that doctors and the colleges were opposed to chelation therapy for heart disease because it is less lucrative than pharmaceutical and surgical alternatives.[210]

The success of legislative and bylaw changes to facilitate expanded access to CAM, including chelation therapy, was not universally celebrated within the medical profession. To the contrary, these developments triggered internal concerns about the legitimacy and credibility of the profession and its self-regulation. For example, Dr. Allan Miller, who was president of the Saskatchewan Medical Association at the time the college passed its new chelation therapy bylaws, was quoted as presenting the following perspective:

> Miller isn't surprised that many physicians have expressed their anger to the college and the SMA. He notes that scientific validity is the major factor separating medicine from other types of health care. "As soon as we start offering treatments where there is no proof of effectiveness or safety, our credibility goes out the window." Miller knows the college faced a tough situation in the chelation debate, but worries that its

Leibovici). The Hon. Ms. Leibovici used the term "witch-hunt" to describe the concern that Bill 209 might give too much power to the College of Physicians and Surgeons of Alberta and drive CAM providers "underground".

[206] British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 6 (2001) at 17402 (Hon. S. Orcherton).

[207] See e.g. Breckenridge & Saunders, *supra* note 57.

[208] Toneguzzi, *supra* note 186.

[209] Grania Litwin, "Alternative Beliefs: Complementary medicine makes progress, but some wonder what has taken so long" *Times-Colonist* (20 March 2001) B1.

[210] See e.g. Edmonton Journal, *supra* note 45. See also Charlotte Grey, "Growing popularity of complementary medicine leads to national organization for MDs" (1997) 157 CMAJ 186 at 188. This article discussed the rise of Citizens for Choice in Healthcare, a national organization that promoted CAM, and suggested the College of Physicians and Surgeons of Alberta had tried to restrict access to such options, including chelation therapy, for financial reasons.

> decision may indicate that public pressure now dictates health care policy. "If we're going to allow the public to decide which therapies are regulated by the college, we might as well roll over and accept a whole lot of unconventional treatments now".[211]

Another medical news article on this topic discussed similar concerns from other physicians, including that regulating chelation could be taken by the public as the college condoning the practice, and that responding to public pressure by licensing this unproven intervention would jeopardize the college's credibility with both doctors and the public.[212] More recent legitimacy critiques of the credibility of the colleges as regulators have focused on their acceptance of CAM interventions that lack evidence of safety or efficacy, and their reticence to act proactively with oversight of physicians' practices. For example, *King v. Gannage*[213] (discussed above) prompted critiques about whether the colleges are fulfilling their mandates to act in the public interest when responding to "non-evidence based treatments that could pose risks to patients".[214] We will return to this point when considering key lessons and future priorities, below, after the following discussion regarding responsiveness and adaptability.

5.2.4 Responsiveness and adaptability

Although they use different terminology, there is literature in both regulatory and governance scholarship that highlights the advantages or strengths of approaches that are flexible in adjusting strategies in response to change, uncertainty, or evolving circumstances. Responsive and "really responsive" regulation describe an approach in which different strategies or instruments, usually with varying degrees of coerciveness, are used at different times, depending on contextual factors including how regulatory targets respond.[215] These ideas embody a degree of flexibility that permits iterative adjustments. Similarly, adaptive capacity describes the ability and willingness for governance actors to adjust strategies in response to lessons learned or new developments.[216] Flexibility in the use of varied strategies and tactics, and the capacity to assess and respond to changing information or circumstances, are strengths in a system of oversight.[217] Although not without challenges such as corresponding threats to predictability,[218] the characteristics captured by the concepts of responsive regulation and adaptative governance are particularly important in situations of uncertainty, contested evidence, and conflicting priorities, and in fast moving fields where information is changing quickly. Timing and instrument

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[211] Oliver, *supra* note 69 at 752.
[212] Deana Driver, "Did bylaw legitimatize chelation therapy?" *Medical Post* (27 May 1997) 25.
[213] *King v. Gannage*, 2020 ONSC 7967, aff'ing *A.B.K. v. J.M.G*., 2019 CanLII 115445 (ON HPARB) [*King*].
[214] Carly Weeks, "Appeal board says no action necessary against alternative-treatment autism doctor", *Globe and Mail* (16 December 2019) A.6 [Weeks, "Appeal board"].
[215] Braithwaite, *supra* note 64; Black & & Baldwin, *supra* note 65. See also the discussion in Chapter 2, 2.1.1, *above*.
[216] Thomas Dietz, Elinor Ostrom & Paul Stern, "The struggle to govern the commons" (2003) 302: 5652 Science 1907. Dietz et al. identify several characteristics of systems oriented towards adaptive governance including providing information, facilitating analytic deliberation, and being prepared for change.
[217] Jessop, *supra* note 191 at 117; see also Gregory Mandel, "Regulating Emerging Technologies" (2009) 1:1 L, Innovation & Technology 75 at 89. See discussion in Chapter 2, Section 2.2.2, *above*, including links to the related concept of anticipatory governance.
[218] Roger Brownsword, "So What Does the World Need Now? Reflections on Regulating Technologies" in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 23 at 37.

selection are relevant considerations in evaluating the adaptive capacity and responsiveness of regulation and governance.[219]

The data I collected in this case study reflected considerable regulatory and governance-related activity regarding access to unproven applications of chelation therapy through the 1990s, which culminated in the legislative and bylaw amendments discussed earlier. These instruments appear to have largely been prompted by political advocacy. They facilitated expanded access to chelation therapy in Canada, albeit generally on a private market basis outside of publicly funded healthcare systems. Subsequent issues related to access to chelation therapy have surfaced periodically over the ensuing decades, primarily through court cases addressing denials of provincial funding, questions of family support, and professional discipline, and have occasionally been featured in news media and legislative discussions. However, these events have not led to any major shifts in regulatory or governance approaches.

The relative stability of regulation and governance of access to chelation therapy over the past three decades is noteworthy given that this intervention remains unsubstantiated by medical research for all but the very limited application of treatment for heavy metal toxicity. The persistence of public and providers' interest in chelation therapy, notwithstanding that the evidence regarding its efficacy is at best inconclusive, is perhaps explained in part by it being situated within the broader CAM narrative. Regulatory and governance responses to chelation therapy by political actors, medical regulatory bodies, and the courts have mirrored efforts to expand and protect patient choice via access to CAM options, so long as they do not involve greater risk than standard of care alternatives. Although it is a truism that absence of evidence is not evidence of absence, the apparent lack of evidence of significant harms associated with unproven applications of chelation therapy in Canada may also serve to support the regulatory and governance status quo.

As discussed above, at present access to unproven applications of chelation therapy is permitted in Canada but not publicly funded. Withholding of public funding is an instrument choice that may reflect responsiveness to both the lack of evidence of efficacy, as well as the absence of evidence of significant harms. In other words, it may serve as a form of regulatory and governance compromise between public demand, and evidence-based health governance decisions. Oversight responsibility for access to chelation therapy in Canada has been left primarily to the colleges of physicians and surgeons, though their authority is constrained by the legislative frameworks discussed above. Notwithstanding criticisms that professional regulatory bodies are not meeting their public interest mandates or their own standards regarding provision of evidence-based care when it comes to CAM options,[220] the data collected in this case study do not suggest regulatory or governance changes in this area are likely to be forthcoming anytime soon. To the contrary, these legislative provisions and related bylaws appear to be well entrenched.[221] There would likely need to be a significant change in context, such as compelling evidence of harms or broad shifts in public demands, for regulatory and governance actors to

[219] See Matthew Wansley, "Regulation of Emerging Risks" (2016) 69 Vand L Rev 401.
[220] See e.g. Weeks, *supra* note 214.
[221] Wansley, *supra* note 219; see also Anna Butenko & Pierre Larouche, "Regulation for innovativeness or regulation of innovation?" (2015) 7:1 L, Innovation & Technology 52 at 70, and related discussion regarding the "Collingridge dilemma", which is credited to David Collingridge, *The Social Control of Technology* (New York: St. Martin's Press, 1980), and discussed in Chapter 2, *above*.

shift course in Canada and take a more restrictive approach to access to CAM, including chelation therapy. Unless chelation therapy is decoupled from CAM, or there is new evidence regarding its harms, access seems likely to continue under the current parameters.

5.3 Key lessons and future priorities

As will become clear in the following two chapters, chelation therapy (for non-standard of care applications) shares several key features with liberation therapy (Chapter 6) and unproven stem cell interventions (Chapter 7) that are relevant when considering questions of regulation and governance. As with these other interventions, chelation therapy can be a non-standard of care medical intervention that promises to address unmet medical need(s), or to address medical needs in a manner that is more satisfactory to the patient than existing treatment options. It has received public attention and, in this case, prompted political advocacy. There has been some degree of scientific uncertainty with conflicting professional views about the intervention. Finally, diverse actors with different spheres of authority and influence have been engaged in matters of access in Canada. Accordingly, it is unsurprising that there are also parallels in the key lessons and future priorities emerging from these case studies that could be used to inform and strengthen future strategies for regulation and governance of access to other unproven medical interventions in Canada. This case study of chelation therapy highlighted three particularly notable lessons and future priorities that are nuanced and closely connected.

The first important lesson and priority is the merit of collaborative governance, with the need to establish and maintain conditions for its success. Multiple actors have had influence over access to chelation therapy in Canada. Most notably, the federal government has exercised its responsibility over approving pharmaceutical chelating agents, provincial governments have used their powers over administration of healthcare to shape the conditions under which chelation therapy can be provided and to limit public funding, and medical regulatory bodies have applied their authority to set and enforce standards of practice for physicians who provide CAMs, including chelation therapy. There are potential benefits of this type of division of responsibilities between different regulatory and governance actors. It can distribute the regulatory burden, maximize expertise, and facilitate more efficient enforcement by the actors best suited to exercise that responsibility. As discussed earlier, at times in the history of chelation therapy in Canada, key regulatory and governance actors acknowledged this division of responsibilities in their decision-making processes.

However, achieving the aspirational benefits of collaborative governance requires role clarity and effective implementation on a wide-spread and sustained basis. If there is a blurring or possibly overstepping of roles, the benefits of expertise may be lost. Although provincial governments are generally considered to have jurisdiction over the administration of healthcare and the practice of medicine, including access to medical interventions (proven and otherwise), they have historically delegated that responsibility to medical regulatory bodies, partly out of recognition of their unique expertise. Nonetheless, some provincial governments used their legislative powers to expand access to CAM, including chelation therapy, notwithstanding initial opposition by their college of physicians and surgeons. That they appear to have done so largely in response to political advocacy points to the need to consider the role of evidence in health policy decision-making, particularly with respect to access to medical interventions. For example, in 2007, Dr. Trevor Theman, Registrar of the College of Physicians and Surgeons of Alberta, appeared before the Community Services Committee to speak to proposed amendments

to the *Medical Professions Act (Bill 41).* Although the specifics of those amendments are not important for this discussion, his reflections on the history of chelation therapy highlight the value of role delineation between governance actors.

> Let us not forget that chelation for the treatment of hardening of the arteries, atherosclerosis, while completely unproven scientifically was supported by the government of the day. We now have an amendment to the Medical Profession Act that prevents us, the regulatory body, from taking action against a physician who practises such nontraditional but unproven and unhelpful therapies. We believe there is value to professionally led regulation, justification for the trust that the public and government has granted to us. We regulators, while respectful of the political realities of the day, can do the right thing without concern for the political exigencies that affect governments regularly.[222]

Rather than maximizing the collective strength of different actors in a coordinated web, if actors fail to exercise their responsibilities, gaps in oversight can emerge. For example, as recently as 2018, Health Canada provided a statement indicating that it has not authorized chelation therapy drugs for use in children as a treatment for autism, but physicians have authority to use drugs for 'off-label' purposes as part of the practice of medicine, which falls under provincial jurisdiction and the regulatory purview of medical regulatory bodies.[223] The implication of this division of responsibility is that if medical regulatory bodies do not exercise their authority by providing sufficient oversight of these off-label practices, there is a risk that children with autism may be treated with ineffective and potentially unsafe or high-risk interventions. Individual physicians also have an important role to play in maintaining an effective governance network or web. Even physicians who do not provide chelation therapy (or other forms of CAM) can exercise influence by acknowledging the prevalence of interest in and use of CAM, asking questions of their patients to get a full picture of the interventions they are using, and sharing the best available evidence and information about the safety and efficacy of these interventions.[224]

The second key lesson and related future priority emerging from this case study is the need for a renewed focus on the role of professional regulatory bodies and the requirements of their public interest mandates. As the Ontario College of Physicians and Surgeons' discipline committee noted when imposing penalties on a member for having engaged in unprofessional conduct in his provision of chelation therapy (along with other forms of CAM), the college must "preserve public confidence in the ability of the profession to regulate itself".[225] However, the approach taken to chelation therapy in the recent case of *King v. Gannage*,[226] discussed above, and the availability of CAM provided by physicians, has prompted critiques of whether the current self-regulatory structures of medical regulation are adequately protecting "vulnerable

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[222] Alberta, Community Services Committee, *Journals of the Legislative Assembly*, 26-3 (1 October 2007) at CS-55 (Dr. Trevor Theman).
[223] Ireland, *supra* note 60.
[224] Canadian Paediatric Society, *supra* note 72; see also Akins, Angkustsiri & Hansen, *supra* note 33 at 316.
[225] *Ontario (College of Physicians and Surgeons of Ontario) v. Wojcicki*, 2016 ONCPSD 9 (CanLII) at 15.
[226] *King, supra* note 213.

patients" and maintaining public trust in healthcare professionals.[227] These critiques echo similar concerns that have prompted broader shifts in approaches to medical professional regulation in other jurisdictions including the United Kingdom, where the state has limited the autonomy of medical self-regulation.[228] They are also consistent with recent recommendations made to modernize British Columbia's health profession regulatory framework. These recommendations were based in part on findings from a review that highlighted a lack of public trust in regulators and insufficient focus on patient safety.[229]

These ongoing regulatory reform activities may be opening a policy window in which it would be an opportune time to examine what it means for professional regulatory bodies to act in the public interest with respect to unproven medical interventions, including forms of CAM. [230] One important question is whether the current complaint-driven reactive approach is sufficient. Another central issue is whether it is justifiable to treat CAM interventions collectively from a regulatory and governance perspective, given the wide variety of CAM options available with their equally diverse potential benefits and risks. The current blanket approach offers efficiency, but it is questionable whether it advances the oft-stated objectives of protecting and promoting health. The potential roles of mission drift and regulatory capture with respect to how access to unproven medical interventions has been approached by professional regulatory bodies would also be valuable avenues for future research to explore as part of larger professional regulatory reform initiatives.

Finally, this case study also highlights the importance of evidence in regulation and governance of access to medical interventions, and the need for greater nuance and transparency regarding how evidence is constructed, understood, and applied in these contexts. The question of evidence has had a strong presence throughout the regulation and governance of access to chelation therapy over time in Canada, but its interpretations and use have varied considerably among different actors and in different contexts. Access to chelation therapy appears to have largely been driven by political advocacy from patients and their supporters, motivated in part by individual anecdotes, rather than by the medical research community or traditional forms of biomedical evidence. For instance, different lines of argument regarding evidence were used in the push for access to chelation therapy for heart disease in the 1990s, including that clinical trials were unnecessary and even perhaps unethical because the effectiveness of the treatment was well known from experience, and that much of medicine is technically 'unproven' in that it

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[227] See Anne Borden King, "Autism case highlights urgent need to reform Ontario's regulatory colleges" *Healthy Debate* (2 November 2020), online: <healthydebate.ca/2020/11/about-healthy-debate/opinions-about-healthy-debate/autism-case-reform-ontarios-regulatory-colleges/>.

[228] Mary Dixon-Woods, Karen Yeung & Charles Bosk, "Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors" (2011) 73 Soc Science & Medicine 1452; see also William Lahey, "Is self-regulation under threat?" (2011) 107(5) Canadian Nurse 7; see also Kristyn Shaw et al, "Shared Medical Regulation in a Time of Increasing Calls for Accountability and Transparency; Comparison of Recertification in the United States, Canada, and the United Kingdom" (2009) 302:18 J American Medical Assoc 2008.

[229] Government of British Columbia Steering Committee on Modernization of Health Profession Regulation, "Recommendations to modernize the provincial health profession regulatory framework" (August 2020), online (pdf): <www2.gov.bc.ca/assets/gov/health/practitioner-pro/professional-regulation/recommendations-to-modernize-regulatory-framework.pdf> at 4.

[230] John Kingdon, *Agendas, alternatives and public policies* (Boston: Little Brown, 1984). Kingdon developed the policy streams theory, which describes the policy window or window of opportunity that arises for policy entrepreneurs seeking to effect change when problem, policy and politics streams align.

has not been validated by double-blind, placebo controlled trials, so there should not be a double standard for alternative options.[231] Many proponents of access to CAM and chelation therapy in particular placed considerable emphasis on the persuasiveness of individual stories of success. The following 2001 excerpt from the British Columbia Hansard reflects the power of anecdote and, more specifically, how the legacy of chelation therapy has been situated within some debates about different forms of evidence in relation to medical interventions:

> I can recall very vividly some ten or 15 years ago encountering a group of people in the area where I live on Vancouver Island who had been fighting the fight for chelation therapy for years and years, and they presented all kinds of what we would call anecdotal evidence to support their conclusions. In the world of contemporary science and medicine, anecdotal evidence doesn't count for anything.
>
> But there, I think, ironically enough, is the tragedy, because anecdotal evidence is indeed evidence-based. It's just that it doesn't measure up to the arbitrarily imposed, so-called scientific standard. I think of that. And I recognize, in dealing with all of those people who were advocating for chelation therapy, that some very articulate, bright, successful and competent individuals were all able to present, frankly, very compelling evidence and arguments as to why it worked for them.
>
> Here's the rub: the grand irony, remember, of the scientific revolution is that when Galileo tried to introduce the whole concept of scientific method and evidence as being the only basis for argument, what did he base it on? He based it on a simple observation.[232]

This case study also illustrates that questions of evidence are particularly complicated when layered with freedom of choice arguments. Access imperatives rooted in arguments about patient choice and freedom still have strong roots in the current CAM policies of colleges of physicians and surgeons across Canada. There is however also a notable tension here between privileging patient choice for non-standard medical options, and the professional responsibilities of physicians, including provision of evidence-based medicine.[233] As will be discussed further in the concluding chapter, there is important work to be done towards identifying and addressing these tensions, ideally in a transparent and principled manner.

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[231] See e.g. Joshua Avram, "If it feels good, it is: doctors who practice alternative therapies resist new regulations" (1997) 24:8 Alberta Report 35. These arguments were advanced by an Alberta physician who was practicing with the Pheonix Chelation Clinic in Edmonton in 1997. He argued that 85% of mainstream medicine has been developed on anecdotal evidence. See also Oliver, *supra* note 69 at 753. This article presents the views of both chelation patients and a provider who were persuaded by anecdotal evidence of its effectiveness.

[232] British Columbia, *Journals of the Legislative Assembly*, 36-5, vol 22, No 19 (4 April 2001) at 17666 (Hon. D. Lovick).

[233] Ries & Fisher, *supra* note 101 at paras 26-27. Ries and Fisher use chelation therapy as an example of these tensions.

CHAPTER 6: CASE STUDY 2 - LIBERATION THERAPY

In this chapter, I will present the results of my case study analysis of the regulation and governance of access to liberation therapy in Canada. Unlike the other two case studies discussed in this thesis which examined interventions that have been used for multiple conditions, liberation therapy was developed as a purported treatment specifically for multiple sclerosis (MS). Accordingly, I will begin the narrative account of liberation therapy in Canada with a brief overview of MS, followed by an explanation of liberation therapy and its origins. I will then review how the liberation therapy phenomenon unfolded in Canada, before proceeding to discuss central findings from my analysis of its regulation and governance.

6.1 Narrative account of liberation therapy in Canada

6.1.1 Multiple Sclerosis (MS) and liberation therapy – an overview

MS is a chronic, degenerative neurological disease that leads to both cognitive and physical impairments. One of its key characteristics is damage to myelin, the protective coating of nerves in the brain and spinal cord. This demyelination impairs nerves' ability to send messages to and from the brain. Common symptoms of MS include fatigue, impaired balance, speech and vision issues, forms of paralysis, and mental impairment such as fogginess and memory issues.[1] MS is usually understood to be a type of autoimmune condition where the body's immune system attacks the myelin, and genetics are often believed to play a causal role, potentially in combination with other factors including environment.[2]

There are different forms of the disease. Relapsing-remitting MS (RRMS) accounts for approximately 85% of cases. It is characterized by an ebbing and flowing of symptoms, where "relapses" (commonly referred to as episodes, attacks, or flare-ups) are followed by "remissions" where the individual's symptoms reduce or disappear for fluctuating periods of time, ranging from days to months.[3] With progressive MS, individuals experience steady decline.[4] The unpredictability and degenerative nature of MS makes it particularly challenging to manage and live with.[5] MS is typically diagnosed between the ages of 15-40.[6] In addition to its impacts on individuals and families, MS has a significant economic burden on society, largely due to its early life onset which can reduce individuals' abilities to work as well as increase needs for supportive care.[7] Canada has one of the highest MS prevalence rates in the world, with over

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[1] For background information on MS, see Multiple Sclerosis International Federation, "Atlas of MS, 3rd Edition" (September 2020), online (pdf): <www.msif.org/wp-content/uploads/2020/10/Atlas-3rd-Edition-Epidemiology-report-EN-updated-30-9-20.pdf>; see also MS Society of Canada, "About MS" (last visited 23 May 2022), online: <mssociety.ca/about-ms>.

[2] Public Health Agency of Canada, "Multiple Sclerosis in Canada" (2018), online (pdf): <www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/multiple-sclerosis-infographic/multiple-sclerosis-infographic.pdf>.

[3] MS Society of Canada, *supra* note 1. In Canada, 75% of people with MS are female.

[4] *Ibid*.

[5] Alberta Health, "The Way Forward; Alberta's Multiple Sclerosis Partnership" (November 2013), online (pdf): *Government of Alberta* <open.alberta.ca/dataset/96473e71-bbee-46ee-969c-bb7c30a0ea34/resource/8deb99b8-a296-450f-abba-357efa5590e0/download/6863363-2013-way-forward-alberta-multiple-sclerosis-partnership.pdf> at 2.

[6] *Ibid*.

[7] Nana Amankwah et al, "Multiple sclerosis in Canada 2011 to 2031: results of a microsimulation modelling study of epidemiological and economic impacts" (2017) 37:2 Health Promotion Chronic Disease Prevention Canada 37.

77,000 Canadian adults living with MS. The global MS prevalence rate is 36 per 100,000, while Canada has a prevalence rate of 290 per 100,000.[8] Saskatchewan has one of the highest prevalence rates in Canada.[9] Although there are pharmaceutical treatments that can slow its progression in some cases, there is no widespread cure for MS.[10] One possibility that has shown some promise is a form of bone marrow transplant similar to treatments used for leukemia. This approach, called autologous haemopoietic stem-cell transplantation, uses a patient's healthy blood stem cells to replace diseased bone marrow cells. It is an extremely high risk and very invasive treatment that involves chemotherapy and immune-depleting antibodies. Thus far, it has only been tested in clinical trials involving small numbers of patients with aggressive MS.[11]

In 2006, Dr. Paolo Zamboni of Italy presented what he termed "the big idea".[12] His theory was that congestion in neck veins contributes to MS because venous reflux (i.e. when blood that cannot drain properly backs-up) leads to a build-up of iron in nervous tissue in the brain, which triggers an inflammatory response causing demyelination.[13] In 2009, Zamboni reported a strong association between these venous abnormalities and MS, and set out ultrasound criteria to identify them.[14] He termed this condition chronic cerebrospinal venous insufficiency (CCSVI), and published promising results using endovascular treatment to widen the veins, correcting for the purported drainage problem.[15] Different terms have been used to describe the purported phenomenon of CCSVI and its treatment, including liberation therapy, liberation treatment, endovascular treatment, and venous angioplasty, among others. For consistency, in this work I use liberation therapy[16] to refer to interventions, including the use of balloon

[8] MS Society of Canada, *supra* note 1; see also Public Health Agency of Canada, *supra* note 2; see also Multiple Sclerosis International Federation, *supra* note 1; see Heather Gilmour, Pamela L. Ramage-Morin & Suzy L. Wong, "Multiple Sclerosis: Prevalence and impact" (2018) online: *Statistics Canada* <www150.statcan.gc.ca/n1/pub/82-003-x/2018001/article/54902-eng.htm>.

[9] Lina H. Al-Sakran et al, "Establishing the Incidence and Prevalence of Multiple Sclerosis in Saskatchewan" (2018) 45:3 Canadian J Neurological Sciences 295. The study determined the prevalence of MS in Saskatchewan in 2013 was 313.6 per 100,000.

[10] Along with pharmaceutical treatments, other supportive interventions including physiotherapy, occupational therapy and cognitive rehabilitation, among others, can help manage the symptoms of MS. Gilmour, Ramage-Morin & Wong, *supra* note 8.

[11] See Harold Atkins et al, "Immunoablation and autologous haemopoietic stem-cell transplantation for aggressive multiple sclerosis: a multicentre single-group phase 2 trial" (2016) 388:10044 Lancet 576. One of the 24 participants in this clinical trial died from transplant-related complications.

[12] Paolo Zamboni, "The big idea: iron-dependent inflammation in venous disease and proposed parallels in multiple sclerosis" (2006) 99 J Royal Society Medicine 589.

[13] *Ibid*.

[14] Paolo Zamboni et al, "Chronic cerebrospinal venous insufficiency in patients with multiple sclerosis" (2009) 80 J Neurol Neurosurg Psychiatry 392; Paolo Zamboni et al, "The value of cerebral Doppler venous heamodynamics in the assessment of multiple sclerosis" (2009) 282 J Neurological Sciences 21.

[15] Paolo Zamboni et al, "A prospective open-label study of endovascular treatment of chronic cerebrospinal venous insufficiency" (2009) 50:6 J Vascular Surgery 1348. The endovascular treatment used was percutaneous transluminal angioplasty (PTA), where a blocked blood vessel is opened using balloon angioplasty.

[16] I have adopted this term because it has been widely used in public and policy domains. I nonetheless acknowledge that it is not an uncomplicated label, in large part because of the rhetorical effect of the word "liberation" and the related potential for unduly positive connotations. For a discussion of the implications of this "loaded terminology" from an anthropological perspective, see Mary Hande, "From Narrowed Veins to Liberation: An Anthropological Analysis of the Canadian Liberation Therapy Movement" (5 January 2012), online: < somatosphere.net/2012/from-narrowed-veins-to-liberation-an-anthropological-analysis-of-the-canadian-liberation-therapy-movement.html/>.

angioplasty, catheters, or stents, used to widen constricted veins with the objective of treating CCSVI as a cause of MS.

Zamboni's hypothesis was "a major paradigm shift" in the general scientific understanding of MS.[17] It prompted what has been described as "one of the most heated debates and controversies in medicine in recent years".[18] Zamboni's early results were critiqued for several reasons. The studies were unblinded, meaning both the researchers and patients knew the intervention was being administered, which led to concerns about biased ultrasound interpretation and placebo effects.[19] Zamboni's participants also remained on their pharmaceutical treatments which made it difficult to ascertain what outcomes were attributable to the intervention as opposed to the existing treatment protocol, or to the natural fluctuations of MS symptoms common in RRMS.[20] Zamboni's studies also did not include practice trials, where participants repeat performance measures such as walking, hand function testing, and cognitive tasks in advance of the intervention. Without a baseline, improvements can be a result of "practice effects", because a participant becomes familiar with the tasks, as opposed to being a result of the intervention.[21] In addition, variability in the scanning processes (timing relative to treatment, equipment, and protocols used, etc.) used in Zamboni's research made it difficult to reliably compare and interpret subsequent research.[22]

There were early enthusiasts about Zamboni's theory, but also many skeptics.[23] It is beyond the scope of this dissertation to detail the numerous studies that followed, or the nuances of the related medical and scientific debates. For this work, it is sufficient to note that the numerous follow-up studies published between 2011 and 2019 failed to reproduce Zamboni's results or validate his theory. Many studies found no higher prevalence of CCSVI among MS patients than in other patients or healthy volunteers, which discredited Zamboni's underlying

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[17] Suresh Vedantham et al, "Interventional Endovascular Management of Chronic Cerebrospinal Venous Insufficiency in Patients with Multiple Sclerosis: A Position Statement by the Society of Interventional Radiology, Endorsed by the Canadian Interventional Radiology Association" (2010) 21 J Vascular & Interventional Radiology 1335 at 1336.

[18] Hector Ferral, "'Brave Dream'" Reanalysis Sheds New Light on Angioplasty for Venous Anomalies in Some Multiple Sclerosis Patients With Chronic Cerebrospinal Venous Insufficiency" (2020) 27:1 J Endovascular Therapy 18 at 18.

[19] Canadian Institutes of Health Research and the Multiple Sclerosis Society of Canada, "Summary Report: CIHR and MS Society of Canada Joint Invitational Meeting on Multiple Sclerosis Research August 26, 2010, Ottawa, Ontario" (2 December 2010), online (pdf): *Government of Canada* <cihr-irsc.gc.ca/e/documents/MSSummaryreport_e.pdf> at 3-4 [CIHR, "Summary Report August 26, 2010"].

[20] *Ibid*.

[21] Alberta Health Services, "Alberta Health Services Statement on Venous Imaging and Venous Angioplasty in Multiple Sclerosis (MS)" (16 February 2010), online: <www.albertahealthservices.ca/news/features/2010/Page1409.aspx> [Alberta Health Services, "Statement on Venous Imaging"].

[22] *Ibid*.

[23] See e.g. Baracchini, Atzori & Gallo, *supra* note 22; J.A. Reekers, "CCSVI and MS: A Never-Ending Story" (2012) 43 European J Vascular & Endovascular Surgery 127; CA. Mayer & U. Ziemann, "CCSVI: Is Blinding the Key?" (2012) 43 European J Vascular & Endovascular Surgery 124; Michael Brant-Zawadzki et al, The "Liberation Procedure" for Multiple Sclerosis: Sacrificing Science at the Altar of Consumer Demand" (2012) 9:5 American College Radiology 305; Michael Rasminsky & Karel terBrugge, "Goodbye to all that: a short history of CCSVI" (2013) 19:11 Multiple Sclerosis J 1425; Dennis Bourdette & Jeffrey Cohen, "Venous angioplasty for "CCSVI" in multiple sclerosis; Ending a therapeutic misadventure" (2014) 83 Neurology 388.

hypothesis regarding the causal connection between vein narrowing and MS.[24] Studies that did find some association between MS and CCSVI could not identify causation,[25] showed fluctuation over time,[26] or found no connection between CCSVI and patients' clinical outcomes.[27] Nonetheless, as will be discussed in more detail below, the suggestion that liberation therapy would offer a surgical solution for MS, which was otherwise a life-long debilitating condition without a cure, generated considerable attention and enthusiasm among patient communities and others.

Notwithstanding the relative simplicity of its underlying concept, liberation therapy is not without risk. Angioplasty is standard of care for arterial blockages, but when used in veins there is risk of re-stenosis as well as of damage to the veins which can cause thrombosis (clotting) with corresponding risk of pulmonary embolus (clots that break free and travel to the heart or lungs, creating blockages).[28] Liberation therapy using stents, which are intended to reduce re-stenosis by keeping the veins open, is an even higher risk procedure because of the potential for blood clots, the risk that stents may dislodge and move to the heart, and the need for blood thinners which are associated with risk of stroke.[29] Reviews of liberation therapy cases from Italy and Canada (two countries where it received a lot of public attention and where many MS patients pursued the intervention) found various adverse events including jugular thrombosis, stent migration, nerve injury, strokes, and cardiac complications.[30]

These potential risks are particularly concerning because the preponderance of evidence from subsequent studies designed with a focus on controls and reproducibility found that

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[24] Giancarlo Comi et al, "Italian multicentre observational study of the prevalence of CCSVI in multiple sclerosis (CoSMo study): rationale, design, and methodology" (2013) 34 Neurological Sciences 1297; see also Anthony Traboulsee et al, "Prevalence of extracranial venous narrowing on catheter venography in people with multiple sclerosis, their siblings, and unrelated healthy controls: a blinded, case-control study" (2014) 383: 9912 Lancet 138; see also Christoph Mayer et al, "The perfect crime? CCSVI not leaving a trace in MS" (2011) 82 J Neurology, Neurosurgery & Psychiatry 436. It is important to note that these were double-blind studies that also included healthy control participants. Many of these studies also used Zamboni's diagnostic criteria. See also Ian Rodger et al, "Evidence against the Involvement of Chronic Cerebrospinal Venous Abnormalities in Multiple Sclerosis. A Case-Control Study" (2013) 8:8 PLOS One e72495 at 1; Maurizio Leone et al, "Chronic Cerebrospinal Venous Insufficiency Is Not Associated with Multiple Sclerosis and Its Severity: A Blind-Verified Study" (2013) 8:2 PLOS ONE e56031 at e56031; see also Nancy Martin et al, "Prevalence of Extracranial Venous Narrowing on Magnetic Resonance Venography Is Similar in People With Multiple Sclerosis, Their Siblings, and Unrelated Healthy Controls: A Blinded, Case-Control Study" (2017) 68 Canadian Assoc Radiologists J 202 at 202.

[25] Francesco Patti et al, "Multiple Sclerosis and CCSVI: A Population-Based Case Control Study" (2012) 7:8 PLOS One e41227 at 1, 5,

[26] *Ibid*; see also Petronella Van den Berg & Leo Visser, "The Fluctuating Natural Course of CCSVI in MS Patients and Controls, a Prospective Follow-Up" (2013) 8:11 PLOS One e78166.

[27] Sirin Gandhi et al, "No association between variations in extracranial venous anatomy and clinical outcomes in multiple sclerosis patients over 5 years" (2019) 19:121 BMC Neurology https://doi.org/10.1186/s12883-019-1350-2 at 1.

[28] Canadian Institutes of Health Research and MS Society of Canada, "Joint Invitational Meeting on Multiple Sclerosis Research - Summary Report" (26 August 2010), online: *Government of Canada* <cihr-irsc.gc.ca/e/42381.html>; see also CIHR, "Summary Report August 26, 2010", *supra* note 19 at 6.

[29] CIHR, "Summary Report August 26, 2010", *supra* note 19 at 6.

[30] A Ghezzi et al, "Adverse events after endovascular treatment of chronic cerebro-spinal venous insufficiency (CCSVI) in patients with multiple sclerosis" (2013) 19:7 Multiple Sclerosis J 961; Jodie Burton et al, "Complications in MS Patients after CCSVI Procedures Abroad (Calgary, AB)" (2011) 38 Canadian J Neurological Sciences 741 at 741.

liberation therapy was not effective in treating MS,[31] meaning the treatment was not only ineffective but also potentially dangerous. The definitive study in Canada was a CIHR-funded Phase I/II trial led by Dr. Anthony Traboulsee, which showed no difference in patient reported, clinical or MRI outcomes between treatment and sham groups.[32] Much of the controversy and attention surrounding CCSVI and liberation therapy diminished in Canada following the Traboulsee trial results, and elsewhere once Zamboni's much anticipated follow-up "Brave Dreams" trial in Italy similarly reported safety but lack of efficacy of venous angioplasty in treating patients with relapsing/remitting MS.[33] However, reanalysis of the Brave Dreams trial results from Zamboni and colleagues in 2020,[34] suggests the story of liberation therapy may yet have another chapter.[35]

6.1.2 How the liberation therapy phenomenon unfolded in Canada

Notwithstanding concerns about his methods, Zamboni's work garnered considerable public attention in Canada, more so than other countries that also have high rates of MS including the United States and the United Kingdom.[36] The Canadian news media played a significant role in drawing attention to Zamboni's theory about CCSVI and MS.[37] A W5

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[31] Adnan Siddiqui et al, "Prospective randomized trial of venous angioplasty in MS (PREMiSe)" (2014) 83:5 Neurology 441. This study suggested liberation therapy may exacerbate underlying disease activity; A Dessa Sadovnick et al, "Patient-Reported Benefits of Extracranial Venous Therapy: British Columbia CCSVI Registry" (2017) 44:3 Canadian J Neurological Sciences 246 at 246. Sadovnick et al. found that patient-reported benefits were not sustained over time; Newfoundland and Labrador, "Multiple Sclerosis Observational Study Results Announced" (7 June 2012) online: *Health and Community Services* <www.releases.gov.nl.ca/releases/2012/health/0607n04.htm>. This study showed no objective benefit one year after the procedure, notwithstanding patients' self-reported improvements; Georgios Tsivgoulis, "'Liberation treatment' for chronic cerebrospinal venous insufficiency in multiple sclerosis: the truth will set you free" (2015) 5:1 Brain & Behavior doi: 10.1002/brb3.297. This paper provides detail on the reproducibility challenges of ultrasound techniques and argued liberation therapy should no longer be provided even in clinical trial settings; Vanitha Jagannath, "Percutaneous transluminal angioplasty for treatment of chronic cerebrospinal venous insufficiency (CCSVI) in people with multiple sclerosis" (2019) 5 Cochrane Database Systematic Revs Art. No.: CD009903. DOI: 10.1002/14651858.CD009903.pub3 at 2. This review as an update of an earlier review published in 2012. Its conclusion was that the evidence indicated liberation therapy was not effective and that no further randomized clinical trials were necessary.

[32] Anthony Traboulsee et al, "Safety and efficacy of venoplasty in MS A randomized, double-blind, sham-controlled phase II trial" (2018) 91 Neurology e1660. doi :10.1212/WNL.0000000000006423 [Traboulsee et al, "Safety and efficacy"]. A "sham" group refers to participants who underwent the same surgical procedure as those in the intervention arm, but without the actual intervention (i.e. no widening of the veins).

[33] Paolo Zamboni et al. "Efficacy and Safety of Extracranial Vein Angioplasty in Multiple Sclerosis; A Randomized Clinical Trial" (2017) 75:1 J American Medical Assoc Neurology 35 [Zamboni et al, "Efficacy and Safety"]; see discussion in Ferral, *supra* note 18 at 19.

[34] Zamboni et al, "Efficacy and Safety", *supra* note 33 at 42; Paolo Zamboni et al, "Effects of venous angioplasty on cerebral lesions in multiple sclerosis: expanded analysis of the Brave Dreams double-blind, sham-controlled randomized trial" (2020) 27:1 J Endovascular Therapy 9.

[35] See e.g. Pietro Bavera, "Chronic cerebrospinal venous insufficiency, ten years after. New headlights on a venous disease that enriched the vascular world" (2020) 9:9053 Veins & Lymphatics 29.

[36] Arie Gafson & Gavin Giovannoni, "CCSVI-A. A call to clinicians and scientists to vocalise in an Internet age" (2014) 3 Multiple Sclerosis & Related Disorders 143 at 145. Gafson and Giovannoni observed that it is unclear why the Canadian media gave so much attention to the CCSVI story, and that there was no corresponding clear and unified response strategy from the Canadian scientific community.

[37] Several analyses of this media coverage have been completed. See e.g. S. Michelle Driedger, Ebenezer Dassah & Ruth Ann Marrie, "Contesting Medical Miracles: A Collective Action Framing Analysis of CCSVI and Venous Angioplasty ("Liberation Therapy") for People With Multiple Sclerosis in News and Social Media" (2018) 40:4

documentary titled "The Liberation Treatment: A Whole New Approach to MS"[38] that aired on CTV on November 21, 2009 is often identified as having been the initial introduction to CCSVI and liberation therapy for many MS patients in Canada.[39] It was critiqued for having been "uncritically positive" in portraying Zamboni's discovery as fueled by love for his wife (who suffered from MS), its use of language such as "stunning medical discovery" and "revolutionary treatment", and for lacking discussion of risks.[40] Different analyses suggest ensuing media activity prompted access-related advocacy, including pressure on decision-makers to fund research.[41] Early polling identified strong public support for government-funded research (75% of respondents), as well as for access to liberation therapy in Canadian hospitals (82% of respondents).[42] The internet and social media were also influential mechanisms for patient communities to share information about liberation therapy, for mobilizing advocacy efforts in favour of research funding and treatment access in Canada, and for critiquing opponents, including physicians and researchers.[43] Liberation therapy was even dubbed the "YouTube Cure".[44] A 2011 *Globe and Mail* article referred to the public campaign to bring liberation therapy to Canada as a "war" fueled in part by the Internet.[45] The competing narratives in these media spheres and online spaces reflected stark tensions in how different kinds of information about liberation therapy, ranging from individual experiences to results from robust scientific studies, were understood and interpreted as forms of evidence. This observation echoes findings

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Science Communication 469 at 475-476. See also Ebenezer Dassah, *Patient Mobility and Medical Tourism for the Liberation Therapy Procedure by Multiple Sclerosis Patients: A Framing Analysis of Canadian Newspapers*, Master of Arts, University of Manitoba, 2014 [unpublished]; see also Brianne Tulk, *Constructing Scientific Controversy: Framing liberation therapy for multiple sclerosis in Canadian mainstream press*, Master of Arts in Communication, University of Ottawa, 2013 [unpublished].

[38] Avis Favaro & Elizabeth St Phillip, "The Liberation Treatment: A whole new approach to MS", *CTV W5* (21 November 2009), online: < www.ctvnews.ca/the-liberation-treatment-a-whole-new-approach-to-ms-1.45661>.

[39] Michelle Ploughman et al, "Navigating the "liberation procedure": a qualitative study of motivating and hesitating factors among people with multiple sclerosis" (2014) 8 Patient Preference & Adherence 1205 at 1209 [Ploughman et al, "Navigating"]. Ploughman et al. also observed that participants with "weaker analytical skills and poorer relationships with their health care teams" tended to look more to the media and internet as sources for trusted advice that outweighed healthcare professionals' advice (at 1212).

[40] A companion news story was published in *The Globe and Mail*. Andre Picard & Avis Favaro, "Researcher's labour of love leads to MS breakthrough" *The Globe and Mail* (20 November 2009), online: < www.theglobeandmail.com/news/national/researchers-labour-of-love-leads-to-ms-breakthrough/article4196866/?page=all>; see also Driedger, Dassah & Marrie, *supra* note 37 at 477.

[41] Ploughman et al, "Navigating", *supra* note 39; Lindsay Machan, Kieran Murphy & Tony Traboulsee, "Multiple Sclerosis and Venous Abnormalities: Medicine in the Age of Social Media" (2012) 63 Canadian Assoc Radiologists J S2 at S2-S3; Chido Vera et al, "Internet-Based Social Networking and Its Role in the Evolution of Chronic Cerebrospinal Venous Insufficiency" (2012) 15:2 Techniques in Vascular & Interventional Radiology 153; see also CIHR, "Summary Report August 26, 2010", *supra* note 19 at 2. This report notes the "unprecedented" nature of the media coverage of Liberation Therapy.

[42] Jane Taber, "Majority backs funding trials of controversial MS treatment", *The Globe and Mail* (16 December 2010), online: <https://www.theglobeandmail.com/news/politics/ottawa-notebook/majority-backs-funding-trials-of-controversial-ms-treatment/article612421/>.13480>.

[43] Roger Chafe et al, "The rise of people power" (2011) 472 Nature 410 at 410; see also Vera et al, *supra* note 41 at 154.

[44] Katie Moisse, "The YouTube Cure", *Scientific American* 304:2 (February 2011) 34. See also Gafson & Giovannoni, *supra* note 36 at 144; Fadhila Mazanderani, Braden O'Neill & John Powell, "'People power' or 'pester power'? YouTube as a forum for the generation of evidence and patient advocacy" (2013) 93 Patient Education & Counselling 420; Setareh Ghahari & Susan Forwell, "Social Media Representation of Chronic Cerebrospinal Venous Insufficiency Intervention for Multiple Sclerosis" (2016) 18 Intl J MS Care 49 at 55.

[45] Carly Weeks, "Patients flex muscle in 'war' over treatment", *The Globe and Mail* (11 May 2011) A3.

discussed in the chelation therapy case study (Chapter 5) and connects to a broader theme regarding conceptions and use of evidence that will be addressed in Chapter 8.

Only a small number of physicians provided liberation therapy to Canadians in a treatment context.[46] However, there were several medical tourism companies in Canada marketing medical travel for testing and treatment of CCSVI.[47] While there are no robust data on the precise numbers, reports suggest that thousands of Canadians received liberation therapy out-of-country,[48] in some cases with ensuing concerns about receiving inadequate follow-up care upon return.[49] Results from interviews conducted with Canadians who pursued liberation therapy outside Canada indicated that some of these individuals had lost faith, hope, and trust in the Canadian healthcare system and its neurologists, and were frustrated that a treatment available in other countries was not accessible in Canada.[50] As noted above, the chronic, lifelong nature of MS likely enhanced the appeal of this intervention and its possibilities for improving quality of life. Findings from interviews with MS patients indicated that while many individuals understood that liberation therapy was unproven and not necessarily the desired miracle cure, it nonetheless generated welcome hope and a willingness to experiment.[51] Some patients saw the ability to participate in clinical trial research in Canada, from which they expected some level of

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[46] British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5921 (Hon. K. Falcon); *Turnbull v. British Columbia (Ministry of Health Services)*, 2011 BCHRT 324 at para 64 [*Turnbull*]. These sources reference two individual who received publicly funded liberation therapy in British Columbia, before the College of Physicians and Surgeons of British Columbia investigated and determined the procedures was still experimental. See also Anne Kingston, "Liberation therapy still locked away" *Maclean's* (20 September 2010) 24. This article suggests a cardio-thoracic surgeon in Ontario provided six CCSVI treatments on a "pro bono" basis.

[47] Leigh Turner, "Beyond "medical tourism": Canadian companies marketing medical travel" (2012) 8:16 Globalization & Health http://www.globalizationandhealth.com/content/8/1/16. Although beyond the scope of this research, it is noteworthy that concerns have been raised in other work regarding Canadian medical tourism brokerage websites, including no shared standard of care and accreditation, and deficient risk communication practices. See Kali Penney et al, "Risk communication and informed consent in the medical tourism industry: A thematic content analysis of Canadian broker websites" (2011) 12:17 BMC Medical Ethics http://www.biomedcentral.com/1472-6939/12/17.

[48] Multiple Sclerosis Advisory Panel of Saskatchewan, "Multiple Sclerosis Advisory Panel Recommendations" (February 2016), online (pdf): *Government of Saskatchewan*: < pubsaskdev.blob.core.windows.net/pubsask-prod/108828/108828-MS-Advisory-Panel-Recommendations.pdf> at 8 [MS Advisory Panel, "Recommendations"]. This report estimated that more than 3,000 Canadians received liberation therapy in other jurisdictions. In other research, 631 Canadian physicians reported a "large number" of MS patients travelling out of country for liberation therapy. See Vivien Runnels et al, "Canadian physicians' responses to cross border health care" (2014) 10:20 Globalization & Health http://www.globalizationandhealth.com/content/10/1/20.

[49] See e.g. "Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*", Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Senator Cordy); see also *Debates of the Senate*, 41-1, vol 148, No 104 (2 October 2012) at 2541 (Hon. Mobina S.B. Jaffer); see also Alberta, *Journals of the Legislative Assembly*, 27-3 (17 November 2010) at 1259 (Hon. Kevin Taft).

[50] Jeremy Snyder et al, "'I knew what was going to happen if I did nothing and so I was going to do something': Faith, hope, and trust in the decisions of Canadians with multiple sclerosis to seek unproven interventions abroad" (2014) 14:445 BMC Health Services Research http://www.biomedcentral.com/1472-6963/14/445.

[51] Fadhila Mazanderani, Jenny Kelly & Ariel Duecy, "From embodied risk to embodying hope: Therapeutic experimentation and experiential information sharing in a contested intervention for Multiple Sclerosis" (2017) 13:1 BioSocieties 232 at 245. See also Shelly Benjaminy et al, "Resilience, trust, and civic engagement in the post-CCSVI era" (2018) 18:366 BMC Health Services Research https://doi.org/10.1186/s12913-018-3130-x at 2. Benjaminy et al.'s research with MS patients also identified hope as a motivator for MS patients to pursue liberation therapy, often against medical advice.

benefit, as a desired form of access.[52] Accordingly, although this thesis generally focuses on unproven interventions provided as treatment as distinct from research,[53] access to liberation therapy in research contexts will be considered in the following analysis of the regulation and governance of access to liberation therapy in Canada.

6.2 Regulation and governance analysis

6.2.1 Actors and instruments

In the sections that follow, I use the conceptual framework presented in Chapter 2 to describe and characterize regulation and governance of access to liberation therapy in Canada. My analysis starts here with identifying key actors including organizations, bodies, institutions, or identifiable individuals that exercised influence over access to liberation therapy in Canada, and by describing the range of instruments they used. In this case study, notable actors included governments and related arms-length bodies, non-profit organizations, colleges of physicians and surgeons, medical professional organizations and associations, advocacy groups, and the courts. As will be discussed in turn, these actors used various instruments, the most prominent of which included information, spending, and legislation.

Information-based instruments were particularly common, perhaps because they are among the most widely accessible instruments for various regulatory and governance actors. In some instances, the targets of these information-based instruments were clear (e.g. guidance to physicians or recommendations to government), while others were more ambiguous, potentially attempting to reach patients, members of the public more broadly, or decision-makers. For example, some provincial and territorial governments and their administrative agencies used information-based instruments to publicly communicate their positions on liberation therapy. In 2010, AHS published an information statement that outlined key weaknesses in Zamboni's early results, stressed the need for further research, noted potential risks, and explained that liberation therapy would not be provided by AHS outside of approved research protocols until there was independent scientific validation of Zamboni's results.[54] This position statement was followed with an online fact sheet that explained the potential relationship between CCSVI and MS and urged caution regarding this purported new treatment.[55] It also stressed that MS patients should be wary of relying on information from media stories and patient blogs, and should seek expert advice.[56] The government of Nova Scotia took a similar approach in 2011 by issuing a position statement for physicians, clarifying that the link between CCSVI and MS was a hypothesis requiring further study, that liberation therapy should not be provided in Nova Scotia outside of

[52] Shelly Benjaminy et al, "Reflections on translation Views of participants in a multisite Canadian CCSVI clinical trial" (2018) 8:3 Neurology: Clinical Practice 232 at 236-237. See also Rita Poliakov, "MS decision applauded; TREATMENT: Sudbury could stage clinical trials", *The Sudbury Star* (4 July 2011) A.1. This story includes quotes from a physician who similarly characterized the ability to participate in research as a means of access to liberation therapy.
[53] This distinction is discussed in Chapter 1, Section 1.3.2, *above*.
[54] Alberta Health Services, "Statement on Venous Imaging", *supra* note 21.
[55] Alberta Health Services, "Multiple Sclerosis (MS) and 'Chronic Cerebrospinal Venous Insufficiency'" (CCSVI); Alberta Health Services Information Sheet" (6 August 2010), online (pdf): *Alberta Health Services*: <www.albertahealthservices.ca/feat/ne-feat-ccsvi-ms-info-sheet.pdf>.
[56] *Ibid* at 6.

approved research protocols, and that patients who received venous angioplasty should be provided with follow-up care as needed.[57]

Other provincial and national governance actors also engaged with questions of access to liberation therapy in Canada using primarily information-based strategies, with a focus on evaluating evolving evidence and urging against routine clinical adoption. For example, between 2009-2011, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a Health Technology Assessment and two environmental scans in which it identified a need for caution and research to provide clarity about the connection between CCSVI and MS, and the safety and efficacy of liberation therapy.[58] In December 2011, the Ontario Health Technology Advisory Committee (OHTAC) issued a recommendation that patients interested in liberation therapy should seek access only via clinical trial participation because it was still experimental.[59] A contemporaneous evidence review from the Ontario Health Quality Council highlighted "considerable inconsistency" in study results exploring the prevalence of CCSVI in MS patients as compared to healthy controls.[60] The Quebec Institut national d'excellence en santé et en services sociaux (INESSS) published a summary report reviewing the state of scientific literature regarding the link between MS and CCSVI in March, 2012. This report indicated that a causal relationship had not yet been proven, and recommended to the Minister of Health and Social Services that diagnosis and treatment for CCSVI be limited to research contexts.[61] The Canadian Institutes of Health Information (CIHI), another independent, not-for-profit, national organization, also completed an Environmental Scan in 2012 in which it characterized

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[57] Nova Scotia Health and Wellness, "Position Statement: Venous Imaging and Venous Angioplasty in Multiple Sclerosis" (17 February 2011), online (pdf): <novascotia.ca/dhw/publications/ms-position-statement-physician-information.pdf>.

[58] Canadian Agency for Drugs and Technologies in Health, "Surgical Procedures Targeting Chronic Cerebrospinal Venous Insufficiency for the Treatment of Multiple Sclerosis: Clinical Effectiveness" (2 December 2009), online (pdf): *CADTH* <cadth.ca/sites/default/files/pdf/K0117_MS_Surgery_final.pdf> [CADTH, "Surgical Procedures"]; Canadian Agency for Drugs and Technologies in Health, "Investigating Chronic Cerebrospinal Venous Insufficiency for the Treatment of Multiple Sclerosis" (21 December 2010), online (pdf): *CADTH* <https://www.cadth.ca/sites/default/files/pdf/Chronic_Cerebrospinal_Venous_Insufficiency_MS_es-15_e.pdf> [CADTH, "Investigating"]. CADTH is an independent, non-profit organization created in 1989 by federal, provincial, and territorial governments in Canada to provide a coordinated approach to evaluating new health technologies with an emphasis on evidence-based decision-making.

[59] Ontario Health Technology Advisory Committee (OHTAC), "Recommendation; Update on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency" (December 2011), online (pdf): <www.hqontario.ca/Portals/0/Documents/evidence/reports/recommendation-update-ms-ccsvi-1112-en.pdf>. The OHTAC makes recommendations to Ontario Health about public funding for healthcare services and medical devices. Its membership includes non-voting representatives from Ontario Health and the Ministry of Health. Voting members represent diverse areas of expertise including healthcare, economic evaluation, clinical epidemiology, ethics, and public or patient perspectives. Ontario Health (Quality), "Ontario Health Technology Advisory Committee Terms of Reference" (10 December 2019), online (pdf): *HQOntario* <www.hqontario.ca/portals/0/documents/evidence/reports/ohtac-terms-of-reference-en.pdf>. With the close links between the OHTAC and Ontario Health, the OHTAC could arguably be identified as a regulatory actor under the umbrella of provincial authority, but also as a governance actor because of its intended arms-length, independent relationship to Ontario Health.

[60] Ontario Health Quality Council, "Update on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency: A Preliminary Evidence Review" (December 2011), online (pdf): <www.hqontario.ca/Portals/0/Documents/evidence/reports/review-update-ms-ccsvi-1112-en.pdf>.

[61] Institut national d'excellence en santé et en services sociaux, "Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency (CCSVI) in People with Multiple Sclerosis (MS)" (March 2012), online (pdf): *INESSS* < www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Traitement/INESSS_Summary_MS_EN.pdf> at 4.

Zamboni's proposed treatment for CCSVI as still "experimental".[62] These varied information-based initiatives are particularly noteworthy because of the close connection between these governance actors and governments.

Acting under delegated provincial authority but with considerable independence, colleges of physicians and surgeons have a great deal of responsibility in the regulation and governance of medical practice. Few of the colleges of physicians and surgeons in Canada took early public action with respect to liberation therapy and access debates in Canada. One exception was the Collège des médecins du Québec, which was proactive in its use of information-based instruments. It announced in June 2010 that testing for CCSVI needed more research and was not advised in Quebec.[63] In November 2010, it confirmed that no testing or treatment for CCSVI was to be provided in Quebec outside of approved research trials.[64] In 2011, it published a physician guidance document for managing patients who returned to Quebec after receiving liberation therapy elsewhere.[65] A spokesperson from the College of Physicians and Surgeons of Ontario similarly gave an early statement to media in 2010 clarifying that while patients are entitled to urgent follow-up care, physicians are not required to redo experimental procedures patients received elsewhere, outside of approved research contexts.[66] When two individuals received liberation therapy at the Victoria General Hospital from an interventional radiologist, the College of Physicians and Surgeons of British Columbia investigated and held that this experimental procedure should only be provided in an ethics-approved research context.[67]

Other organizational actors also sought to inform or influence the conduct of physicians with respect to liberation therapy using information-based instruments. For example, a 2010 Position Statement by the Society of Interventional Radiology, endorsed by the Canadian Interventional Radiology Association, characterized the published literature on CCSVI and MS as "inconclusive", noted that the particular vulnerabilities of MS patients require protection of safety when new treatments are being evaluated, and supported the urgent need for high-quality clinical study to assess safety and efficacy.[68] In 2011, the Canadian Medical Association published a Statement on Emerging Therapies in which it acknowledged the "desperation" with which MS patients seek treatment to alleviate their symptoms, and stressed the need for rigorous clinical research and evidence-based decision-making.[69] There were also examples where individual physicians urged caution in professional publications, including Dr. Traboulsee who

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[62] Canadian Institutes of Health Information, *Canadian Multiple Sclerosis Monitoring System: Environmental and Technical Scan* (Ottawa, Ont.: CIHI, 2012) at 8 [CIHI, "MS Monitoring"]. CIHI's mandate is to provide information "to accelerate improvements in health care, health system performance and population health across the continuum of care". See Canadian Institutes of Health Information, "Vision and Mandate" (last visited 25 May 2022), online: <www.cihi.ca/en/about-cihi/vision-and-mandate>.

[63] CIHI, "MS Monitoring", *supra* note 62 at 21.

[64] *Ibid*.

[65] *Ibid*.

[66] See e.g. Joanna Smith, "Fate of MS patients abroad brings new dilemma for doctors" *The Toronto Star* (20 November 2010) A.16.

[67] British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5921 (Hon. K. Falcon); *Turnbull*, *supra* note 46 at para 64.

[68] Vedantham et al, *supra* note 17 at 1335-1336.

[69] Canadian Medical Association, "CMA Statement on Emerging Therapies" (2011), online: <policybase.cma.ca/en/permalink/policy10352>. It is important to note that while contemporaneous with debates about liberation therapy, this statement was not specific to that particular intervention.

led the CIHR-funded clinical trial.[70] Ontario's Minister of Health and Long-Term Care, the Honourable Deb Matthews, reportedly acknowledged the difficulty physicians faced in providing follow-up care in the absence of details regarding the care originally provided.[71] At her request, Ontario's MS Expert Advisory Group issued recommendations outlining potential post-procedure complications, and identifying symptoms for physicians to be alert to.[72]

The exercise of its spending power is another instrument commonly used by governments to shape behaviour, whether by providing incentives or otherwise influencing behaviour (e.g. by directing the choices available to individuals or firms).[73] Liberation therapy was not available as part of publicly funded healthcare in any province or territory. This funding constraint likely served to restrict widespread, routine access to the intervention in Canada. As is discussed below, individuals who challenged denials of provincial funding for liberation therapy as an out-of-country medical procedure were also generally unsuccessful. Governments did however fund provision of urgent follow-up care as well as information and advice provided as part of standard clinical interactions. In a unique approach, New Brunswick subsidized residents who obtained liberation therapy outside Canada by way of a matching funding program, where patients could apply for a one-time grant of up to $2,500 to support them in obtaining liberation therapy outside the province.[74] This fund was controversial among some members of the medical community, and in 2013, the New Brunswick Medical Society reportedly asked the provincial government to cease this funding support,[75] a request echoed by physician and MLA, the Honourable Jim Parrott.[76] There were also reports that some individuals successfully received a form of

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[70] See e.g. Machan, Murphy & Traboulsee, *supra* note 41.

[71] Keith Leslie, "Ontario looks at after care of MS patients who get liberation therapy abroad", *iPolitics* (1 March 2011), online: <ipolitics.ca/2011/03/01/ontario-looks-at-after-care-for-ms-patients-who-get-liberation-therapy-abroad/>.

[72] *Ibid*.

[73] Robert Baldwin & Martin Cave, *Understanding Regulation; Theory, Strategy, and Practice* (Oxford: Oxford University Press, 1999) at 336. Baldwin and Cave argue for a view of regulation that includes, among others, information strategies, resource allocation, and use of incentives.

[74] Canadian Agency for Drugs and Technologies in Health, "An Update on the Investigation of Chronic Cerebrospinal Venous Insufficiency for the Treatment of Multiple Sclerosis; Environmental Scan" (4 May 2011), online (pdf): <www.cadth.ca/sites/default/files/pdf/MS_Liberation_Update_es-20_e.pdf> at 3 [CADTH, "Update"]. Toronto Star, "New Brunswick launches fund for controversial multiple sclerosis treatment" (15 June 2011), online: <www.thestar.com/news/canada/2011/06/15/new_brunswick_launches_fund_for_controversial_multiple_sclerosis_treatment.html>. The requirement for matching funds raised some controversy when an individual's application was reportedly rejected because she had funded the initial portion herself, rather than via a third party such as a community fundraiser, prompting the following critique: "This pernicious policy reduces access to health care, which is every New Brunswicker's birthright, to a popularity contest: those with the social connections to be granted community fundraisers get partial reimbursement for treatment, while those who do not must pay the full cost themselves". See Anonymous, "One rule for all MS patients", *Telegraph-Journal; Saint John* (18 July 2011) A.4. This funding reportedly came under the authority of the Department of Finance rather than Health, because it was intended to support travel rather than healthcare, the latter of which could have run afoul of the *Canada Health Act*. See Shawn Berry, "MLA wonders why Finance Department approving MS funding" *Telegraph-Journal* (19 January 2012) A.2.

[75] Brian Owens, "End funding for liberation therapy, say New Brunswick MDs" (2013) 185:13 CMAJ E604. This story includes data indicating that between 2011-2013, 84 patients received this funding, at a total cost of $210,000.

[76] Shawn Berry, "Rescind fund for 'ineffective' MS treatment, MLA urges", *Telegraph-Journal; Saint John* (25 May 2013) A.3.

government subsidy for out-of-country liberation therapy by claiming it as a medical tax credit on their income tax return.[77]

More commonly, governments across Canada facilitated limited and controlled access to liberation therapy by way of research funding. Saskatchewan took an early and self-professed leadership role in allocating $5 million in funding for clinical trials.[78] When initial efforts to host a local trial failed for lack of appropriate applications, Saskatchewan committed $2.2 million to support Saskatchewan residents' participation in a clinical trial in Albany, New York.[79] Manitoba and Yukon also committed funding for clinical trials.[80] Rather than facilitate access through clinical trial funding, Newfoundland and Labrador and Alberta supported observational studies of individuals who received liberation therapy outside Canada ($320,000 and $1 million respectively).[81] British Columbia's Ministry of Health similarly provided $700,000 funding for a CCSVI registry intended to advance understanding about the outcomes of liberation therapy, and to help inform best practices for provision of follow-up care.[82]

The CIHR was a prominent federal actor in regulation of access to liberation therapy in Canada, using both information-based and funding instruments. CIHR is accountable to Parliament through the Minister of Health and is part of the federal government's health portfolio.[83] It operates under statutory authority pursuant to the *Canadian Institutes of Health Research Act*[84], and is designated as an agent of the Crown.[85] In 2010, CIHR collaborated with the MS Society of Canada to convene a Scientific Expert Working Group on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency (the Scientific Expert Working Group). This Scientific Expert Working Group met at least five times between 2011 – 2017 to consider the

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[77] CBC News, "MS patients claim vein therapy on taxes" (26 October 2010), online: <www.cbc.ca/news/technology/ms-patients-claim-vein-therapy-on-taxes-1.924554>. See also Tom Blackwell, "Unproven treatments get indirect subsidies; Tax credits given for foreign health procedures", *National Post* (29 November 2010) A.1.

[78] Government of Saskatchewan, "Province of Saskatchewan Slates $5 Million for MS Liberation Clinical Trials" (19 October 2010), online: <www.saskatchewan.ca/government/news-and-media/2010/october/19/province-of-saskatchewan-slates-$5-million-for-ms-liberation-clinical-trials> [Saskatchewan, "$5 Million"].

[79] Government of Saskatchewan, "Application deadline approaches for MS Clinical Trial" (7 February 2012), online: < www.saskatchewan.ca/government/news-and-media/2012/february/07/application-deadline-approaches-for-ms-clinical-trial>.

[80] Province of Manitoba, "Saskatchewan and Manitoba Partner on MS Liberation Clinical Trial Research" (5 April 2011), online: <news.gov.mb.ca/news/index.html?archive=&item=11189>; Yukon Government, "Yukon signs on to Saskatchewan's MS liberation clinical trials" (21 April 2011), online: <open.yukon.ca/data/sites/default/files/20110421YukonSignsOnToSKMSLiberationClinicalTrials.pdf>.

[81] Government of Newfoundland and Labrador, "Province to Fund Observational Study of MS Patients" (13 September 2010), online: *Health and Community Services* <www.releases.gov.nl.ca/releases/2010/health/0913n07.htm> [Newfoundland & Labrador, "Province to Fund"]; Government of Alberta, "News Release: Alberta commits to study MS Treatment" (16 December 2010), online (pdf): Government of Alberta: <www.alberta.ca/release.cfm?xID=29688F01DDE29-0DD7-1BF7-C08FCC884BD11EA0>.

[82] Vancouver Coastal Health Research Institute, "British Columbia CCSVI Registry Launched" (8 December 2011), online: <www.vchri.ca/ccsvi-news/articles/2011/12/08/british-columbia-ccsvi-registry-launched>.

[83] Canadian Institutes of Health Research, "About us", online: *Government of Canada* <cihr-irsc.gc.ca/e/37792.html>. The Health Portfolio is comprised of Health Canada, the Public Health Agency of Canada, CIHR, the Patented Medicines Review Board, and the Canadian Food Inspection Agency. See Government of Canada, "Health Portfolio", online: <www.canada.ca/en/health-canada/corporate/health-portfolio.html>.

[84] S.C. 2000, c. 6.

[85] *Canadian Institutes of Health Research Act*, SC 2000, c 6 at s 3(2).

evolving evidence on CCSVI and liberation therapy and to provide recommendations.[86] The reports from these meetings were publicly available on the CIHR website. Following its June 2011 meeting, the Scientific Expert Working Group recommended that CIHR support a Phase I/II interventional trial,[87] and CIHR ultimately funded the Traboulsee trial, discussed above.[88]

There is an interesting legislative history surrounding liberation therapy in Canada. Although each was ultimately unsuccessful, bills introduced in Parliament, the Senate, and at the provincial level in Nova Scotia, prompted considerable debate about access to liberation therapy in Canada. The nuances of these debates are discussed in greater detail in later sections of this chapter. Bill C-280, *An Act to establish a National Strategy for Chronic Cerebrospinal Venous Insufficiency (CCSVI)*[89], was a private member's bill introduced by MP, the Honourable Kirsty Duncan. Bill C-280 was unusual in several respects. Its preamble included assertions about the potential of liberation therapy as a treatment for MS, and noted what it framed as early research and positive patient results.[90] Bill C-280 sought to establish a national strategy for liberation therapy, including clinical trial planning and funding (with trials to begin by March 1, 2012), and mandating follow-up care for individuals who obtained liberation therapy outside Canada.[91] The bill was defeated at Second Reading on February 29, 2012. Companion legislation, Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*[92], was introduced to the Senate by the Honorable Senator Cordy, with similarly strong and controversial claims about liberation therapy's efficacy as a treatment for MS. Bill S-204 was referred to the Standing Senate Committee on Social Affairs, Science and Technology after Second Reading where Dr. Alain Beaudet, then President of CIHR, appeared as a witness and testified regarding the uncertain state of the evidence regarding the safety of liberation therapy.[93] The Standing Senate Committee ultimately recommended that Bill S-204 not proceed.[94]

In Nova Scotia, a private member's bill titled the *Multiple Sclerosis Patient Support Act*[95] was introduced in 2010 by the Honourable Alfie MacLeod. It required the Minister to establish a

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[86] Canadian Institutes of Health Research, "Scientific Expert Working Group" (last modified 30 March 2017), online: *Government of Canada* <cihr-irsc.gc.ca/e/44360.html>.
[87] Canadian Institutes of Health Research, "Highlights from the June 28th, 2011 CIHR Scientific Expert Working Group Meeting" (last visited 22 September 2020), online: *Government of Canada* <cihr-irsc.gc.ca/e/43952.html>.
[88] Traboulsee et al, "Safety and efficacy", *supra* note 32.
[89] 1st Sess, 41st Parl, 2011 (first reading 21 September 2011). This Bill was defeated at second reading, on February 29, 2012.
[90] Bill C-280, *An Act to establish a National Strategy for Chronic Cerebrospinal Venous Insufficiency (CCSVI),* 1st Sess, 41st Parl, 2011 (first reading 21 September 2011) at preamble [*Bill C-280*].
[91] *Ibid* at s 3.
[92] Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI),* 1st Sess, 41st Parl, 2011 (first reading 26 June 2011) [*Bill S-204*].
[93] "Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*", Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Senator Verner & Dr. Alain Beaudet).
[94] Canada, The Standing Senate Committee on Social Affairs, Science and Technology, "Fifteenth Report of the Committee", *Debates of the Senate*, 41-1 (22 November 2012).
[95] Bill 80, *An Act to Require Clinical Trials Respecting Multiple Sclerosis Liberation Therapy*, 2nd Sess, 61st Gen Ass, Nova Scotia, 2010 (first reading 2 November 2010) [*Bill 80*]. Subsequent versions of this Bill were introduced over the next two years. These included Bill 66, *An Act to Establish Clinical Trials Respecting Multiple Sclerosis Liberation Therapy and Observation of Multiple Sclerosis Patients in Receipt of Liberation Therapy*, 4th Sess, 61st Gen Ass, Nova Scotia, 2012 (first reading 27 April 2012) and Bill 70, *An Act to Require Clinical Trials Respecting Multiple Sclerosis Liberation Therapy*, 4th Sess, 61st Gen Ass, Nova Scotia, 2012 (first reading 1 May 2012). These

Multiple Sclerosis Liberation Therapy Fund to support clinical trial research into liberation therapy, and an Advisory Panel that would advise the Nova Scotia Health Research Foundation regarding an associated research proposal process. The Bill included a clause requiring that these clinical trials begin by April 30, 2011.[96] Like the federal legislation, this bill was unsuccessful. As is discussed below, concerns about mandate and the inappropriate politicization of scientific research drove opposition to all three of these pieces of proposed legislation.

To some extent, this legislative activity appears to have been prompted by advocacy efforts from individuals and groups. Although some of these actors (not including the MS Society of Canada) lack the organizational structure and formal status of other regulatory and governance actors discussed in this section, data from this case study indicates that they had some influence over decision-making regarding access to liberation therapy in Canada, including via political pressure and by disseminating information among patient communities with whom they likely held at least some credibility. Accordingly, it is important to note the involvement of these advocacy actors as part of the governance network for the purpose of this discussion.

The MS Society of Canada was particularly prominent in promoting research into liberation therapy, using its strong public presence and well-organized advocacy systems.[97] It lobbied the federal government for research funding and did its own fundraising for clinical trials.[98] Patients and their supporters also self-organized into advocacy groups of different forms and used online information-based strategies to raise awareness and garner support for liberation therapy. For example, there were regional and provincial Facebook pages that served as forums for sharing information, fundraising, advocacy, and for connecting patient communities.[99] The group CCSVI Ontario used media to, among other topics,[100] challenge representations that framed liberation therapy as being new, controversial, or dangerous, as well as characterizations that presented MS patients as "desperate".[101] Other advocacy groups, such as the MS Liberation Group, focused on fundraising and encouraging awareness to facilitate training of technicians who would be able to offer CCSVI diagnostic testing in Canada.[102] As is discussed further in

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Bills pushed back the required start date for the clinical trials to October 20, 2011 and October 30, 2012, respectively.

[96] *Bill 80*, *supra* note 95, s 7.

[97] MS Society of Canada, "About us" (last visited 27 May 2022), online: <mssociety.ca/about-us>. The MS Society of Canada is a national voluntary organization that receives some support from government but relies largely on individual, corporate, and foundation donations to provide services and fund research.

[98] In June 2010, the MS Society of Canada joined the United States National MS Society in a $2.4 million commitment for 7 studies to explore the role of CCSVI in MS. CADTH, "Update", *supra* note 74 at 2.

[99] See CCSVI Calgary (last visited 27 May 2022), online: <www.facebook.com/ccsvicalgary/>; CCSVI Ontario (last visited 27 May 2022), online: <www.facebook.com/CCSVI-Ontario-153103851427194/>; CCSVI Vancouver (last visited 27 May 2022), online: <www.facebook.com/CCSVI-VANCOUVER-111351528901644/>; CCSVI Saskatchewan (last visited 27 May 2022), online: <www.facebook.com/CCSVI-SASKATCHEWAN-120646727952155/?ref=page_internal>.

[100] Other topics included challenging concerns about risks (including death) of CCSVI, drawing on comparisons with MS drugs and deaths from MS in general. See CCSVI Ontario, "Chronic Cerebrospinal Venous Insufficiency; How dangerous is the treatment for chronic cerebrospinal venous insufficiency (CCSVI)?" (n.d.), online: Wire Service <https://www.wireservice.ca/index.php?module=News&func=display&sid=7987>.

[101] CCSVI Ontario, "CCSVI 101; CCSVI Ontario sets the record straight on the 'controversial' MS Liberation Treatment" (last visited 21 September 2020), online: *Wire Service* <www.wireservice.ca/index.php?module=News&func=display&sid=8004>.

[102] CBC News, "MS patients want access to new surgery", *CBC News* (12 April 2010), online: <www.cbc.ca/news/technology/ms-patients-want-access-to-new-surgery-1.898359>. See also MS Kick for the Cure,

Section 6.2.3, these diverse advocacy efforts appear to have resonated with different regulatory and governance actors in their decision-making regarding access to liberation therapy.

Finally, there were three notable issues about which courts and tribunals across Canada exerted influence over access to liberation therapy in Canada via their role in interpreting and applying the law. These issues included funding claims for out-of-country medical expenses, claims of discrimination, and allegations of professional misconduct. Provincial and territorial legislation provides the authority for medical funding decisions under publicly funded health insurance systems in Canada, including regarding out-of-country medical expenses. There is a small body of case law where decisions to deny provincial funding requests for out-of-country liberation therapy were tested and upheld upon review.[103] For example, *F.D.E. v Ontario Health Insurance Plan (General Manager)*[104] was an appeal from a decision of the Ontario Health Services Appeal and Review Board (ON HSARB). The ON HSARB denied the applicant's appeal of F.D.E.'s request for reimbursement of out-of-country medical services for liberation therapy received in Bulgaria and related testing received in California. The ON HSARB confirmed these expenses were not insured services eligible for reimbursement pursuant to the *Health Insurance Act* because they had not been "shown to be medically necessary for a person in the Appellant's medical circumstances", were considered to be "experimental by Ontario's standards for a person in the Appellant's medical circumstances", and were not "shown to be generally accepted treatment by Ontario standards for a patient in the Appellant's medical circumstances".[105] This decision confirmed that the words "generally accepted" in the context of this legislative scheme "means approval of the treatment by the medical community in Ontario", and that in such cases, the Applicant bears the onus of establishing that fact on a balance of probabilities.[106]

There are also cases confirming that denial of access to screening and treatment for CCSVI did not constitute discrimination pursuant to provincial human rights legislation, because it was an experimental treatment.[107] These cases are noteworthy given that allegations of discrimination were made in the Senate debates around Bill S-204.[108] For example, in a 2010 British Columbia Human Rights Tribunal decision, the complainant alleged that he was discriminated against by the province of British Columbia, as represented by the Ministry of the Health, the Medical Services Commission, the College of Physicians and Surgeons of British Columbia, and the Vancouver Island Health Authority, when he was denied screening and

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"CCSVI" (last visited 27 May 2022), online: <www.mskickforthecure.com/ccsvi.php>. The latter had a dedicated section on its webpage for CCSVI that framed CCSVI with positive patient testimonials about Liberation Therapy.

[103] See *D.G. v. Ontario Health Insurance Plan (General Manager)*, 2011 CanLII 40455 (HSARB); see also *J.B. v. Ontario Health Insurance Plan (General Manager)*, 2011 CanLII 71987 (HSARB) and *J.B. v. Ontario Health Insurance Plan (General Manager)*, 2012 CanLII 19918 (HSARB); see also *S.W. v. Ontario Health Insurance Plan (General Manager)*, 2013 CanLII 52880 (HSARB).

[104] 2011 CanLII 101469.

[105] *Ibid* at para 14.

[106] *Ibid* at para 43.

[107] *Borowska-Machala obo others v. B.C. (Ministry of Health Services and Medical Services Commission) and others*, 2012 BCHRT 402; *Butcher v. Ontario (Minister of Health and Long Term Care)*, [2013] OHRTD No. 1329, 2013 HRTO 1327 [*Butcher*].

[108] For example, see Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Senator Cordy); see also Senate of Canada, 42-1, vol 150, Issue 14 (28 September 2011) at 1550 (Hon. Jane Cordy).

diagnostic services for CCSVI and liberation therapy, when angioplasty is otherwise routinely provided and funded by British Columbia's Medical Services Plan. The Human Rights Tribunal dismissed the complaint, finding that he was denied liberation therapy because it was an unauthorized experimental treatment, not because of his MS.[109]

As already discussed, it seems there were few instances of physicians providing liberation therapy in Canada outside of approved research contexts, and thus professional disciplinary decisions did not feature prominently in my data. However, there is one notable decision which is particularly interesting because it bridges this case study with that of unproven stem cell interventions (Chapter 7) and speaks to professional obligations with respect to providing unproven medical interventions. In *Krause (Re)*[110], Dr. Krause was charged with professional misconduct, displaying a lack of knowledge, skill, or judgment in the practice of medicine, and demonstrating unfitness to practice medicine. These charges flowed from her participation in what was represented to be a clinical research study where individuals suffering from MS, ALS, and other neurological conditions were treated using a "combined treatment protocol" that involved liberation therapy as well as stem cell injections at a clinic in Pune, India. Patients paid fees as high as $45,000.00 USD to participate in this "research". The discipline review panel of the Manitoba College of Physicians and Surgeons found that Dr. Krause had both personal and financial conflicts of interests that conflicted with her patients' interests and demonstrated an incapacity or unfitness to practice medicine.[111] The facts of this particular case were somewhat exceptional,[112] but key aspects of the decision are important from a governance perspective. The disciplinary review panel emphasized that physicians must be "mindful of the distinction between therapy and treatment on the one hand and research and study on the other hand", and of the standards regarding conflicts of interest and providing non-traditional therapies.[113]

Overall, the jurisprudence addressing liberation therapy access issues (albeit limited) reflected a more measured approach to the topic than I observed in other realms, including legislative and parliamentary arenas. Courts and tribunals that considered liberation therapy in different contexts focused largely on the experimental nature of this technology when determining questions of access. Judicial independence may have provided the courts with some protection from the forces of public pressure that otherwise appeared to have been fairly impactful on decision-making with respect to liberation therapy in Canada. This finding arguably reflects a form of technological neutrality, where a legal system "treats different technologies fairly and is resistant to difficulties associated with technological change".[114] When utilized, this type of approach leaves courts in Canada's common law system well placed to provide an

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[109] *Turnbull, supra* note 46 at para 86.
[110] 2019 LNMBCPS 1 [*Krause*].
[111] *Ibid* at paras 2-4, 10, 15. Dr. Krause pled guilty to additional charges.
[112] Dr. Krause had had an intimate relationship with the individual at the head of the clinic and behind the study, provided him with significant personal funds as an investment, and became increasingly involved over time with patient recruitment and promotion of the clinical trial.
[113] *Krause, supra* note 110 at paras 51-52.
[114] Lyria Bennett Moses, "Recurring Dilemmas: The Law's Race to Keep Up with Technological Change" (2007) 7 University Illinois JL Technology & Policy 239 at 244 & 270. Moses distinguishes this systems-level conception of technological neutrality with narrower versions that focus on technology-neutral statutory drafting. The broader approach considers the role of courts, administrative agencies, and law reform bodies in "helping law adapt to technological change" (at 285).

important role in providing predictability and stability in areas that are evolving quickly, such as is often the case with new medical interventions. As highlighted by the related discussions in chapters 5 and 7 about the roles that courts and tribunals played with respect to access to chelation therapy and unproven stem cell interventions, liberation therapy was not unique in the broader issues it raised in this domain, including how different forms of evidence were evaluated and utilized to inform decisions about access.

6.2.2 Clarity of Purpose

As discussed in Chapter 5, exploring goals or purposes is a helpful first step in evaluating regulation and governance and, in particular, questions of fit with instruments used, as well as effectiveness in achieving desired outcomes.[115] I identified two primary goals that appeared to drive much of the regulatory and governance activity surrounding liberation therapy in Canada. The first goal can be described broadly as protection and promotion of health; the second related though sometimes conflicting goal can be characterized as facilitating rapid access to the intervention. There were three particularly notable priorities or imperatives operating within the broader goal of protecting and promoting health. They included: (i) an emphasis on evidence and high-quality research to support evidence-informed decision-making, (ii) risk identification and mitigation or avoidance, and (iii) an emphasis on political capital, primarily in the form of leadership. The latter priority of political capital also crossed over to underpin regulatory and governance efforts to facilitate rapid access. To a large extent, these priorities or imperatives were features of how regulation and governance activities and decisions regarding access to liberation therapy in Canada were approached (e.g. use of evidence), and the motivations that accompanied these activities (e.g. gaining political capital among potential voters).

Evidence-informed or evidence-based decision-making is often highlighted within governments' regulatory strategies in Canada and can play a role in strengthening or reinforcing regulatory and governance legitimacy, but it is not an uncomplicated concept.[116] As discussed in Chapter 5, and as will be addressed as a theme cutting through the remainder of this thesis, there are important questions to be considered about how evidence is constructed, interpreted, and applied in regulation and governance of access to unproven medical interventions, including by different actors and in different contexts. Like the chelation therapy and unproven stem cell intervention case studies, the data in this case study reflect varied forms of information or 'evidence' that appear to have influenced regulatory and governance approaches to access including, but not limited to, individual anecdotes, expert opinion, observational studies, and

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[115] See Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 11; see also Karen Yeung, "Towards an Understanding of Regulation by Design" in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 79 at 91.

[116] See e.g. Government of Canada, "Government priorities for coming year to strengthen science in Canada" (27 June 2018), online: <www.canada.ca/en/innovation-science-economic-development/news/2018/06/government-priorities-for-coming-year-to-strengthen-science-in-canada.html>; Public Health Agency of Canada, "Evidence-Informed Decision-Making: Information and Tools" (25 July 2014), online: *Government of Canada* <cbpp-pcpe.phac-aspc.gc.ca/resources/evidence-informed-decision-making-information-and-tools/>. It is beyond the scope of this work to discuss the potential differences between evidence-based and evidence-informed decision-making, or the complexities involved in use of evidence in public decision-making contexts. See e.g. Brian Head, "Toward More 'Evidence-Informed' Policy Making?" (2015) 76:3 Public Administration Rev 472. For the purpose of this work, I will use these terms interchangeably.

double-blind placebo-controlled clinical trials. However, there was often a corresponding lack of nuance in how different sources (with their varied strengths and limitations) were presented and used to inform decision-making, which raises questions about the corresponding impact on the robustness and credibility of those processes, as discussed further below.

The priority or imperative of evidence-informed decision-making was particularly prominent in government debates and communications regarding access to liberation therapy in Canada, generally in association with the broader goal of protecting and promoting health.[117] As an example, Alberta's Minister of Health and Wellness, the Honourable Gene Zwozdesky, said the following about the province's observational study: "Our government is committed to help build the body of evidence that will provide a clear indication, one way or the other, about the safety and effectiveness of this new treatment. This study is an important step in that process".[118] Similarly, British Columbia's Minister of Health, the Honourable K. Falcon, acknowledged the "understandable sense of urgency" to give hope to MS sufferers, but stressed government's responsibility to ensure people are not exposed to experimental procedures that may harm or put them at risk before there is a "foundation of some clinical evidence and support".[119] The 2010 Saskatchewan Speech from the Throne described Saskatchewan's funding for clinical trials as intended to help give MS patients "the best answers science can provide".[120] Other key governance actors including national and provincial administrative agencies (CADTH, CIHI, INESS, OHTAC), professional actors (including colleges of physicians and surgeons), and courts and tribunals, also shared the goal or objective of prioritizing evidence-informed decisions regarding access to liberation therapy. For example, CADTH and the CIHR Expert Scientific Working Group consistently noted the need for caution and rigorous study to better understand CCSVI, any connection it may have to MS, and the safety and efficacy of liberation therapy.[121] The information-based instruments used by these actors were consistent with this goal.

The pursuit of evidence and research knowledge to inform decision-making as a rationale or imperative for regulatory actions was often linked with the narrower priority of understanding and mitigating risk to patients. This finding is consistent with regulatory scholarship that identifies management, control, or reduction of risk as a common purpose of regulation.[122] It is also consistent with the federal government's position that managing risk is a central part of its role as regulator.[123] Perhaps unsurprisingly then, the desire to control (avoid or mitigate) the potential risks of liberation therapy for individuals was a consistent theme in the different

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[117] See e.g. Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (24 November 2010) at 3971 (Hon. Jamie Baillie). The goal of gathering strong scientific evidence to make informed decisions was presented as a reason to support Nova Scotia's proposed legislation and the clinical trials it sought to mandate.
[118] Government of Alberta, *supra* note 81.
[119] British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5919 (Hon. K. Falcon).
[120] Saskatchewan, *Journals of the Legislative Assembly*, 26-4 (27 October 2010) at 5675.
[121] See e,g. CIHR, "Summary Report August 26, 2010", *supra* note 19 at 2.
[122] See e.g. Baldwin & Cave, *supra* note 73 at 138. See also Fiona Haines, "Regulation and Risk" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 181.
[123] Minister of Health of Canada, "Strategic Risk Communications Framework; For Health Canada and the Public Health Agency of Canada" (2006), online (pdf): <www.canada.ca/content/dam/hc-sc/migration/hc-sc/ahc-asc/alt_formats/pacrb-dgapcr/pdf/pubs/ris/ris-comm-eng.pdf>.

regulatory and governance activities explored in this case study.[124] For example, the AHS Statement on Venous Imaging and Venous Angioplasty in Multiple Sclerosis emphasized that, "[t]he nature and frequency of the risks on venous angioplasty are not yet fully understood. Without a clear indication that venous angioplasty carries a clinical benefit that outweighs the risks, it cannot yet be supported as standard practice".[125] Alberta's corresponding position on clinical trials was that they would be supported only "if and when it is safe and ethical to proceed", and that its observational study was intended to help identify risks of liberation therapy and determine if it was safe.[126]

On the whole, regulatory and governance actors' use of information-based instruments that identified liberation therapy as being experimental and thus not appropriate for routine clinical use, as well as funding-based strategies to advance research, served the purpose of supporting evidence-informed decision-making as well as, to some degree, risk management. There were interesting parallels in how the need for evidence was used as a rationale in favour of public funds to support clinical research into both liberation therapy and chelation therapy (discussed in Chapter 5). However, as is discussed below, the apparently large numbers of Canadians who sought liberation therapy in other jurisdictions, as with those who pursued chelation therapy, may suggest that more could have been done with public-facing communication strategies to identify relevant risks in both cases.

It is important to note that the emphasis on the need for research to support evidence-based decision-making about liberation therapy, including regarding risk management, was not universally shared among regulatory and governance actors. Several governance actors, including some patients and advocacy groups, appeared to operate with the goal of facilitating rapid access to testing and treatment for CCSVI, without a corresponding emphasis on whether there was or was not sufficient evidence of safety or efficacy to support the use of liberation therapy. The ways in which some of these actors used information-based approaches and advocacy including via political forums was coherent with the goal of facilitating rapid access, but ran counter to other actors' prioritization of evidence.

For example, there were notable tensions in legislative debates between evidence-based imperatives and the goal of facilitating rapid access to this intervention. Although prioritizing rapid access would not necessarily be mutually exclusive from a focus on the need for evidence, or an emphasis on risk mitigation, in this case study these priorities generally appeared to be quite distinct. In some jurisdictions, there was a notable pattern where members of the opposition spoke in favour of advancing rapid access to liberation therapy, while government members (often represented by the Minister of Health), adopted a more cautionary approach with an

[124] See e.g. British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5918 (Hon. Adrian Dix). Dix emphasized that while providing MS sufferers with hope is important, "at least minimum research" is necessary to avoid unnecessary harm and risk.
[125] Alberta Health Services, "Statement on Venous Imaging", *supra* note 21.
[126] Government of Alberta, *supra* note 81.

emphasis on the need for scientific evidence.[127] The following Hansard excerpt from Newfoundland and Labrador is one example of these types of exchanges[128]:

> [Ms. Jones, Honourable Leader of the Opposition] Many people who have MS are now speaking out on this issue, Mr. Speaker, because they want to have access to the test for CCSVI… Why are patients and their family being denied access…
>
> [Mr. Kennedy, Honourable Minister of Health and Community Services]: … As a government, Mr. Speaker, we are committed to providing the best quality health care we can … However, we are dealing with science and when science accepts that certain procedures are worthwhile we will certainly look at that. It is my understanding, from the reading I did yesterday, Mr. Speaker, that this procedure is still questionable as to whether or not it actually works and will achieve the purpose that was originally thought. So, we will monitor this very closely. My officials are watching it, and I can assure, Mr. Speaker, the Leader of the Opposition and MS patients in this Province that anything that we can do to alleviate their condition and help their condition we certainly will, but again, it has to be based on science and research. [129]

There were similar tensions found in the Standing Senate Committee's discussion about Bill S-204, where in the face of support for the Bill, other Senators emphasized the need for evidence to inform action.[130] For example, Senator Raynell Andreychuk suggested that a focus on evidence is part of the strength and legitimacy of Canada's publicly funded healthcare system which, in her words, "does not react impulsively every time a new treatment comes onto the market".[131]

The lack of consensus regarding regulatory goals and imperatives reflected in government debates is unsurprising in that political context, where parties often take different positions on issues. However, more importantly for this research, it may also be connected to the third priority or imperative that appears to have motivated some elected officials, which was a desire for political capital, particularly in the form of being recognized as a leader with respect to advancing liberation therapy. In other words, some government actors appear to have been motivated by efforts to curry political favour with constituents by responding favourably to demands for access, which appear to generally have been motivated by the underlying assumption that liberation therapy would provide benefits and thus improve the health of MS

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[127] These divisions were noted between government representatives and members of the opposition, regardless of specific party lines. An exchange between Alberta's Minister of Health Gene Zwozdesky and MLA Ken Allred serves as another illustrative example - see Alberta, *Journals of the Legislative Assembly*, 27-3 (2 November 2010) at 1061-1062 (Hon. Ken Allred & Hon. Gene Zwozdesky). See also Ontario, *Journals of the Legislative Assembly*, 39-2 (1 March 2011) (Hon. Deborah Matthews). Then Minister of Health and Long-Term Care Deborah Matthews explained that Ontario would not advocate for or fund Liberation Therapy without proof of efficacy. Saskatchewan was an exception to this pattern, with its strong government support for advancing clinical trials.

[128] See e.g. Manitoba, *Journals of the Legislative Assembly*, 39-4 (11 May 3010) (Mrs. Driedger & Hon. Theresa Oswald); see also Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (24 November 2010) at 3973 (Hon. Maureen MacDonald).

[129] Newfoundland & Labrador, *Journals of the Legislative Assembly*, 46-3, vol XLVI, No 26 (25 May 2010).

[130] See e.g. Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Senator Seidman). Senator Seidman stressed the importance of "rigorous scientific procedure" to ensure safety.

[131] *Debates of the Senate*, 41-1, vol 150, Issue 39 (8 December 2011) (Hon. Raynell Andreychuk).

sufferers. There were again notable parallels here with the chelation therapy case study, where an emphasis on leadership via facilitating access was also expressed by some political actors.

With liberation therapy, early and decisive government action to fund clinical trials was framed by some actors as a laudable demonstration of leadership. For example, the Saskatchewan Hansard record reflects descriptions such as "courage", "fortitude", "bold step", and "leadership" to describe Saskatchewan as "the first of its kind to fund clinical trials of MS liberation procedure".[132] In other instances where governments took more cautious approaches, some opposition members characterized that caution as demonstrating a lack of leadership. For example, the Honourable Carolyn Bennet spoke in favour of Bill C-280 and suggested the need for it was "a total failure" of federal leadership.[133] The use of leadership (or lack thereof) as a form of critique of government restraint also appeared in legislative debates. For example, Alberta MLA, the Honourable Kevin Taft asked the Minister to "show some leadership and commit to providing the necessary funding and urge the fast-tracking of clinical trials".[134] Interestingly, I did not find instances where leadership was used in a similar way to encourage or support approaches that prioritized risk management or mitigation. In this way, it seems that with respect to access to liberation therapy in Canada, political narratives of leadership were most closely connected with pro-access approaches. On the whole, regulatory and governance actors in this case study operated with fairly clear goals, using instruments that were largely coherent with those goals and associated priorities. However, the potential conflict between the goals of protecting health and of facilitating access, layered with the pursuit of political capital, made for complex and sometimes inconsistent decision-making contexts, discussed further in the next section.

6.2.3 Legitimacy

The process by which regulatory and governance decisions are made is a critical element of their quality and legitimacy. In this case study, I identified procedural questions about the influence of advocacy and the role of public engagement, as well as related challenges to legitimacy including issues of mandate, expertise, and conflicts of interest.

One of the most striking features in this case study data was the extent and reach of public and patient advocacy directed towards decision-makers, and their prominence within government debates. The Chair of the MS Society of Canada's Board of Directors spoke about its intention to lobby the federal government for $10 million in research funding into the link between CCSVI and MS, saying, "The MS community has spoken. They want access to diagnostics and treatment for CCSVI in Canada".[135] Patient rallies took place across the country,

[132] Saskatchewan, *Journals of the Legislative Assembly*, 26-4 (1 November 2010) at 5718 (Mr. Wyant). For a similar example, see Saskatchewan, *Journals of the Legislative Assembly*, 26-4 (8 November 2010) at 5877 (Hon. Ms. Eagles) where Ms. Eagles reported on positive feedback from her constituency, noting Saskatchewan's "true leadership" in this area.
[133] *House of Commons Debates*, 41-1, vol 146, No 081 (15 February 2012) (Hon. Carolyn Bennett).
[134] Alberta, *Journals of the Legislative Assembly*, 27-3 (17 November 2010) at 1259 (Hon. Kevin Taft). Manitoba's approach was similarly described as a "lack of leadership around MS", see Manitoba, *Journals of the Legislative Assembly*, 39-4 (11 May 2010) (Hon. Mrs. Driedger).
[135] Melissa Martin, "MS Society endorses new theory", *Winnipeg Free Press* (6 May 2010) A.10.

including at provincial legislatures.[136] In Saskatchewan, this advocacy activity prompted questions from an MLA to the Minister of Health about "when can Saskatchewan MS patients expect to be able to access the liberation procedure?"[137] There are also many examples in Hansard records of patient stories being shared by members of the assemblies, with the apparent goal of driving access, whether via research funding or in treatment contexts. In some cases, elected members presented patient stories from their constituents.[138] In other instances, members of the public were guests of the assembly and advocated directly for access to liberation therapy.[139] On other occasions, elected officials spoke to their own personal experiences with MS and liberation therapy. For example, the Honourable Malcolm Allen shared his father's struggles with MS when supporting Bill C-280, and framed the legislation as a way to give hope and a chance to MS sufferers and their families.[140] Some elected members presented Resolutions to their assemblies containing individual patient stories, urging government to provide access (e.g. via clinical trial funding).[141] There were also numerous petitions brought to governments across Canada seeking access to liberation therapy and funding for clinical trials.[142] For example, the following petition was presented in 2010 to the NS legislative assembly and garnered 10,283 signatures: "This is a petition to ask the Provincial Government to make available angioplasty to repair blood flow problems (CCSVI) for Multiple Sclerosis (MS) Sufferers in Nova Scotia".[143] Although I found many examples of individual liberation therapy 'success' stories introduced to legislative assemblies, there was a dearth of corresponding presentations from medical or research communities speaking to questions or concerns about the purported treatment.

Many of these advocacy efforts involved the use of individual anecdotes which appear to have been accepted as a form of evidence in decision-making regarding regulation and

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[136] See e.g. Alberta, *Journals of the Legislative Assembly*, 27-3 (16 November 2010) at 1208 (Hon. Brian Mason); see also CTV Calgary, "MS patients want access to experimental treatment", *CTV News* (9 April 2010), online: <calgary.ctvnews.ca/ms-patients-want-access-to-experimental-treatment-1.500647>; see also Radhika Panjwani, "MS rally demands treatment", *Brampton Guardian* (5 May 2010), online: < www.bramptonguardian.com/news-story/3074957-ms-rally-demands-treatment/>; see also Melissa Martin, "MS Society endorses new theory", *Winnipeg Free Press* (6 May 2010) A.10.

[137] Saskatchewan, *Journals of the Legislative Assembly*, 26-3 (10 May 2010) at 5431 (Hon. Ms. Junor).

[138] *House of Commons Debates*, 41-1, vol 146, No 63 (8 December 2011) at 1839 (Hon. Kirsty Duncan).

[139] See e.g. Alberta, *Journals of the Legislative Assembly*, 27-3 (27 October 2010) at 970 (Hon. Brian Mason). There are more than eleven such instances found in Alberta Hansard records from 2010 alone. Similar examples were found through 2011 – 2013 as well, and in other provinces and territories. See e.g. British Columbia, *Journals of the Legislative Assembly*, *Select Standing Committee on Finance and Government Services*, 39-2, (22 September 2010) at 1135 (Hon. Sherry McLeod).

[140] *House of Commons Debates*, 41-1, vol 146, No 081 (15 February 2012) (Hon. Malcolm Allen).

[141] See e.g. Manitoba, *Journals of the Legislative Assembly*, 39-5 (2 December 2010) at 76-77 (Hon. Myrna Driedger). This Resolution concluded with the following: "THEREFORE BE IT RESOLVED that the Legislative Assembly of Manitoba urge the Provincial Government to consider making Manitoba a leader in CCSVI research and to move forward with clinical trials as soon as possible"; See also Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (2 November 2010) at 2817-2818 (Hon. Chuck Porter). This is but one example of ten similar resolutions presented on the same day, each by different members.

[142] See e.g. Alberta, *Journals of the Legislative Assembly*, 27-4 (2 March 2011) at 152 (Hon. Kent Hehr); see also Ontario, *Journals of the Legislative Assembly*, 39-2 (22 September 2010) (Hon. Howard Hampton). Over forty petitions were presented to the Ontario legislature between 2010-2012, all seeking funding for and access to Liberation Therapy, or clinical trials, or both. See also Manitoba, *Journals of the Legislative Assembly*, 39-5 (17 November 2010) (Hon. Rick Borotsik). This example is one of many of the same petitions presented throughout the 5th session.

[143] Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (2 November 2010) at 2803 (Hon. Alfie MacLeod).

governance of access to liberation therapy or, at the very least, as having had an influence on those processes. For example, Minister of Health, the Honourable Leona Aglukkaq indicated that the federal government's decision to support Phase I/II trials was motivated in part by "'moving' anecdotal evidence from MS patients and their families".[144] The Alberta government's news release regarding its funding for an observational research study indicated that the "study is a response to the remarkable interest amongst MS patients in the new MS treatment proposed by Dr. Zamboni".[145] When discussing New Brunswick's funding for individuals to receive liberation therapy in other jurisdictions, Premier David Alward noted having received emails urging him to provide this funding,[146] and said that: "What continues to buoy my sense that this is the right thing to do is when you meet people like Tim [an MS sufferer who received liberation therapy in New York] or the others who have received the positive benefits".[147]

As outlined in my conceptual framework (Chapter 2, Table 1), the influences that shape or impact decision-making, including considerations of expertise, evidence, political priorities, and advocacy, are important elements in understanding and evaluating the credibility and legitimacy of regulation and governance actors and their activities. However, it seems reasonable to suggest that in order for the use of evidence to be a strength in decision-making processes, there must be an assessment of what different sources and types of 'evidence' offer, along with their respective limitations. For example, the individual anecdotes relied on by some actors in this case study may have provided useful insights into the lived experiences of some patients and their disease-management priorities, but arguably were not sufficient to evaluate the effectiveness or potential risks of liberation therapy. As such, it remains a matter of debate whether reliance on anecdote and related forms of information can be claimed to advance evidence-based or evidence-informed decision-making priorities when it comes to decisions regarding access to unproven medical interventions.

Along with being considered by some as a type of evidence or relevant information for decisions about access, it could also be argued that patient advocacy is a form of public engagement. Public engagement can be an element of good governance in situations of uncertain risk, insofar as it can enhance legitimacy and encourage public trust.[148] It has similarly been identified in regulatory scholarship as an appropriate part of the regulatory process, particularly where – as was the case here – there is uncertainty and some different perspectives regarding questions of risk.[149] However, advocacy alone is not a robust or procedurally sound mechanism for public or patient engagement, or stakeholder consultation, in part because it can exclude

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[144] Wayne Kondro, "CIHR to develop therapeutic clinical trial of liberation therapy for multiple sclerosis" (2011) 183:12 CMAJ E793.
[145] Government of Alberta, *supra* note 81.
[146] Kevin Bisset, "Expert says New Brunswick's MS 'liberation' fund has political motives" *The Globe and Mail* (5 December 2010), online: <login.libproxy.uregina.ca:8443/login?url=https://www.proquest.com/docview/2385131487?accountid=13480>.
[147] Kevin Bissett, "MS patients who had liberation therapy call on Canada, provinces to support it", *The Canadian Press* (5 May 2011), online: <login.libproxy.uregina.ca:8443/login?url=https://www.proquest.com/docview/865135917?accountid=13480>.
[148] Shawn HE Harmon, Graeme Laurie & Gill Haddow, "Governing risk, engaging publics and engendering trust: New horizons for law and social science?" (2013) 40:1 Science & Public Policy 25 at 26.
[149] Ortwin Renn, "Stakeholder and Public Involvement in Risk Governance" (2015) 6 Intl J Disaster Risk Science 8; see also Roger Brownsword, "Responsible Regulation: Prudence, Precaution and Stewardship" (2011) 62 N Ir Leg Q 573.

important perspectives from those who lack political access. If only select perspectives are accounted for in a decision-making process, the resulting regulation or governance initiatives can be subject to criticisms that they are exclusionary or lack political legitimacy.[150] In this case, I found no evidence to suggest that the advocacy which occurred was intentionally permitted and considered by decision-makers as a form of "engagement", or with consideration given to matters of equity or representation in terms of whose voices and perspectives were heard, and whose may have been missing. These limitations likely weaken any claim that this form of engagement served to strengthen or lend legitimacy to the associated regulatory and governance activities.

Jurisdiction and mandate are other important elements of regulatory and governance legitimacy. Jurisdiction in this sense most commonly refers to legal authority, whereas mandate can capture broader elements of roles and responsibilities. Some of the debates surrounding Bills C-280 and S-204 focused on whether it was appropriate for government to legislate research priorities and encroach on independent scientific decision-making processes. For example, the Honourable Colin Carrie expressed concern about politicians "trying to legislate scientific research" and suggested "it is a very dangerous precedent for politicians to start trying to force research and science by politicizing this issue".[151] Senator Raynell Andreychuk similarly suggested that Bill S-204 fell outside the purview of the Senate by going beyond its scope and legislative mandate, and risked setting a precedent for "politicizing the process through which scientific experts set Canada's health research priorities".[152] Senator Andreychuk cited Chief Justice Dickson in *Fraser v. P.S.S.R.B.*[153], as support for her concern that Bill S-204 overstepped the legislature's law-making authority by attempting to engage in policy administration and implementation, which fall to the executive branch of government.[154] In its final report on Bill S-204, the Standing Senate Committee concluded that: "in regards to CCSVI, MS, and health matters generally, the best path forward should be determined by science and medicine, not by Parliament".[155] Had Bill C-280 or S-204 been successful, there may also have been fertile grounds for a constitutional argument that regulating medical testing and follow-up care, as these bills purported to do, would have been *ultra vires* the federal government's jurisdiction, as matters falling within provincial authority over the regulation of medical practice.

A related aspect of legitimacy is the degree to which regulatory and governance actors have, or are perceived to have, the necessary or appropriate expertise to make decisions in a particular area. In this case, the CIHR Scientific Expert Working Group faced challenges of legitimacy related to alleged deficiencies in relevant expertise, because its members did not include individuals with experience providing liberation therapy or other proponents of CCSVI-related work. For example, the Honourable Kirsty Duncan expressed the following critique in parliamentary debate: "It was an expert group with no experts in the imaging and treatment of

[150] Albert Weale, "New Modes of Governance, Political Accountability and Public Reason" (2011) 46:1 Government & Opposition 58 at 62.
[151] *House of Commons Debates*, 41-1, vol 146, No 63 (8 December 2011) at 1845 (Hon. Colin Carrie). See also, Canada, 41-1, vol 146, No 081 (15 February 2012) (Hon. Joy Smith).
[152] Senate of Canada, 42-1, vol 150, Issue 14 (28 September 2011) at 1549 (Hon. Jane Cordy).
[153] [1985] 2 SCR 455.
[154] Senate of Canada, 41-1, vol 150, Issue 39 (8 December 2011) at 1610 (Hon. A. Raynell Andreychuk).
[155] Canada, The Standing Senate Committee on Social Affairs, Science and Technology, "Fifteenth Report of the Committee", Debates of the Senate, 41-1 (22 November 2012).

CCSVI".[156] Similar, albeit more vehement, criticisms were also levied toward the work of this group by advocacy organizations including the CCSVI Society of Alberta.[157] Others suggested there was insufficient public representation in this body.[158] Dr. Alain Beaudet, CIHR President and Chair of the Scientific Expert Working Group, indicated that the decision to exclude liberation therapy providers, anyone vocally opposed to the procedure, and clinicians who were not researchers was intended to help facilitate a frank and unbiased discussion.[159] Accordingly, criticisms notwithstanding, decisions about the group's composition and processes appear to have been made deliberately with the goal of strengthening the legitimacy of the group's decisions. In this manner, Dr. Beaudet's comments reflect a recognized tension in regulation between expertise and detachment.[160]

The extent to which members of parliament and legislative assemblies appear to have relied on media sources for their information about liberation therapy also raises questions related to legitimacy. Hansard records include examples of elected officials referring to information presented in media stories as part of their rationale for driving the liberation therapy access agenda forward.[161] For example, Nova Scotia MLA, the Honourable Alfie MacLeod pointed to comments made by Dr. Zamboni in a *Globe and Mail* article, saying "His point, Mr. Speaker, is well taken, and I find it difficult to understand or accept why governments in Canada cannot seem to understand the need to move forward on this potentially life-saving medical issue in a much faster fashion".[162] The perception that news and social media helped advance access to liberation therapy in Canada is widespread. For example, Dr. Diaz-Mitoma, Vice-President of research at Sudbury Regional Hospital, was quoted in one media article as follows: "The real reason we're doing clinical trials in Canada is that patients got involved. Social media has been a real influence".[163] It is beyond the scope of this research to explore the extent of media influence on individual or institutional actors.[164] However, when elected officials appear to use media stories as sources of evidence in parliamentary debates, questions of legitimacy arise regarding the quality of information being used to inform legislative activity.

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[156] *House of Commons Debates*, 41-1, vol 146, No 63 (8 December 2011) at 1839 (Hon. Kirsty Duncan).

[157] Anonymous, Press Release, "The Chronic Cerebrospinal Venous Insufficiency (CCSVI) Society of Alberta Challenges MP Colin Carrie's refusal to support Bill C-280, a national strategy for CCSVI" (last visited 6 October 2020), online: *Wire Service* <https://www.wireservice.ca>.

[158] Andreas Laupacis & Arthur Slutsky, "Endovascular treatment for multiple sclerosis: The intersection of science, policy and the public" (2010) 4:4 Open Medicine E197.

[159] Kingston, *supra* note 46.

[160] See Roger Brownsword, "So What Does the World Need Now? Reflections on Regulating Technologies, in Roger Brownsword & Karen Yeung, eds, *Regulating Technologies; Legal Futures, Regulatory Frames and Technological Fixes* (Portland, OR: Hart Publishing, 2008) 23 at 37.

[161] See e.g. Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Hon. Kirsty Duncan). Duncan referenced "MS Wars" which aired on the Nature of Things, and an article by journalist Anne Kingston.

[162] Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (24 November 2010) at 3979 (Hon. Alfie MacLeod).

[163] Poliakov, *supra* note 52.

[164] There is an established body of literature exploring the potential power of media framing in setting agendas. See e.g. Dietram Scheufele & David Tewksbury, "Framing, Agenda Setting, and Priming: The Evolution of Three Media Effects Models" (2007) 57 J Communication 9.

Governments also faced criticism that their access decisions were politically motivated, in that they were responding to pressure rather than being guided by science or medical expertise.[165] Interestingly, this criticism followed both decisions to facilitate access and to limit or restrict it. For example, critics of New Brunswick's funding program argued it was "rooted in politics rather than science",[166] while the Honourable Kirsty Duncan suggested that the federal debate around liberation therapy, "was never based on the science it should have been, but rather wilful blindness, medical politics and collusion with special interest groups".[167] Building on the discussion above regarding how evidence is constructed and used in regulatory and governance processes, these credibility challenges demonstrate the potential malleability with which ideas about "science" and "evidence" can be used in support of very different priorities or agendas.

Related threats to regulatory and governance legitimacy can include concerns about conflicts of interest and lack of transparency in decision-making processes. In this case study, concerns of this nature appear to have been fairly limited in number and, in at least some instances, stemmed from sources strongly committed to advancing liberation therapy. For example, the head of the Reformed Multiple Sclerosis Society questioned the legitimacy of CIHR's Expert Scientific Working Group's initial recommendation not to fund clinical trials, suggesting individual conflicts of interest inappropriately swayed members of the group.[168] In an open letter to Alberta's Minister of Health, Dr. Ashton Embry (President and Research Director of Direct-MS, a charity focused on diet research into the cause and treatment of MS) criticized the AHS position statement, suggesting potential conflicts of interest.[169] There were also reports of strong criticism and other forms of backlash targeted at individual neurologists in Canada who did not support liberation therapy. In one news story, several neurologists shared what they described as unprecedented patient mobilization, including angry letters and phone calls, patients leaving their practices and online "vitriol" alleging conspiracies and arrogance.[170] When regulatory and governance actors' legitimacy is challenged due to perceived conflicts of interest or lack of transparency, it is reasonable to anticipate that their influence will be diminished for at least some groups or individuals.

6.2.4 Responsiveness and adaptability

Responsiveness and adaptability are characteristics of strong regulation and governance when they facilitate approaches that adjust to new developments and respond to changes in

[165] See e.g. Tom Blackwell, "Liberals blast Tories over MS treatment; Doctors divided; Do more to probe controversial new theory" *National Post* (5 January 2011) A.6.
[166] Bisset, *supra* note 146.
[167] Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Hon. Kirsty Duncan).
[168] Anonymous, "MS Activist Group Slams Ottawa for CCSVI Clinical Trial Rejection" *Marketwire; Toronto* (7 September 2010), online: <login.libproxy.uregina.ca:8443/login?url=https://www.proquest.com/docview/749695947?accountid=13480>.
[169] Ashton Embry, "Honourable Gene Zwozdesky, Alberta Minister of Health Regarding the August 6, 2010, Alberta Health Services Report on MS and CCSVI" (2010), online: <www.direct-ms.org/document/an-open-letter-to-the-honourable-gene-zwozdesky-alberta-minister-of-health-regarding-the-august-6-2010-alberta-health-services-report-on-ms-and-ccsvi/>.
[170] Joanna Smith & Megan Ogilvie, "MS doctors attacked for their skepticism", *Toronto Star* (25 September 2010) A.1.

context over time.[171] Assessing the responsiveness of regulation and the adaptability of governance is intricately linked with considerations of timing and instrument selection. Timing regulatory activities effectively is an acknowledged challenge in regulatory scholarship, particularly in the context of emerging technologies or new risks.[172] As noted above, once the story of liberation therapy was profiled by Canadian media in November 2009, Canadians quickly began pursuing liberation therapy in other jurisdictions while also increasing pressure on decision-makers to facilitate domestic access. Information in the public domain suggests these factors spurred regulatory activity with some sense of urgency, particularly in the form of research funding intended to produce evidence about liberation therapy that would inform decisions about access.[173] For example, Nova Scotia's Minister of Health and Chair of the provincial and territorial health meetings, the Honourable Maureen MacDonald, said the following: "As ministers of health, we are in complete agreement that we want to act as quickly as possible to get the expert advice we need to make informed decisions for MS patients".[174] Similarly, in a government press release detailing Saskatchewan's plans to support the Albany clinical trial, Minister of Health the Honourable Don McMorris stressed the urgency of this work, saying: "Patients need answers as soon as possible about the efficacy of the liberation therapy as a treatment for MS".[175] Although controversial for other reasons including opportunity cost (recognizing that when resources are finite, allocating funds to one area will reduce the funds available for other areas), these early allocations of public funds for research reflected proactive and timely response to liberation therapy, which was then a new, fast-moving, and highly controversial field.

As already noted, over the twenty-four months following the late 2009 high-profile media stories that introduced liberation therapy to Canada, there was a series of public announcements regarding research funding for both observational and interventional work along with early statements from regulatory and governance actors that emphasized the experimental nature of liberation therapy and which urged caution.[176] Unlike some other jurisdictions including the

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[171] See e.g. Margot Hurlbert & Joyeeta Gupta, "An institutional analysis method for identifying policy instruments facilitating the adaptive governance of drought" (2019) 9 Environmental Science & Policy 221; see also Gregory Mandel, "Regulating Emerging Technologies" (2009) 1:1 L Innovation & Technology 75 at 89.

[172] See e.g. Anna Butenko & Pierre Larouche, "Regulation for innovativeness or regulation of innovation?" (2015) 7:1 L Innovation & Technology 52 at 70 and discussion of the Collingridge dilemma, which is credited to David Collingridge, *The Social Control of Technology* (New York: St. Martin's Press, 1980); see also International Risk Governance Council, "Introduction to the IRGC Risk Governance Framework" (2017), online: *Lausanne: EPFL International Risk Governance Center* <irgc.org/publications/core-concepts-of-risk-governance/> at 19; see also the discussion in Chapter 2, Sections 2.1.2- 2.1.3, *above*.

[173] See e.g. Newfoundland & Labrador, "Province to Fund", *supra* note 81. Minister Kennedy emphasized that in funding this observational study, Newfoundland and Labrador was doing its part to facilitate research, noting the "significant impact" MS has on suffers and their families; see also British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5918 (Hon. A. Dix); see also Andy Ivens, "B.C. should help Sask. on MS: Dix", *The Province* (29 July 2010) A.6; see also Jen Skerritt, "'Liberation treatment' Province cautious on trials for multiple sclerosis therapy", *Winnipeg Free Press* (29 July 2011) A.4.

[174] Government of Nova Scotia, "Minister Chairing National Health Meetings" (14 September 2010), online: <novascotia.ca/news/release/?id=20100914007>.

[175] Government of Saskatchewan, "Saskatchewan entering partnership to advance MS research" (23 September 2011), online: <www.saskatchewan.ca/government/news-and-media/2011/september/23/saskatchewan-entering-partnership-to-advance-ms-research>.

[176] Alberta Health Services, "Statement on Venous Imaging", *supra* note 21; CIHI, "MS Monitoring", *supra* note 62 at 21; CADTH, "Surgical Procedures", *supra* note 58; Government of British Columbia, "The Health and Well-being of Women in British Columbia; Provincial Health Officer's 2008 Annual Report" (2 December 2011), online

United States, Canada did not develop a sizable private market for liberation therapy, nor did liberation therapy make significant inroads into publicly funded healthcare contexts. Although my research does not lead to conclusions on causation, it seems reasonable to infer that the early information-based instruments from regulatory and governance actors including CADTH[177], AHS[178], and The Collège des médecins du Québec[179], among others, may have helped frame the procedure as experimental and discourage physicians who might otherwise have been inclined to use it in a treatment context. In general, communications from these actors emphasized more robust forms of clinical evidence as opposed to individual anecdotes as the appropriate basis for clinical applications of this intervention.

Nonetheless, the fervent advocacy efforts in support of liberation therapy, the seemingly large numbers of Canadians who pursued it out-of-country, and even the zealous debates that took place in legislative assemblies, may point to weaknesses or limitations in such information-based strategies, including those that prioritized more traditional biomedical research models and related standards of evidence. While one can only speculate, faster, clearer, and more consistent public facing communications from established regulatory and governance actors regarding the important uncertainties in Zamboni's theory and the potential risks of liberation therapy may have helped clarify the information environment to minimize demands for urgent access. The potential merits of communication and engagement strategies that also account for individual experiences and related stakeholder priorities will be discussed in Section 6.3, below.

Some regulatory and governance actors adjusted their approaches in response to emerging evidence and evolving knowledge in the field. In doing so, they demonstrated a degree of responsiveness or adaptive capacity. CIHR moved from not recommending interventional trials to ultimately funding its Phase I/II trial once there was sufficient preliminary evidence to justify this next stage.[180] Yukon altered its approach between October 2010, when then Minister of Health, the Honourable Glenn Hart indicated Yukon would not be funding clinical trials,[181] to 2011 when it announced $250,000 in support of Saskatchewan's clinical trials.[182] Manitoba similarly vacillated before ultimately joining Saskatchewan in funding trials.[183] Whether these regulatory shifts are most accurately

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(pdf): *Ministry of Health* <www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/reports-publications/annual-reports/annual-report-2008.pdf> at 189-190.

[177] CADTH, "Surgical Procedures", *supra* note 58.

[178] Alberta Health Services, "Statement on Venous Imaging", *supra* note 21.

[179] CIHI, "MS Monitoring", *supra* note 62 at 21.

[180] When he appeared as a witness before the Senate Standing Committee as it considered Bill S-204, CIHR President Dr. Alain Beaudet explained it would not have been scientifically or ethically justifiable for CIHR to fund Phase III clinical trials for Liberation Therapy without first establishing the safety of the procedure. Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Dr. Alain Beaudet). For a sample news story from the fall of 2010 quoting CIHR President Alain Beaudet's explanation that a trial would be unlikely to receive ethics approval at that point, given the state of the evidence and the need for patients to stop their medications, see Laura Payton, "Agency rejects treatment before test" *Sudbury Star* (1 September 2010) A.6.

[181] CADTH, "Investigating", *supra* note 58 at 3.

[182] Yukon Government, "Yukon signs on to Saskatchewan's MS liberation clinical trials" (21 April 2011), online (pdf): <open.yukon.ca/data/sites/default/files/20110421YukonSignsOnToSKMSLiberationClinicalTrials.pdf>.

[183] Kim Lawson & Tammy Karachuk, "In centre of 'liberation' storm; The medical facts in a frequently disabling disease" *Winnipeg Free Press* (27 December 2010). A.6. This article references a freedom of information request

attributed to evolving evidence, or to escalating advocacy, is debatable. Either way, they adjusted to the changing context. There were also examples of individuals within government changing their perspectives over time along with the evolving evidence, which may have contributed to collective shifts. For example, Senator Angus noted emerging challenges to liberation therapy as well as evolving information about adverse results suffered by individuals who pursued it elsewhere, and indicated these "new data" were moving him to be cautious.[184]

As these select e6xamples illustrate, the public record reflects adjustments made in regulatory and governance approaches to liberation therapy over time, at least some of which appear linked to changing information including emerging research. However, these shifts were not consistent across Canada, nor did they occur in isolation from other influences, including public and patient advocacy, and the related political forces discussed earlier. The speed with which the liberation therapy phenomenon unfolded in Canada may have been one reason I did not find many notable adjustments in approaches by individual governance actors. If we take a broad view of the relevant governance matrix and consider the collective activities of governance actors, including governments, there was a discernible shift over time. The most telling reflection of adaptability or responsiveness in regulation and governance of access to liberation therapy in Canada was arguably that the early momentum driving pursuit of evidence and access via research channels waned and ultimately ceased following the CIHR-funded Phase I/II trial which established that the intervention was ineffective in treating MS.

6.3 Key lessons and future priorities

The regulation and governance of access to liberation therapy in Canada made for a rich case study. Described as a "vivid lesson to the medical community",[185] the liberation therapy phenomenon exhibited several features that were key to its momentum, and important for questions of regulation and governance. The most salient and impactful of these features included the following: a new or non-standard of care medical intervention that promised to address unmet medical need(s); public attention or advocacy in news and social media; some degree of scientific uncertainty with conflicting professional views about the intervention, and a diverse set of actors with different spheres of authority and influence. The intersection of these features, particularly in this "hope for a cure" context, made for complex decisions about access.[186] I have identified four key lessons from this case study that could be used to inform and strengthen future strategies for regulation and governance of access to other unproven medical interventions in Canada that share similar features, each of which is discussed in turn below.

The first suggested area of focus for future regulation and governance of unproven medical interventions is a greater emphasis on coordination among state actors, particularly regarding public-facing messaging and instrument selection. There was clear and early interest by several provincial and territorial governments in cooperating with a coordinated national approach, often framed as intended to facilitate expediency in research with the goal of finding

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that identified fourteen briefing notes on liberation therapy given to the Manitoba Minister of Health between 2009 – 2010.

[184] Senate of Canada, 42-1, vol 150, Issue 14 (28 September 2011) at 1600 (Hon. David Angus).

[185] Machan, Murphy & Traboulsee, *supra* note 41 at S2-S3.

[186] Christy Simpson, "The impact and influence of hope and hype in decision-making about health technologies" (2015) 28:5 Healthcare Management Forum 218 at 218.

answers as quickly as possible.[187] For example, at their 2010 annual meeting, Ministers of Health from across Canada expressed support for Canadian research into the link between MS and CCSVI and resolved to work together to coordinate clinical trials if and when supported by emerging scientific evidence, and "to do everything they can to accelerate progress in this area".[188] However, notwithstanding expressions of collaborative goodwill, federal, provincial, and territorial responses were varied both in substance and in their timing. Inconsistencies in the messaging[189] and instruments[190] used by different governments may have contributed to uncertainty among the public and policy-makers alike in how to interpret information coming from disparate sources.[191] By extension, it may also have fueled access demands and contributed to individual decisions to pursue liberation therapy out-of-country.

Part of the challenge in seeking to advance a coordinated Canadian approach or national strategy for the regulation of some types of medical interventions is the lack of federal authority over the practice of medicine and the delivery of healthcare. Nonetheless, there is a history of health policy issues in Canada where federal leadership and national consistency have played an important role, often using funding instruments.[192] In future, greater coordination through the First Ministers Meetings or the Conference of Provincial-Territorial Ministers of Health, with the goal of taking consistent approaches to the messaging around emerging and high-profile interventions such as liberation therapy, may assist with clarifying the information environment within which individual patients and healthcare providers make testing and treatment

[187] See e.g. Manitoba, *Journals of the Legislative Assembly*, 39-4 (11 May 2010) (Hon. Theresa Oswald); see also Northwest Territories, *Journals of the Legislative Assembly,* 16-5 (15 October 2010) at 5070 (Hon. Sandy Lee); see also Yukon, *Journals of the Legislative Assembly,* 32-1 (4 October 2010) at 6671 (Hon. Mr. Hart); see also British Columbia, *Journals of the Legislative Assembly*, 39-2, vol 19, No 2 (27 May 2010) at 5918 (Hon. K. Falcon), where Minister of Health Falcon noted that there is a role for the federal government via a national research effort. See also Senate of Canada, 41-1, vol 150, Issue 39 (8 December 2011) at 1610 (Hon. A. Raynell Andreychuk).

[188] Government of Newfoundland and Labrador, "Federal, Provincial and Territorial Health and Healthy Living / Wellness Ministers Agree on Ways to Strengthen the Health of Canadians" (14 September 2010), online: *Health and Community Services* <www.releases.gov.nl.ca/releases/2010/health/0914n11.htm>.

[189] For example, contrast the emotive messaging from supporters of Bill C-280 and S-204 with the far more cautious communications made by the CIHR Expert Working Group.

[190] For example, contrast Saskatchewan's vigorous pursuit to fund interventional clinical trials with Alberta and BC's more restrained approaches in starting with observational research.

[191] Similar questions are raised by different governments' responses to the COVID19 pandemic, and regarding the impact that divergent messaging and regulatory strategies (e.g. regarding masking, shut-downs, social distancing requirements, etc.) have had on public trust and compliance.

[192] The National Wait Times Initiative is one example. See Government of Canada, "National Wait Times Initiative" (01 December 2009), online: <www.canada.ca/en/health-canada/services/health-care-system/funding/health-care-policy-contribution-program/national-wait-times-initiative.html>. Related examples are the 10-year Plan To Strengthen Health Care and the federal wait time reduction fund. See Government of Canada, "A 10-year Plan To Strengthen Health Care" (16 September 2004), online: <www.canada.ca/en/health-canada/services/health-care-system/health-care-system-delivery/federal-provincial-territorial-collaboration/first-ministers-meeting-year-plan-2004/10-year-plan-strengthen-health-care.html>. A more recent example is the federal Emergency Treatment fund which provided $150 million to provinces and territories for improving access to evidence-based treatment and services to address the opioid crisis. See Government of Canada, "Emergency Treatment Fund" (26 October 2020), online: < www.canada.ca/en/health-canada/services/substance-use/problematic-prescription-drug-use/opioids/responding-canada-opioid-crisis/emergency-treatment-fund.html>.

decisions.[193] It may also help strengthen the quality of information policy-makers draw on when setting agendas related to unproven medical interventions.

A second priority is for governments to facilitate enhanced deliberate collaborative governance strategies that engage, at minimum, professional regulatory bodies, leaders in clinical and research communities, and patient representatives, to leverage resources, expertise, reach, and impact. Collaborative governance and cooperative approaches to regulation that are flexible and involve intentional consultation are advantageous in complex spheres, including regulation of innovation.[194] They are also, I would argue, particularly important in contexts where there are resource and capacity constraints, such as in the Canadian health policy context. The relatively narrow and identifiable collection of regulatory and governance actors that have influence over access to unproven medical interventions in Canada enhances the feasibility of collaboration and coordination of key actors.

As is true for other areas of health policy and different kinds of medical interventions, the decision-making context surrounding liberation therapy in Canada was one of multi-level governance, where both state and non-state actors played important roles. This case study illustrates how important strong governance networks are for matters that do not fall solely within the state's regulatory authority. Governments are not always well placed to respond in isolation to the issues raised by unproven medical interventions like liberation therapy, particularly where there is the potential for patients and healthcare providers to exit publicly funded healthcare systems,[195] and where there are different forms of access involved (e.g. via treatment, research, out-of-country providers, etc.). Notable examples of collaboration in this case study included the work of the CIHR Scientific Expert Working Group, which involved a range of medical experts and government observers, and the Phase I/II CIHR funded trial, which was a collaborative effort involving CIHR, provinces and territories, and the MS Society of Canada.[196]

Together, the network of governance actors engaged in this case offered strengths in professional legitimacy (e.g. professional guidance endorsed by the Canadian Interventional Radiology Association), reach (e.g. the MS Society in its advocacy role), and expertise in evaluating evidence (e.g. CADTH's expert reviews). However, this collective strength could likely have been enhanced through more extensive and deliberate collaboration among an even broader range of governance actors. Notably, there was limited information in the public domain regarding collaboration or coordination among provincial or territorial governments and the

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[193] Work done in relation to COVID-19 response could provide a useful template for future health challenges of national importance. See e.g. Government of Canada, "Prime Minister hosts First Ministers' Meeting on fighting COVID-19 and strengthening health care" (10 December 2020), online: *Prime Minister of Canada* <pm.gc.ca/en/news/news-releases/2020/12/10/prime-minister-hosts-first-ministers-meeting-fighting-covid-19-and>.

[194] See Butenko & Larouche, *supra* note 172 at 77; see also Lisa Bingham, "Collaborative Governance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 386 at 388; Jeff Sellers, "State-Society Relations" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 124, and related discussions in Chapter 2, *above*.

[195] Albert Hirschman, *Exit, voice and loyalty: responses to decline in firms, organizations, and states* (Cambridge, Mass: Harvard University Press, 1970).

[196] See remarks by CIHR President Dr. Alain Beaudet in Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Dr. Alain Beaudet).

colleges of physicians and surgeons, or other governance actors with influence over the medical profession. One example of valuable collaboration was an update that CIHR provided to the colleges regarding its recommendation against the use of liberation therapy to treat or manage MS,[197] presumably with the intent to inform the colleges' approaches to this issue. Collaboration between governments and professional regulatory bodies including the colleges of physicians and surgeons requires careful management, because maintaining separation from government may help protect the independence of these regulatory authorities. However, given that these bodies act with delegated government authority and generally are required to serve the public interest,[198] transparent and robust provincial oversight to ensure they are fulfilling their mandate is arguably appropriate and necessary.

At a more individual level, interviews with patients indicated that Canadian physicians, and neurologists in particular, had the potential to play an important role in helping MS patients navigate the complex information about liberation therapy and, perhaps, in dissuading early pursuit of this unproven intervention.[199] A 2012 study found that MS patients had a range of experiences when trying to discuss liberation therapy with their neurologists, including being met with caution and critique as well as refusals to discuss the intervention at all, which sometimes led to communication breakdowns in those treatment relationships.[200] These findings suggest that medical professionals' influence in patient decision-making was under-utilized, not utilized constructively, or, at the very least, under-supported as a governance strategy with respect to liberation therapy.[201] It also points to the need to have appropriately tailored information from trusted sources available to patients who may not receive it from their regular care providers.

Apart from the MS Society of Canada, there was also a paucity of information regarding deliberate government engagement with patient representatives. Public and stakeholder engagement can strengthen regulation and governance by adding legitimacy and fostering trust in the resulting framework.[202] However, the largely informal approach observed in this case arguably did not serve those purposes. The voices heard through public pressure and patient

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[197] Canadian Institutes of Health Research, "Highlights from the March 7, 2017 CIHR Scientific Expert Working Group on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency Meeting" (30 March 2017), online: *Government of Canada* <cihr-irsc.gc.ca/e/50159.html>; see also College of Physicians and Surgeons of Saskatchewan, "Executive Summary of the June 16 & 17, 2017 Council Meeting" (last visited 23 May 2022), online: <www.cps.sk.ca>.

[198] For example, bylaws and amendments made by the College of Physicians and Surgeons of Saskatchewan must be laid before the Provincial Assembly, and if found "to be beyond the powers delegated by the Legislature or in any way prejudicial to the public interest, the bylaw or amendment ceases to have effect and is deemed to have been revoked". *The Medical Profession Act, 1981*, SS c M-10.1 at s 90(2).

[199] See e.g. Ploughman et al, "Navigating", *supra* note 39 at 1205. In this study, Ploughman et al. found that good relationships with trusted sources such as neurologists and an ability to "critically analyze the CCSVI hypothesis" were "hesitating factors" in individuals' decisions whether to pursue liberation therapy.

[200] S. Michelle Driedger et al, "Caught in a no-win situation: discussions about CCSVI between persons with multiple sclerosis and their neurologists – a qualitative study" (2017) 17:176 BMC Neurology doi.10.1186/s12883-017-0954-7.

[201] This observation is not intended to diminish the importance of trust between patients and their healthcare providers or to discount its fragility, particularly in emotionally charged areas of uncertainty. For an analysis of these tensions as reflected by online discourse in a German MS Society Forum, see Janka Koschack et al, "Scientific Versus Experiential Evidence: Discourse Analysis of the Chronic Cerebrospinal Venous Insufficiency Debate in a Multiple Sclerosis Forum" (2015) 17:7 J Medical Internet Research e159.

[202] Harmon, Laurie & Haddow, *supra* note 148 at 26.

advocacy appear to have been those with the capacity and motivation to identify and use channels of influence such as news and social media, as well as personal appeals to elected officials and decision-makers, to advocate for expanded access to liberation therapy. These perspectives were not necessarily representative of broader communities, including other MS patients.[203]

More structured and deliberate mechanisms of engagement with members of the public and patients to improve equality of access to decision-makers, as well as to advance transparency and accountability in related decision-making processes, would be valuable. It is likely not feasible or even desirable to engage in extensive public or patient engagement regarding decisions about access to all new unproven medical interventions. However, targeted engagement to better understand the issues and priorities of these key stakeholders may assist in developing regulatory and governance responses (including communication strategies) that will more effectively advance the goals of minimizing risk and supporting evidence-informed decision-making. It may also increase trust in regulatory and governance processes and in so doing, perhaps discourage patients from exiting the system. CIHR's developing best practices in patient-oriented research could provide instructive guidance on such a process,[204] as could existing examples of collaboration in other areas of MS policy work that involve patient representatives, medical experts, and community partners.[205] With their regulatory responsibilities and central role in the governance matrix, governments are well situated to serve as a catalyst and facilitator of such collaboration.

The third suggested strategy is for both regulatory and governance actors to develop new ways of understanding and functioning in today's social media-driven online information environment, with communication strategies based on evolving understanding of best practices in this field. For example, the growing body of work regarding the COVID-19 "Infodemic" may provide useful guidance.[206] Communication via information-based instruments was a key part of regulatory and governance responses to liberation therapy in Canada. However, the levels of conflicting information and the prominence of anecdote over evidence in different forums, including not only news and social media but also among political debates, reflected a muddied informational environment that was likely difficult for patients and their supporters, as well as other influential actors, to navigate. Clinicians and researchers will need to be part of future outreach strategies to promote timely and accurate understandings of scientific realities in the context of new interventions, including via news and social media.[207] Ideally, evidence regarding

[203] Benjaminy et al, *supra* note 51. This research with MS patients who did not receive liberation therapy identified critical views regarding divesting MS research funding to CCSVI.
[204] Canadian Institutes of Health Research, "Strategy for Patient-Oriented Research; Putting Patients First" (2014) online (pdf): *Government of Canada* <cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf>.
[205] For example, Alberta's Multiple Sclerosis Partnership is a collaborative effort between government and non-government governance actors, including the MS Society of Canada, and community partners such as local MS clinics. See Alberta Health, *supra* note 5 at 12. In a similar vein, partly in response to the termination of the Albany trial, in 2014 the government of Saskatchewan convened a Multiple Sclerosis Advisory Panel (the SK Panel) to develop recommendations for improving MS care, education, and research in Saskatchewan. The SK Panel membership included people living with MS, MS advocates, researchers, and medical specialists. See MS Advisory Panel, "Recommendations", *supra* note 48.
[206] See e.g. Timothy Caulfield, Tania Bubela, Jonathan Kimmelman & Vardit Ravitsky, "Let's do better: public representations of COVID-19 science" (2021) 6 Facets 403.
[207] See e.g. Gafson & Giovannoni, *supra* note 36 at 143; See also Ben Paylor et al, "Collision or convergence? Beliefs and politics in neuroscience discovery, ethics, and intervention" (2014) 37:8 Trends in Neurosciences at 412;

the factors that influenced individual decisions regarding whether to pursue out-of-country liberation therapy will be taken into consideration in developing future information-based strategies.[208] Strengthening the scientific literacy of political decision-makers, media, and the public is important given the influence that advocacy efforts, media activity, and individual anecdotes appear to have had on patients' pursuit of liberation therapy out-of-county, as well as on regulatory and governance actors' strategies.[209]

This point brings us to the fourth and final lesson for future regulation and governance of unproven medical interventions in Canada: the value in transparency, particularly with respect to changes in established processes, and role clarity. The way in which research funding was used as a regulatory instrument in this case highlights the merits of a greater focus on transparency and due process. The public funding provided to support observational and clinical trial research into the safety and efficacy of liberation therapy did not follow the standard pathways for identifying research priorities and allocating resources. It is rare to see governments provide direct funding for specific projects and research questions, rather than through resources provided to scientific funding organizations which then have internal processes for crafting funding programs. Rather, as discussed earlier, government funding decisions regarding support for research into liberation therapy appear to have been closely tied to public pressure that decision-makers faced at various levels.[210] In the reality of limited resources, such departures from established processes carry an opportunity cost to other avenues of exploration, including other promising avenues of research.

There may be circumstances when it is appropriate for publicly funded scientific research to respond to public demand. For example, Chafe et al. use the term "Facebook equipoise" to describe today's era of social media influence on patients and suggest there may be rare

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see also Driedger, Dassah & Marrie, *supra* note 37 at 474. Driedger et al. argue that there are likely to be future medical controversies like liberation therapy, which will require improved science communication strategies.

[208] See e.g. Luanne Metz et al, "Medical Tourism for CCSVI Procedures in People with Multiple Sclerosis: An Observational Study" (2016) 43 Canadian J Neurological Sciences 360 at 365. This study found that greater disability and longer disease duration were predictors of whether people pursued liberation therapy; see also Michelle Ploughman et al, "Predictors of chronic cerebrospinal venous insufficiency procedure use among older people with multiple sclerosis: a national case–control study" (2015) 15:161 BMC Health Services Research doi 10.1186/s12913-015-0835-y at 8; see also Cynthia Murray et al, "The Liberation Procedure Decision Making Experience for People With Multiple Sclerosis" (2014) Global Qualitative Nursing Research doi:10.1177/2333393614551413. Murray et al. compared early embracers (i.e. those who moved quickly to pursue liberation therapy) to those who exhibited more skepticism and desire for information and evidence. See also Mazanderani, Kelly & Duecy, *supra* note 51 at 233-234. Mazanderani et al.'s work points to the persuasiveness of "embodied" experience over traditional standards of evidence-based medicine when navigating uncertainties around risk and efficacy.

[209] Chafe et al, *supra* note 43 at 411. Chafe et al. suggest that strengthening scientific literacy in this manner is particularly important to avoid public funds being used to explore potentially ineffective or harmful interventions, and because the public is not necessarily deferential to expert opinion.

[210] For observations on the "unprecedented" nature of this public funding from Nova Scotia's Minister of Health, see Nova Scotia, *Journals of the Legislative Assembly*, 61-2 (24 November 2010) at 3975 (Hon. Maureen MacDonald). For a commentary addressing standard research approaches and critiquing variations, including reliance on single-centre publications that lack independent verification, as well as promotion of unproven interventions in media and online sources, see Jim Reekers, "A Swan Song for CCSVI" (2014) 37 Cardiovascular & Interventional Radiology 287 at 288. For a news media comment on the role of emotion in government decision-making with a concluding emphasis on reasonableness, see Murray Mandryk, "Drop liberation therapy notion", *Saskatoon Star Phoenix* (11 September 2013) A:8.

instances where interventional research is justified even where traditional clinical equipoise is lacking, when the alternative is large numbers of patients paying high costs for potentially risky and ineffective interventions.[211] Nonetheless, at the very least, thoughtful consideration should be given to determining a reasonable and transparent process for these decisions.[212] There are potential parallels here with efforts to increase transparency around patient appeals for expanded access (i.e. compassionate use, "Right-to-Try") regimes for experimental pharmaceuticals.[213] Having more transparent and robust processes in place to address situations of public demand may help reduce concerns that the research community will be left "repeatedly at the mercy of advocacy campaigns and decisions based on political expediency and opportunism".[214]

The value of political and professional public servant role separations,[215] and of expertise in decision-making about access to medical interventions was highlighted by government debates about liberation therapy. There was a marked distinction between the cautionary, evidence-based approach reflected in official statements by public service actors such as CIHR and AHS, and the emphasis on anecdote and advocacy expressed by many members of the legislative branches of governments across Canada. There is a strong public interest argument in favour of decision-making processes that prioritize robust scientific forms of evidence and subject matter expertise when dealing with unproven medical interventions that carry potential risks to identifiable individuals who pursue them, to healthcare systems (e.g. costs from follow-up care), and to those who otherwise stand to benefit from diverted research resources. The information asymmetries inherent to many areas of medicine are also particularly salient with new and unproven interventions where the evidence is evolving, and many risks are still unknown. In these circumstances, drawing on appropriate subject matter expertise to evaluate developing information is arguably an important element of the balancing exercise involved in access decisions.

Although there was potentially some blurring of roles and under-emphasis on evidence and expertise in the political arena surrounding liberation therapy, I found nothing to suggest

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[211] Chafe et al, *supra* note 43 at 411. Clinical equipoise refers to when there is a lack of consensus regarding whether a treatment is preferable (i.e. more effective, safer) than existing alternatives. The influence of social media-based marketing practices on physicians is another issue that, while beyond the scope of this discussion, raises related and important questions about the need to explore the basis upon which physicians make treatment decisions (e.g. medical evidence and clinical judgment, as opposed to effective marketing). See e.g. Amy Snow Landa & Carl Elliott, "From community to commodity: the ethics of pharma-funded social networking sites for physicians" (2013) 41:3 JL Medicine & Ethics 673.

[212] See Michael Brant-Zawadzki et al, *supra* note 23. Interestingly (given the case study selection for this doctoral research project), these authors compare liberation therapy to chelation therapy for atherosclerosis. They emphasize the importance of considering what is reasonable when accommodating pressure from patient advocacy groups and consumerism. See also Judy Illes, Anthony Traboulsee & Shelly Benjaminy, "Science and society must collaborate; Civic engagement vitally important", *The Vancouver Sun* (18 March 2017) G.4. Illes et al. suggest that proactive public deliberation and benchmarks for levels of evidence required for research agendas are important elements of these decision-making processes.

[213] See e.g. Tim Mackey & Virginia Schoenfeld, "Going "social" to access experimental and potentially life-saving treatment: an assessment of the policy and online patient advocacy environment for expanded access" (2016) 14:17 BMC Medicine doi.org/10.1186/s12916-016-0568-8.

[214] Matthew Stanbrook, "Access to treatment for multiple sclerosis must be based on science, not hope" (2010) 182:11 CMAJ 1151 at 1151. See also Driedger, Dassah & Marrie, *supra* note 37 at 492.

[215] The public service is the professional and non-political part of the executive branch of government and is responsible for serving the public interest. See Government of Canada, "Values and Ethics Code for the Public Sector" (15 December 2011), online: <www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049>.

there were similar concerns with either the courts or research ethics oversight processes. In the case law reviewed above, courts followed established precedent to evaluate issues regarding liberation therapy testing and treatment pursuant to provincial legislation and professional bylaws. I also did not identify critiques of research ethics review processes in association with the liberation therapy-related research that occurred across Canada. Given the confidentiality of research ethics review processes, salient concerns and internal debate would not be publicly available. However, the lack of public critique of relevant research ethics processes or approvals in media, Hansard records, and relevant literature is still noteworthy, particularly given the contrast to Dr. Zamboni's home country of Italy, where research ethics review processes were criticized for "being held hostage by the 'will of the people' and becoming accomplices in the distortion of evidence-based medicine".[216] It is important to be cautious not to overstate the conclusions that can be drawn from the limited data in this case study regarding research ethics processes as related to liberation therapy. However, it appears that courts and potentially research ethics oversight may have served to strengthen legitimacy of governance of access to liberation therapy in Canada with their consistent and measured approach to access decisions under their purview, arguably highlighting the importance of these independent actors.

Overall, there is much we can learn from the regulation and governance of access to liberation therapy in Canada to better prepare for similar issues in future before, as Driedger et al. warn, "the next breakthrough takes the public, and by extension the political system, by storm".[217] This discussion will carry over into Chapter 8, where I will offer strategies for strengthening future regulation and governance of access to unproven medical interventions in Canada.

[216] M Antonella Piga, "About Patients, Inventors, Journalists, Scientists and IRBs (To Say Nothing of the Institutions: CCSVI and MS" (2014) 33:4 Med & L 177 at 187. Piga's discussion in this article focuses on the circumstances surrounding approval of research into CCSVI, but it begins with a discussion of similar patterns that unfolded in the Stamina stem cell controversy in Italy. This link is noteworthy for the purpose of this doctoral research and the inclusion of both unproven stem cell interventions and liberation therapy as case studies of the same broader phenomenon, i.e, unproven medical interventions.

[217] Driedger, Dassah & Marrie, *supra* note 37 at 492.

CHAPTER 7: CASE STUDY 3- UNPROVEN STEM CELL INTERVENTIONS IN CANADA

In this chapter, I will present the results of my case study analysis of regulation and governance of access to unproven stem cell interventions in Canada. The chapter will follow the same format as the previous two, starting first with a narrative account that will include a brief introduction to stem cells and their clinical use. This first section will also include an explanation of what "unproven stem cell intervention" means in the context of this research and an overview of private market offerings of such interventions, with a discussion of their potential risks. I will next review the status of the Canadian market for unproven stem cell interventions, and then proceed to address the results of my regulation and governance analysis and lessons learned.

7.1 Narrative account of the market for unproven stem cell interventions in Canada

7.1.1 Stem cells – an overview

Stem cell research is a branch of regenerative medicine with high expectations regarding its potential to advance treatment options for a wide range of medical conditions. This potential is rooted in stem cells' ability to self-renew and, through a process called 'differentiation', to develop into different cell types. If these abilities can be controlled and directed, stem cells could be used to replace or repair damaged cells in the body.[1] There are different kinds of stem cells and sources, each with varied research and treatment potential, as well as potentially different risks. "Adult" or tissue-specific stem cells are found in blood (hematopoietic cells), skin (somatic cells), bone marrow (mesenchymal cells), and other tissues. They have limited differentiation capacity as they can generally only produce cells of their own cell type (i.e. blood stem cells produce blood cells).[2] In contrast, pluripotent stem cells, sourced from embryos,[3] or created through reprogramming factors (the latter of which are called induced pluripotent stem cells, or IPSCs)[4], can differentiate into any type of cell in the body (e.g. blood, nerve, muscle, bone, etc.).[5] "Allogenic" describes when cells or tissues are donated by another individual, while "autologous" describes cell therapies where an individual's own cells or tissues are used.[6]

Safe and effective stem cell therapies require understanding and control of the cells' renewal and differentiation process, to ensure they achieve the desired function while avoiding adverse effects such as tumours and other unwanted effects.[7] There are many clinical trials currently investigating the safety and efficacy of different stem cell interventions, but most of

[1] Tsung-Ling Lee et al, "Regulating the stem cell industry: needs and responsibilities" (2017) 95 Bull World Health Organization 663.
[2] See Barbara von Tigerstrom & Erin Schroh, "Regulation of Stem Cell-Based Products" (2007) 15 Health LJ 175.
[3] Embryonic stem cell research can be controversial because it involves the destruction of human embryos. There is a well-developed body of literature exploring this issue, but it is beyond the scope of this case study.
[4] See Shinya Yamanaka, "Induced Pluripotent Stem Cells: Past, Present, and Future" (2012) 10 Cell Stem Cell 678.
[5] Heather Main, Megan Munsie & Michael O'Connor, "Managing the potential and pitfalls during clinical translation of emerging stem cell therapies" (2014) 3 Clinical & Translational Medicine 10.
[6] Health Canada, "Guidance Document: Preparation of Clinical Trial Applications for use of Cell Therapy Products in Humans" (21 August 2015), online: *Government of Canada* <www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/guidance-document-preparation-clinical-trial-applications-use-cell-therapy-products-humans.html> [Health Canada, "Clinical Trial Guidance"].
[7] Main, Munsie & O'Connor, *supra* note 5 at 4.

these trials are still in early, pre-clinical phases (i.e. not being used in humans).[8] Broadly, clinical trials are intended to produce reliable data to support risk/benefit analyses for prospective stem cell treatments based on the unique characteristics of different cell types used in varied contexts.[9]

Although much of stem cells' clinical potential is still theoretical, stem cell transplants are standard of care treatment for several cancers (lymphoma, leukemia, and multiple myeloma) and aplastic anemia. While potentially life-saving, these treatments carry grave risks including graft-versus-host disease, rejection, liver disease, and infection, along with many other serious short and long-term complications.[10] Some of these treatments, including bone marrow transplants for leukemia, developed as medical innovations outside the clinical trial process.[11] There remains considerable debate in medical and scientific communities regarding the appropriateness and respective roles of medical innovation and clinical trial models for the development of stem cell treatments.[12] The International Society for Stem Cell Research (ISSCR),[13] recommends that medical innovation with unproven stem cell interventions should be a "one-off", not used widely or commercially until safety and efficacy have been established, and should require robust scientific rationale, peer review, appropriate follow-up, and informed consent, among other safeguards, as well as a commitment to move to clinical trials.[14]

As discussed in Chapters 1 and 3, this case study is focused on unproven stem cell interventions provided by physicians in Canada in a therapeutic context, rather than as part of clinical research or other approved special access regime. One of the challenges in studying stem cell interventions is that it is common to find a lack of precision in language describing the intervention, including the kinds of stem cells used and the mechanism of administration.[15]

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[8] See e.g. Julia Deinsberger, David Reisinger & Benedikt Weber, "Global trends in clinical trials involving pluripotent stem cells: a systematic multi-database analysis" (2020) 5 npj Regenerative Medicine https://doi.org/10.1038/s41536-020-00100-4. Deinsberger et al. reviewed research trends for clinical trials using different kinds of pluripotent stem cells, drawing on data from ClinicalTrials.gov.

[9] Health Canada, "Clinical Trial Guidance", *supra* note 6. As of December 2022, Health Canada has only granted market authorization for one stem cell therapy through the clinical trial process, Prochymal", a treatment for Graft Versus Host Disease. See Health Canada, "Health Canada is advising Canadians about the potential health risks associated with unauthorized cell therapy treatments such as stem cell therapy" (15 May 2019), online: *Government of Canada* <hhealthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69974a-eng.php> [Health Canada, "Advisory"].

[10] Alberta Health Services, "Allogeneic Stem Cell Transplant" (last modified 29 April 2020), online: *MyHealth.Alberta* <myhealth.alberta.ca/health/tests-treatments/pages/conditions.aspx?Hwid=tv7978> [Alberta Health Services, "Allogeneic SC Transplant"]. These complications can include mouth sores, hair loss, bleeding disorders, nausea, vomiting, diarrhea, infection, infertility, and organ damage, among others.

[11] Main, Munsie & O'Connor, *supra* note 5.

[12] Olle Lindvall & Insoo Hyun, "Medical Innovation versus Stem Cell Tourism" (2009) 324:5935 Science 1664. Lindvall and Hyun suggest that responsible stem cell-based medical innovation requires a scientific rationale and pre-clinical evidence of safety and efficacy as well as peer review. They further suggest it should only be available for a small number of seriously ill patients, and that the intent should be to move to clinical trials when possible.

[13] The ISSCR is a global, non-profit organization. It was founded in 2002 and presents itself as "the leading professional organization of stem cell scientists, representing more than 4,000 members across 67 countries … dedicated to the advancement of responsible stem cell research. See International Society for Stem Cell Research, "About ISSCR" (last visited 15 June 2022), online: <www.isscr.org/about-isscr>.

[14] It has been suggested that these early transplants may have been premature and perhaps unlikely to be approved under modern research ethics review processes. See George Daley, "The Promise and Perils of Stem Cell Therapeutics" (2012) 10:6 Cell Stem Cell 740.

[15] Nicolas Piuzzi et al, "Ethical and Practical Considerations for Integrating Cellular ("Stem Cell") Therapy into Clinical Practice" (2020) 13 Current Revs in Musculoskeletal Medicine 525 at 526.

Definitional and descriptive clarity is important for understanding risk and for characterizing an intervention for the purpose of regulation and governance.[16] However, defining "unproven stem cell interventions" for the purpose of this research is complicated.

Various domestic and international governance actors have offered interpretations of unproven stem cell interventions and, in so doing, are playing a boundary-drawing role in suggesting what stem cell treatments are appropriate to provide, under what conditions. For example, the Australian Stem Cell Handbook distinguishes unproven stem cell therapies from "currently accepted, widely used, proven safe and effective stem cell treatments" (i.e. those that are peer reviewed, where safety has been proven through large scale clinical trials or years of experience, and where cell quality and safety are regulated by government), and from "investigational / experimental stem cell treatments" (i.e. part of robust clinical trials or medical innovation).[17] It provides the following indicators of "unproven stem cell therapies":

> Scientific rationale may not be made clear; Evidence of safety and efficacy in preclinical (animal) models may not be provided or referenced; Treatment plan has not been peer reviewed by an Ethics Committee; Payment is required; Benefit the practitioner (financially) and the patient (possibly); Offered to patients who feel they have no other viable alternative; Offered by direct marketing (eg via the Internet) and often for a wide range of unrelated conditions; May be offered by doctors who are not experts in the condition being treated; May be performed at institutions with little track record of publications and research; Fully informed consent is often not obtained; Legal recourse if something goes wrong is often not clear; Medical insurance eligibility is often not clear; Limited or no long term care or follow-up provided.[18]

I have drawn on this approach to characterize unproven stem cell interventions as those that do not have Health Canada approval, are not conducted as part of sanctioned clinical research (REB or Health Canada approved), and which are not standard of care. This framing admittedly prioritizes a biomedical model of scientific evidence.[19] The role of different approaches to

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[16] Amy Zarzeczny et al, "The stem cell market and policy options: a call for clarity" (2018) 5:3 JL & the Biosciences 743 at 746 [Zarzeczny et al, "Call for clarity"]. In this work, we discussed a need for informational clarity about stem cell interventions in three key and interconnected areas including regulation, scientific and clinical transparency, and with patient communication and engagement strategies.

[17] The features of medical innovation identified in this work include: a clear scientific rationale, evidence of safety and efficacy from animal models, peer review of treatment plan, intended to benefit patient, offered when no viable alternative, done by experts, done in "institutions with good track record and experience in the technique", informed consent is obtained, treatment team is responsible to provide care if there are complications. National Stem Cell Foundation of Australia and Stem Cells Australia, "The Australian Stem Cell Handbook; What you should know about stem cell therapies: *now and in the future*" (April 2015), online (pdf): <stemcellsaustralia.edu.au/assets/Uploads/Australian+Stem+Cell+Handbook+2015-APRIL24.pdf> at 10, Figure 2.

[18] *Ibid* at 10, Figure 2.

[19] In so doing, I acknowledge the normative debate that surrounds this terminology and framing, including the argument that it privileges a Western worldview. See Margaret Sleeboom-Faulkner, "The large grey area between 'bona fide' and 'rogue' stem cell interventions—Ethical acceptability and the need to include local variability" (2016) 109 Technological Forecasting & Soc Change 76. See also Saheli Datta, "Emerging dynamics of evidence and trust in online user-to-user engagement: the case of 'unproven' stem cell therapies" (2018) 28:3 Critical Public Health 352 at 354 [Datta, "Emerging dynamics"]. Datta suggests using the concept of "unproven" privileges scientific evidence and delegitimises those relying on other types of evidence such as experience.

evidence in regulation and governance of access to unproven medical interventions more generally is a key theme emerging from this work that will be discussed in Chapter 8.

In 2011, "stem cell" was described as the science "buzzword of the decade",[20] and by 2018, as "one of the most hyped technological advancements of the last decades".[21] This enthusiasm has helped advanced the field but has likely also raised unrealistic expectations and fueled public demand for treatments that do not exist or which are not ready for widespread use.[22] Media coverage of stem cell research and of unproven treatment options is often framed in an overly positive manner, with an emphasis on the benefits and on compelling personal narratives and minimal discussion of risks.[23] Stories about public figures pursuing unproven stem cell interventions may further legitimize unproven options and encourage public interest in access.[24] The growth of organized misinformation (or "fake news") has added further complexity to this information environment.[25] Positive framing about stem cell research can also be found in other contexts such as research funding announcements. For example, an announcement regarding $20 million in federal government funding to establish the Centre for Advanced Therapeutic Cell Technologies stated that "Regenerative medicine has emerged as a promising approach to disease prevention and treatment, harnessing the power of stem cells to repair, regenerate, or replace damaged cells, tissues, and organs affected by disease".[26]

Given this context, public expectations regarding the readiness of stem cell treatments are not surprising. For example, "Adult stem cell treatments to re-grow knee/hip meniscus" were included in suggestions from British Columbians about what the Medical Services Plan should cover,[27] notwithstanding that this is not a standard of care treatment. This type of intervention is

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[20] Carolyn Abraham, "Dr. Brinkley's Stem Cell Lotion & Magic Elixir", *The Globe and Mail* (8 January 2011), online: <www.theglobeandmail.com/>.

[21] I. Glenn Cohen & Shelly Simana, "Regulation of Stem Cell Therapy Travel" (2018) 4 Current Stem Cell Reports 220 at 220. Cohen and Simana define hype "as the exaggeration of scientific progress". See also Timothy Caulfield et al, "Confronting stem cell hype" (2016) 352:6287 Science 776.

[22] Tania Bubela et al, "Is belief larger than fact: expectations, optimism and reality for translational stem cell research" (2012) 10 BMC Medicine 133 at 9.

[23] See e.g. Kalina Kamenova & Timothy Caulfield, "Stem cell hype: media portrayal of therapy translation" (2015) 7 Science Translational Medicine 278; see also Amy Zarzeczny et al, "Stem cell clinics in the news" (2010) 28:12 Nature Biotechnology 1243 [Zarzeczny et al, "Clinics in the news"]; see also Kimberly Sharpe, Nina Di Pietro & Judy Illes, "In the know and in the news: how science and the media communicate about stem cells, Autism and Cerebral Palsy" (2016) 12:1 Stem Cell Revs & Reports 1. Sharpe et al.'s research reflects variation between different types of publications, finding that small local papers overwhelmingly highlight positive human-interest stories, while investigative pieces in major newspapers show more balance.

[24] Professional athletes are one type of public figure that have been studied in this context. See Timothy Caulfield & Amy McGuire, "Athletes' Use of Unproven Stem Cell Therapies: Adding to Inappropriate Media Hype?" (2012) 20:9 American Society Gene & Cell Therapy 1656 at 1657; see also Li Du et al, "Gordie Howe's "Miraculous Treatment": Case Study of Twitter Users' Reactions to a Sport Celebrity's Stem Cell Treatment" (2016) 2:1 JMIR Public Health & Surveillance e8. doi: 10.2196/publichealth.5264.

[25] Alessandro Marcon, Blake Murdoch & Timothy Caulfield, "Fake news portrayals of stem cells and stem cell research" (2017) 12:7 Regenerative Medicine 765.

[26] Government of Canada, "Prime Minister announces support to Canadian Centre for Advanced Therapeutic Cell Technologies" (13 January 2016), online: *Prime Minister of Canada* <pm.gc.ca/en/news/news-releases/2016/01/13/prime-minister-announces-support-canadian-centre-advanced-therapeutic>.

[27] These suggestions were captured as part of consultations during the 2007 BC Conversation on Health. See British Columbia, Ministry of Health, "Part II: Envisioning a Strong and Sustainable System of Care; Medical Services Plan" (2007) online (pdf): <www.health.gov.bc.ca/library/publications/year/2007/conversation_on_health/PartII/PartII_MSP.pdf> at 12.

however one of many available on the private market for unproven stem cell interventions. This global market operates largely through marketing on a direct-to-consumer basis, generally, though not exclusively, over the internet.

Identifying the size, scope, and operations of this market is difficult. Much of what is known has been drawn from systematic reviews of public-facing information found on provider websites,[28] analyses of patients' blogs,[29] media stories,[30] and interviews with patients[31] and providers.[32] Stem cell interventions are advertised for innumerable and diverse conditions (e.g. heart disease, multiple sclerosis, ALS, spinal cord injury, autism, etc.),[33] as well as natural life processes (e.g. aging).[34] Clinic websites often reference various cell types (e.g. autologous, umbilical cord, placental, embryonic, etc.) and methods of administration (e.g. injection, intravenous, topical, etc.), and it is not uncommon for one treatment protocol to be described for conditions with very different etiology. It was not long into the current global pandemic before purported stem cell treatments for COVID-19 emerged, many of which focused on "immune boosting" claims,[35] which demonstrates the opportunistic aspect of many market offerings. Patient testimonials are prominent in the marketing of unproven stem cell interventions, and there is a growing body of research exploring the role of social media in facilitating the sharing of information among patients, and in the promotion of unproven stem cell interventions.[36]

The potential that people will be harmed is a key concern associated with access to unproven stem cell interventions,[37] particularly given questions regarding whether individuals

[28] See e.g. Ruairi Connolly, Timothy O'Brien & Gerard Flaherty, "Stem cell tourism – A web-based analysis of clinical services available to international travelers" (2014) 12 Travel Medicine & Infectious Disease 695; see also Ubaka Ogbogu, Christen Rachul & Timothy Caulfield, "Reassessing direct-to-consumer portrayals of unproven stem cell therapies: is it getting better?" (2013) 8:3 Regenerative Medicine 361.
[29] Christen Rachul, "What have I got to lose?: an analysis of stem cell therapy patients' blogs" (2011) 20:1 Health L Rev 5; see also Aaron Levine, "Insights from patients' blogs and the need for systematic data on stem cell tourism" (2010) 10:5 American J Bioethics 28.
[30] See e.g. Zarzeczny et al, "Clinics in the news", *supra* note 23.
[31] See e.g. Alan Petersen, Kate Seear & Megan Munsie, "Therapeutic journeys: the hopeful travails of stem cell tourists" (2013) 36:5 Sociology Health & Illness 670.
[32] See e.g. Aarone Levine & Leslie Wolf, "The roles and responsibilities of physicians in patients' decisions about unproven stem cell therapies" (2012) 40 JL Medical Ethics 122.
[33] See e.g. Stem Cells Transplant Institute, "Ontario; Stem Cells Therapy" (last visited 27 May 2022), online: <stemcellstransplantinstitute.com/ontario/>; see also Stem Cells Transplant Institute, "Calgary; Stem Cells Therapy" (last visited 27 May 2022), online: <stemcellstransplantinstitute.com/calgary/>. As of October, 2020, this site listed the following conditions: "Diabetes, Cardiovascular Disease, Rheumatoid Arthritis, Osteoarthritis, Knee Injury, Myocardial Infarction, Neuropathy, Alzheimer, Parkinson, Chronic Obstructive pulmonary disease, Critical limb isquemia, Erectile Dysfunction, Lupus and Multiple Sclerosis".
[34] Christen Rachul & Timothy Caulfield, "The Fountain of Stem Cell-Based Youth? Online Portrayals of Anti-Aging Stem Cell Technologies" (2015) 35:6 Aesthetic Surgery J 730.
[35] Leigh Turner, "Preying on Public Fears and Anxieties in a Pandemic: Businesses Selling Unproven and Unlicensed 'Stem Cell Treatments' for COVID-19" (2020) 26:6 Cell Stem Cell 806.
[36] Kalina Kamenova, Amir Reshef & Timothy Caulfield, "Representations of stem cell clinics on Twitter" (2014) 10:6 Stem Cell Revs & Reports 753; see also Bethany Hawke et al, "How to Peddle Hope: An Analysis of YouTube Patient Testimonials of Unproven Stem Cell Treatments" (2019) 12 Stem Cell Reports 1186; see also Datta, "Emerging dynamics", *supra* note 19 at 354.
[37] For a summary of features and risks of unproven stem cell interventions, see Cambray Smith et al, "Challenging misinformation and engaging patients: characterizing a regenerative medicine consult service" (2020) 15:3 Regenerative Medicine 1427.

are provided with sufficient information to be able to provide informed consent.[38] Following a broad review of literature and web-based searches, Bauer et al. (2018) identified 35 cases of "acute or chronic complications" following alleged unproven stem cell interventions.[39] The Pew Charitable Trusts identified 360 reports of people who suffered adverse events following "unapproved SCRIs [stem cell and regenerative medicine interventions] outside of clinical trials" between 2004 and 2020.[40] Under-reporting of adverse events is an ongoing concern.[41] Identified harms have included tumours[42] and vision loss (following treatment for macular degeneration).[43] While autologous transplants are sometimes presented as safer than allogenic options, Health Canada has clarified that they carry risks including unwanted immune reactions and tissue or tumour formation, along with risks from processing activities such as introduction of bacteria or viruses.[44] The novelty of stem cell interventions also brings higher degrees of uncertainty, and the inability to remove cells that have proliferated and differentiated within the body creates greater potential for long-term safety issues than many traditional therapeutic products.[45]

There are also concerns regarding financial exploitation. Although robust data on treatment costs are lacking, indications are that they tend to be expensive and paid out-of-pocket. Informal self-report polling found costs of $2,000-20,000 USD were most common, with some

[38] Lee et al, *supra* note 1 at 663. See also Mitchell Ng, Michael Mont & Nicolas Piuzzi, "Analysis of readability, quality, and content of online information available for "stem cell" injections for knee osteoarthritis" (2020) 35:3 J Arthroplasty 647. This research highlights problematic characterizations of stem cell interventions marketed on digital platforms.

[39] Gerhard Bauer, Magdi Elsallab & Mohamed Abou-El-Enein, "Concise review: a comprehensive analysis of reported adverse events in patients receiving unproven stem cell-based interventions" (2018) 7:9 Stem Cells Translational Medicine 676.

[40] Pew, "Harms Linked to Unapproved Stem Cell Interventions Highlight Need for Greater FDA Enforcement" (2021), online: < www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/06/harms-linked-to-unapproved-stem-cell-interventions-highlight-need-for-greater-fda-enforcement>. These adverse events included serious bacterial infections, blindness, paraplegia, pulmonary embolism, cardiac arrest, tumours, lesions or other growths, and organ damage or failure.

[41] Peter Marks & Stephen Hahn, "Identifying the Risks of Unproven Regenerative Medicine Therapies" (2020) 324:3 J American Medical Assoc 241. Marks and Hahn (FDA Commissioner) advocate strongly in favour of reporting of adverse events from stem cell products or treatments, to inform FDA's oversight practices.

[42] Claire Woodworth et al, "Intramedullary cervical spinal mass after stem cell transplantation using an olfactory mucosal cell autograft" (2019) 191 CMAJ E761; Ninette Amariglio et al, "Donor-derived brain tumor following neural stem cell transplantation in an ataxia telangiectasia patient" (2009) PLoS Med https://doi.org/10.1371/journal.pmed.1000029; see also Aaron Berkowitz et al, "Glioproliferative lesion of the spinal cord as a complication of 'stem-cell tourism'" (2016) 375 New Engl J Med 196.

[43] Ajay Kuriyan et al, "Vision Loss after Intravitreal Injection of Autologous 'Stem Cells' for AMD" (2017) 176:11 New Eng J Med 1047.

[44] Health Canada, "Health Canada Policy Position Paper – Autologous Cell Therapy Products" (last modified 17 January 2020), online: *Government of Canada* <www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/cell-therapy-policy.html> [Health Canada, "Position Paper"].

[45] von Tigerstrom & Schroh, *supra* note 2 at 215. See also Amanda MacPherson & Jonathan Kimmelman, "Ethical development of stem-cell-based interventions" (2019) 25:7 Nature Medicine 1037. MacPherson and Kimmelman identify 7 features of stem cell-based interventions that differ from other areas of drug development, including unclear definition, regulatory authority, pharmacokinetics (i.e. cells can be difficult or impossible to remove, potentially resulting in long term and irreversible harms), complexity, public expectation, political sensitivities, and competitive pressures.

people spending over $100,000.[46] Individuals have sought funding support in various ways including media appeals with community fundraisers[47] and online crowd funding platforms.[48] For example, a 2015 article in the Saskatoon Star Phoenix described a 28-year-old North Battleford man who raised over $61,425 in a gofundme.com campaign to support his travel to Malaysia for stem cell treatment for liver disease.[49] Another broader concern is that the widespread proliferation of ineffective and potentially harmful unproven stem cell interventions may ultimately damage public trust and support for stem cell research,[50] to the detriment of a broader class of patients who might benefit from future therapies.[51]

Early research on the market for unproven stem cell interventions identified the largest presence of clinics in countries understood to have more permissive systems of oversight for cell therapies and clinical research,[52] including China,[53] India,[54] and Mexico.[55] Over time, subsequent

[46] Paul Knoepfler, "How much does stem cell therapy cost in 2021?" (last visited 23 May 2022), *The Niche*, online: <ipscell.com/how-much-does-stem-cell-therapy-cost-in-2021/#Stem-cells-often-cost-from-$2,500-to-$20,000>.
[47] Zarzeczny et al, "Clinics in the news", *supra* note 23.
[48] Jeremy Snyder, Leigh Turner & Valorie A. Crooks, "Crowdfunding for Unproven Stem Cell–Based Interventions" (2018) 319:8 J American Medical Assoc 1935. Snyder et al. identify deeper concerns regarding these crowd funding campaigns, including their tendency to underemphasize risk and exaggerate efficacy while using compelling personal narratives. See also Jeremy Snyder & Leigh Turner, "Selling stem cell 'treatments' as research: prospective customer perspectives from crowdfunding campaigns" (2018) 13:4 Regenerative Medicine 375.
[49] Jonathan Charlton, "$61k raised for Sask. man's Malaysian stem cell treatment", *Saskatoon Star Pheonix* (27 January 2015), A.1.
[50] See e.g. Michelle Bowman et al, "Responsibilities of Health Care Professionals in Counseling and Educating Patients With Incurable Neurological Diseases Regarding 'Stem Cell Tourism' Caveat Emptor" (2015) 72:11 J American Medical Assoc Neurology 1342; see also Tamra Lysaght et al, "The deadly business of an unregulated global stem cell industry" (2017) 43 J Medical Ethics 744 at 745.
[51] Gene therapy has been used as a cautionary tale for stem cell research, where the tragic loss of early trial participant Jesse Gelsinger largely halted progress in the field for decades. See James Wilson, "Medicine. A history lesson for stem cells" (2009) 324:5928 Science 727.
[52] It is important to note that such characterizations are not unproblematic or uncontroverted. See e.g. Margaret Sleeboom-Faulkner et al, "Comparing national home-keeping and the regulation of translational stem cell applications: An international perspective" (2016) 153 Soc Science & Medicine 240. There are also others who suggest the "endogenous and inherent disruptive attributes" of stem cell interventions have greater influence over market growth than regulatory systems. Saheli Datta, "An endogenous explanation of growth: direct-to-consumer stem cell therapies in PR China, India and the USA" (2018) 13:5 Regenerative Medicine 559.
[53] See e.g. Margaret Munro, "China makes great leap in stem cell advances; Canada left far behind as 'wild, wild east' moves aggressively forward in regenerative medicine, report shows" *Edmonton Journal* (9 January 2010), A.16.
[54] Prasanna Kumar Patra & Margaret Sleeboom-Faulkner, "Bionetworking and Strategic Linking between India and Japan: How Clinical Stem Cell Intervention Continues despite New Regulatory Guidelines" (2017) 11 East Asian Science, Technology & Society: An International Journal 353 at 353.
[55] See Darren Lau et al, "Stem cell clinics online: the direct-to-consumer portrayal of stem cell medicine" (2008) 3:6 Cell Stem Cell 591; see also Alan Regenberg et al, "Medicine on the fringe: Stem cell-based interventions in advance of evidence" (2019) 27:9 Stem Cells 2312; see also Kirsten Ryan et al, "Tracking the rise of stem cell tourism" (2010) 5:1 Regenerative Medicine 27; see also Ogbogu, Rachul & Caulfield, *supra* note 28; see also Connolly, O'Brien & Flaherty, *supra* note 28.

studies[56] have detailed market growth in Australia,[57] Japan,[58] and the United States[59] The growing market in the US has expanded options for Canadians to access unproven stem cell interventions closer to home,[60] including through private cross-border care services, with clinics offering shuttle[61] or other "concierge" services,[62] some with Canadian physicians serving as representatives.[63] The United States is not the only jurisdiction from which clinics advertise Canadian links as part of a recruitment strategy. For example, the Stem Cells Transplant Institute ®'s website includes pages targeting Ontario and Calgary patients for stem cell treatments in Costa Rica.[64] Treatments provided out-of-country are largely beyond the scope of this research. However, they have implications for regulation and governance within our borders when advertised within Canada, or when they involve Canadian physicians as representatives or sources of referrals.

7.1.2 The Canadian market for unproven stem cell interventions

From the late 2000s – 2010s, Canada was largely an exporter of "stem cell tourists" (i.e. individuals who travelled to other countries to receive unproven stem cell interventions not available domestically).[65] Many media articles detailed the personal stories of Canadians who

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[56] For an international summary, see Isreal Berger et al, "Global distribution of businesses marketing stem cell-based interventions" (2016) 19 Cell Stem Cell 158.
[57] Alison McLean, Cameron Stewart & Ian Kerridge, "Untested, unproven, and unethical: The promotion and provision of autologous stem cell therapies in Australia" (2015) 6:1 Stem Cell Research & Therapy 12.
[58] Misao Fujita et al, "The current status of clinics providing private practice cell therapy in Japan" (2015) 11:1 Regenerative Medicine 23.
[59] Leigh Turner & Paul Knoepfler, "Selling stem cells in the USA: Assessing the direct-to-consumer industry" (2016) 19:2 Cell Stem Cell 154; see also Leigh Turner, "The US Direct-to-consumer marketplace for autologous stem cell interventions" (2018) 61:1 Perspectives in Biology & Medicine 7; see also Emma Frow et al, "Characterizing direct-to-consumer stem cell businesses in the Southwest United States" (2019) 13:2 Stem Cell Reports 247. Frow et al. evaluated close to 170 stem cell businesses operating in the southwest US. See also Paul Knoepfler, "Rapid change of a cohort of 570 unproven stem cell clinics in the USA over 3 years" (2019) 14 Regenerative Medicine 735. Knoepfler noted that while approximately 25% of firms first identified in 2015-2016 were no longer marketing stem cells in 2019, other firms had expanded the numbers of their clinics, with the result that the total number of clinics was greater in 2019 than 2015-2016.
[60] Miranda Gathercole, "B.C. businessmen open stem cell therapy clinic in Washington State", *Victoria News* (29 June 2018), online: <www.vicnews.com/business/b-c-businessmen-open-stem-cell-therapy-clinic-in-washington-state/>.
[61] Elizabeth Payne, "U.S. stem cell clinic offering unapproved therapies brings direct-to-consumer marketing to Ottawa", *The Ottawa Citizen* (18 November 2019), online: <ottawacitizen.com/news/local-news/u-s-stem-cell-clinic-brings-aggressive-direct-to-consumer-marketing-to-ottawa>.
[62] See e.g. IMTJ Team, "Stem cell treatment potential in Canada" (18 August 2017), online: <www.laingbuissonnews.com/imtj/news-imtj/stem-cell-treatment-potential-in-canada/>.
[63] See e.g. Tom Blackwell, "Canadians seek out U.S. stem-cell therapies; Unregulated" *The National Post* (5 July 2016) A.1. This story discusses the experiences of several Canadians who travelled to the US for unproven stem cell treatments, and identifies the California Stem Cell Treatment Centre as identifying a Canadian cosmetic surgeon from Vancouver as a representative. See also Spine Institute Northwest, "Getting Access to Stem Cell Therapy in Canada" (21 June 2016), online: <www.fixmypain.ca/getting-access-to-stem-cell-therapy-in-canada/>. This site offers Canadians suffering with chronic injury the alternative of travelling to receive "regenerative treatments like stem cell therapy".
[64] Stem Cells Transplant Institute, "Ontario; Stem Cells Therapy" (last visited 27 May 2022), online: <stemcellstransplantinstitute.com/ontario/>; see also Stem Cells Transplant Institute, "Calgary; Stem Cells Therapy" (last visited 27 May 2022), online: <stemcellstransplantinstitute.com/calgary/>. Last visited October 1, 2020.
[65] Although commonly used in early work on this issue, the terms "stem cell tourism" and "stem cell tourists" are less common in more recent literature. Two particularly influential critiques against these descriptors were first, that

elected to pursue stem cell treatment options in other countries, often (though not always) in sympathetic and uncritical terms.[66] Much of the early Canada-centric work on this issue focused on the role of physicians in relation to patients seeking stem cell interventions out of country.[67] In 2013-2014, I conducted interviews with representatives from six of the provincial Colleges of Physicians and Surgeons and at that time, there was no notable market in Canada.[68] However, a domestic market for unproven stem cell interventions has now developed in Canada.[69] By 2019, a media article described the Canadian "direct-to-consumer cell therapy industry" as "thriving".[70] One media story from February 2017 reported an Alberta clinic had treated "nearly 400 people over the past 18 months", at a cost of "$2,000 for the initial bone marrow harvesting and the injection into one site on the body, and then $100 for each additional injection site".[71]

Two key studies have provided insight into the size and content of the Canadian market. In 2018, Turner identified 30 Canadian businesses marketing stem cell interventions at 43 different clinic locations across the country, with 24 clinics in Ontario, eight in British Columbia, six in Alberta, three in Quebec, and one in both Nova Scotia and Saskatchewan. Autologous stem cells were the most common product promoted.[72] Turner observed that overall, "the range of claims about types of stem cells used by Canadian businesses selling putative stem cell treatments is narrower than the breadth of claims about stem cell types made by their United States counterparts".[73] Most providers in Canada focused on treatments for "orthopedic diseases and injuries, pain management and treatment of sports injuries", with two notable exceptions (one in British Columbia and one in Ontario), where clinics advertised treatments for conditions including ALS, Parkinson's, stroke, MS, muscular dystrophy, Crohn's disease, asthma, lung

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by linking the practice to holidays or tourism, they minimize the difficult circumstances that many individuals seeking unproven interventions are facing, and second, that the travel element no longer fits given that more individuals can access unproven stem cell interventions in their home jurisdictions.

[66] See e.g. Michelle Lang, "Climbing a new mountain; Paraplegic Calgarian puts his faith in controversial Chinese stem cell treatments", *The Calgary Herald* (24 June 2007), B.1.

[67] Amy Zarzeczny & Timothy Caulfield, "Stem cell tourism and doctors' duties to minors–a view from Canada" (2010) 10:5 American J Bioethics 3; see also Jeremy Snyder et al, "Navigating physicians' ethical and legal duties to patients seeking unproven interventions abroad" (2015) 61:7 Canadian Family Physician 584; see also Amy Zarzeczny et al, "Professional regulation: a potentially valuable tool in responding to 'stem cell tourism'" (2014) 3 Stem Cell Reports 379. For a discussion from a US perspective, see Levine & Wolf, *supra* note 32.

[68] Amy Zarzeczny & Marianne Clark, "Unproven stem cell-based interventions & physicians' professional obligations; a qualitative study with medical regulatory authorities in Canada" (2014) 15 BMC Medical Ethics 75.

[69] This market and associated issues, including regulatory responses, has attracted media attention. See e.g. Kelly Crowe, "Unapproved stem cell therapies on the market in Canada", *CBC News* (16 November 2017), online: <www.cbc.ca/news/health/stem-cell-private-clinic-health-canada-osteoarthritis-1.4401391>; see also Tom Blackwell, "Canadian clinics begin offering stem-cell treatments experts call unproven, possibly unsafe", *National Post* (3 July 2017), online: < nationalpost.com/news/canada/canadian-clinics-begin-offering-stem-cell-treatments-experts-call-unproven-possibly-unsafe>; see also CBC News, "Health Canada investigates Canadian stem cell clinics" (9 September 2017), online: <www.cbc.ca/news/health/second-opinion170909-1.4281703>.

[70] Kelly Crowe, "Stem Cell' therapies offered at private clinics need to be approved as drugs, Health Canada says", *CBC News* (18 May 2019), online: <www.cbc.ca/news/health/autologous-stem-cell-bone-marrow-fat-private-clinic-health-canada-regulation-1.5141299>.

[71] Erica Stark, "Healing ourselves; Can our own stem cells be used to minimize pain", *Calgary Herald SW* (17 February 2017) SW.25.

[72] Leigh Turner, "Direct-to-consumer marketing of stem cell interventions by Canadian businesses" (2018) 13:6 Regenerative Medicine 643 [Turner, "Marketing by Canadian businesses"]. This study included only Canada-based providers marketing stem cell interventions not approved by Health Canada, not provided as current standard of care, and which have not been established to be safe and effective via clinical trials.

[73] *Ibid* at 648.

disease, congestive heart failure and cardiomyopathy, erectile dysfunction, male incontinence, autism, and diabetes.[74]

Another study of 15 websites by Ogbogu et al. in 2018 identified that physicians were then the dominant providers of unproven stem cell interventions in Canada, with seven in Ontario, three in Saskatchewan, two in Alberta, and one each in British Columbia, Quebec, and Nova Scotia.[75] The involvement of physicians who are licensed to practice medicine in Canada has important implications for regulation and governance in terms of the potential role for professional regulatory bodies. For example, one clinic specifically indicated that its physicians specialize in regenerative medicine, and the four physician biographies provided on the website suggested that they were licensed to practice medicine in Canada.[76] Ogbogu et al. also found that autologous adult stem cells were the most common stem cell intervention offered, for varied conditions including musculoskeletal issues, spinal cord injury, and diabetes. Some providers did not identify specific conditions, and others advertised stem cell interventions for stress, fatigue, and cosmetic or health enhancement. The authors observed an emphasis on the efficacy and benefits of treatment on these websites, with minimal to no discussion of risks or regulatory concerns.[77]

My data confirmed that clinic websites in Canada vary in the type and depth of information provided, including whether and how they address questions about approval status. Some websites provide limited information and invite potential candidates to contact them.[78] One Vancouver-based clinic's website explained that they do not store cells because "Health Canada requires that stem cell procedures are 'minimally manipulated … and further, that the stem cells are re-injected into the affected joint within 3 hours".[79] Another clinic marketing what it termed "investigational stage" autologous stem cell treatments provided the following response to a FAQ asking, "Is our procedure Health Canada Approved?":

> No. Like many investigational treatments, stem cell therapy has not yet been evaluated or approved by Health Canada. The OSCTC's surgical procedures fall under the category of the physician's practice of medicine, wherein the physician and patient are free to consider their chosen course of treatment. Obtaining Health Canada approval is a major goal of the Cell Surgical Network® and the Ontario Stem Cell Treatment Centre…Until such time as Health Canada has evaluated and approved stem cell

[74] *Ibid* at 649.
[75] Ubaka Ogbogu, Jenny Du & Yonida Koukio, "The involvement of Canadian physicians in promoting and providing unproven and unapproved stem cell interventions" (2018) 10 BMC Medical Ethics 32. This study also excluded any Health Canada-approved treatments.
[76] See e.g. Trimetrics, "kinetix" (last visited 27 May 2022), online: <www.trimetricsphysio.com/kinetix-prp-stem-cell-treatment-information/>. It is noteworthy that research comparing information on US stem cell clinic websites to state licensing medical board databases suggests many physicians providing stem cell interventions are acting outside their scope of training. Wayne Fu et al. "Characteristics and Scope of Training of Clinicians Participating in the US Direct-to-Consumer Marketplace for Unproven Stem Cell Interventions" (2019) 321:4 J American Medical Assoc 2463. To my knowledge, there is no similar research to-date on physicians practising in the Canadian market.
[77] Ogbogu, Du & Koukio, *supra* note 75.
[78] See e.g. Toronto PRP and Stem Cell, "Stem Cell Injections" (last visited 1 October 2020), online: <www.torontoprpandstemcell.ca/stem-cell-injections/>.
[79] See e.g. Trimetrics, "kinetix" (last visited 27 May 2022), online: <www.trimetricsphysio.com/kinetix-prp-stem-cell-treatment-information/>.

> treatments in Canada, our treatments are considered to be in the investigational stage. Each treatment is part of an ongoing investigation to track optimal parameters for treatment, to evaluate for effectiveness and adverse effects. It is essential that patients understand they are participating in these investigational (research) analyses.[80]

This excerpt illustrates the inconsistencies in many such public-facing communications by clinics that simultaneously claim the treatments they provide do not fall under Health Canada's authority, while indicating they are pursuing Health Canada approval. It is important to note that despite the assertion made to the contrary in the above quotation, Health Canada does exercise oversight over investigational health products via the *Food and Drugs Act* (discussed below). It is also far from settled that the interventions described by this clinic should be characterized as surgical procedures and part of the practice of medicine.

7.2 Regulatory and governance analysis

The potential risks associated with access to unproven stem cell interventions have prompted calls for improved oversight,[81] and a wide range of responses in jurisdictions around the world including shutting down clinics,[82] new regulatory regimes,[83] and use of professional discipline,[84] among others. The United States Food and Drug Administration (FDA) has been increasingly active in its enforcement efforts.[85] Even Google responded by implementing a policy seeking to restrict advertising of "unproven or experimental medical techniques such as most stem cell therapy, cellular (non-stem) therapy, and gene therapy".[86] Many of these efforts have been applauded, but the market for unproven stem cell interventions has continued to grow and diversify.[87] More recent work has focused on the need for a broader variety of regulatory and governance strategies including professional guidelines, accreditation, use of consumer

[80] Ontario Stem Cell Treatment Centre, "FAQ" (last visited 28 October 2020), online: <https://stemcellrepair.ca/faq/>.

[81] See e.g. Cynthia Cohen & Peter Cohen, "International stem cell tourism and the need for effective regulation" (2010) 20:1 Kennedy Institute Ethics J 27; see also Kurt Gunter et al, "Cell therapy medical tourism: Time for action" (2010) 12:8 Cytotherapy 965. This early work focused on calls for better information and education for patients, heightened responsibilities for cell therapy investigators and physicians, coordinated efforts from governance actors including the International Society for Cellular Therapy and the International Society for Stem Cell Research, including both information-based measures for patients and caregivers, as well as leveraging expertise to promote global regulatory harmonization.

[82] See e.g. Gretchen Vogel, "Authorities Shut Controversial German Stem Cell Clinic", *Science* (10 May 2011), online: <www.sciencemag.org/news/2011/05/authorities-shut-controversial-german-stem-cell-clinic>.

[83] See e.g. Achim Rosemann & Margaret Sleeboom-Faulkner, "New regulation for clinical stem cell research in China: expected impact and challenges for implementation" (2015) 11:1 Regenerative Medicine 5.

[84] See e.g. General Medical Council. (2010). Re Dr Robert Theodore Henri Kees TROSSEL Reg. No. 6049460. Fitness to Practise Panel Minutes, online (pdf): <www.casewatch.org/foreign/trossel/sanction.pdf>.

[85] See e.g. United States Food & Drug Administration, "Advancing the Development of Safe and Effective Regenerative Medicine Products" (last modified 21 April 2021), online: <www.fda.gov/news-events/fda-voices/advancing-development-safe-and-effective-regenerative-medicine-products>.

[86] Google, "A new policy on advertising for speculative and experimental medical treatments" (2019), online: <support.google.com/google-ads/answer/9475042?hl=en>.

[87] Noted regulatory challenges associated with this growing market include: direct-to-consumer advertising via the internet; "regulatory loopholes" (e.g. minimal manipulation; surgical procedure exception); lack of harmonization, and patient activism. See Cohen & Simana, *supra* note 21 at 224.

protection and truth in advertising frameworks,[88] and residency requirements.[89] The market for unproven stem cell interventions is a global phenomenon that will likely require some degree of international cooperation. [90] However, the focus of this case study is on regulation and governance of access to unproven stem cell interventions in Canada. As such, in the analysis that follows I will draw on international activities only where necessary to frame the relevant context.

7.2.1 Actors and instruments

Similar to the chelation therapy and liberation therapy case studies, a range of regulatory and governance actors have exerted influence over access to unproven stem cell interventions in Canada using different instruments. In this section, I will review the most prominent actors, including the federal government via Health Canada, provincial government actors, colleges of physicians and surgeons, scientific organizations, patient advocacy and consumer protection groups, as well as "experts" and members of the research community. Courts and tribunals also played a role in interpreting and applying relevant laws and standards. Following a similar approach to the previous two case studies, I will loosely follow the responsive regulation pyramid concept to order my discussion of instruments,[91] starting with information as the least coercive, and moving to consider spending, professional standards and discipline, and finally legislation and related enforcement activities.[92]

Information-based instruments were used by several actors. On May 16, 2019, Health Canada released an advisory statement warning Canadians about the "potential health risks associated with unauthorized cell therapy treatments such as stem cell therapy".[93] It identified what it termed the "trend" of "for-profit clinics offering a process called 'autologous cell therapies,' which may also be offered to patients under other names, such as 'bone marrow aspirate concentration (BMAC) injections,' 'stromal vascular fraction (SVF),' or 'adipose-derived stem cells'", and emphasized that these interventions have not been proven to be safe or effective, notwithstanding contrary claims often made by providers. Health Canada's Policy Position Paper on Autologous Cell Therapy Products, updated in January 2020,[94] provided further clarification regarding the regulatory status of this form of stem cell intervention. There, Health Canada clarified that all cell therapies are "drugs" that fall under the regulatory regime

[88] Ubaka Ogbogu, "Combatting Unlicensed Stem Cell Interventions through Truthful Advertising Law: A Survey of Regulatory Trends" (2015-2016) 9 McGill JL & Health 311; see also Barbara von Tigerstrom, "Regulating the advertising and promotion of stem cell therapies" (2017) 12:7 Regenerative Medicine 815.
[89] Cohen & Simana, *supra* note 21 at 220; see also Timothy Caulfield & Blake Murdoch, "Regulatory and policy tools to address unproven stem cell interventions in Canada: the need for action" (2019) 20:51 BMC Medical Ethics doi.org/10.1186/s12910-019-0388-4.
[90] Lee et al, *supra* note 1. Lee et al. point to a role for the WHO. Discussions of the need for a global approach go back over a decade. See e.g., Carmel Shalev, "Stem Cell Tourism—A Challenge for Trans-National Governance" (2010) 10:5 American J Bioethics 40.
[91] John Braithwaite, "Types of responsiveness" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 117.
[92] It should be noted that the market for unproven stem cell interventions is still evolving. Most of my data were collected in the Fall of 2020, and thus may not capture more recent developments.
[93] Health Canada, "Advisory", *supra* note 9.
[94] Health Canada, "Position Paper", *supra* note 44.

established in the *Food and Drugs Act*[95] and the *Food and Drug Regulations*.[96] Health Canada also noted that autologous cell therapies offered outside that process carry potential life threatening or life altering risks.[97]

At the provincial level, AHS has also used online, information-based strategies to help the public understand what stem cells are, when and how they are used in transplants, and what the risks are.[98] It provided targeted information about stem cell treatments for osteoarthritis, clarifying that they are not an approved treatment in Canada and are still experimental, to be provided only in research contexts.[99] This focus is noteworthy because treatments for orthopedic and musculoskeletal indications (e.g. osteoarthritis, ligament and tendons, cartilage damage) were the most common offerings found on the Canadian market.[100] This document also noted the availability of stem cell treatments for osteoarthritis in other countries. It explained that safety depends on factors including how and where the cells are prepared and administered, along with whether autologous or allogenic cells are used.

Although well positioned to do so, few colleges of physicians and surgeons appear to have used information-based instruments to provide publicly available guidance regarding unproven stem cell interventions. In a 2019 edition of its newsletter, the College of Physicians and Surgeons of Saskatchewan reported having sought clarification from Health Canada about the "legal status of stem cell treatments" after receiving enquiries about "whether physicians can be involved in establishing clinics that provide stem cell therapies". It clarified that physicians can only use a stem cell therapy if Health Canada has granted market or clinical trial authorization.[101] In a different vein, the College of Physicians and Surgeons of British Columbia included a stem cell case study in its 2017 Education Day, the theme of which was: "Twenty-first century challenges: informing medical practice in an era of increasing complexity and rising expectations". [102] The hypothetical patient pursued stem cell injections for his osteoarthritic knee after seeing media reports of professional athletes doing so. Citing the alternative medicine

[95] *Food and Drugs Act*, RSC 1985, c F-27.
[96] *Food and Drug Regulations*, CRC, c 870. There is an exception for lymphohematopoietic cells, derived from bone marrow, peripheral blood or cord blood and islet cells, which have been minimally manipulated and are intended for homologous use in transplantation. These are governed by the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, SOR/2007-118.
[97] Health Canada, "Position Paper", *supra* note 44 at Statement 3.
[98] Alberta Health Services, "Allogeneic SC Transplant", *supra* note 10.
[99] Alberta Health Services, "Stem Cell Treatment for Osteoarthritis" (last modified 27 Feb 2020), online: *MyHealth.Alberta* <myhealth.alberta.ca/Alberta/Pages/stem-cell-treatment-for-osteoarthritis.aspx> [Alberta Health Services, "Osteoarthritis"]. This treatment is common among Canadian offerings of unproven stem cell interventions.
[100] Turner, "Marketing by Canadian businesses", *supra* note 72. Twenty-six of the thirty businesses studied offered these types of treatment.
[101] College of Physicians and Surgeons of Saskatchewan, "Stem Cell Therapies – Health Canada Requirements" (2019) 6:2 *DocTalk* 11, online (pdf): <www.cps.sk.ca/iMIS/Documents/Newsletters/DOCTALK%20Vol%206%20issue%201.pdf>.
[102] College of Physicians and Surgeons of British Columbia, "College Case Studies; 2017 Education Day and Annual General Meeting - Twenty-first century challenges: informing medical practice in an era of increasing complexity and rising expectations" (last visited 27 May 2022), online (pdf): <www.cpsbc.ca/files/pdf/2017-ED-AGM-College-Case-Studies.pdf>.

provisions of the *Health Professions Act*,[103] the case study concluded that physicians in British Columbia can provide unproven therapies as long as the patient is fully informed and the unproven therapy does not carry more risk than conventional care.

Other notable governance actors, including scientific organizations, have also sought to exert influence over the market for unproven stem cell interventions using information-based strategies. Internationally, the ISSCR released a series of guidelines for stem cell research and its clinical translation that have addressed the question of unproven stem cell interventions in an evolving manner.[104] The 2021 version emphasizes ISSCR's condemnation of "the administration of unproven stem cell-and other cell- and tissue-based interventions outside of the context of clinical research or medical innovation that is compliant with the guidelines".[105] For a brief time, the ISSCR also ran a website called "A Closer Look at Stem Cells", which was intended to curate information on clinics submitted by members of the public.[106] Although it lacks enforcement powers and is international in scope, ISSCR's activities are relevant because of its normative force within the stem cell research field and its ties to the Canadian stem cell research community.[107] Domestically, the Stem Cell Network has played a similar governance role using information-based instruments.[108] It commissioned a publicly available information paper outlining issues and concerns with stem cell treatments that have not been proven to be safe or effective.[109] It also funded development of a Patient Information Booklet titled, "What you need to know about stem cell therapies", which aimed to provide accessible information about stem cell research, prospective treatments, and the risks of unproven interventions, along with tips for how to spot unproven interventions and questions to ask about them.[110] CellCAN (a pan-

[103] *Health Professions Act*, RSBC 1996, c. 183 at s 25.4. This provision prevents the college from acting against a registrant solely because they provide non-standard of practice therapy, unless it poses a greater risk to health or safety than the prevailing treatment.

[104] International Society for Stem Cell Research, "Guidelines for the Conduct of Human Embryonic Stem Cell Research" (2006), online: <www.isscr.org/docs/default-source/all-isscr-guidelines/hesc-guidelines/isscrhescguidelines2006.pdf?sfvrsn=91f5f996_0>; International Society for Stem Cell Research, "Guidelines for the Clinical Translation of Stem Cells" (2008), online: <www.isscr.org/docs/default-source/all-isscr-guidelines/clin-trans-guidelines/isscrglclinicaltrans.pdf?sfvrsn=fd1fa5c8_6>; International Society for Stem Cell Research, "Guidelines for Stem Cell Research and Clinical Translation" (2016), online (pdf): <www.isscr.org/docs/default-source/all-isscr-guidelines/guidelines-2016/isscr-guidelines-for-stem-cell-research-and-clinical-translationd67119731dff6ddbb37cff0000940c19.pdf>.

[105] International Society for Stem Cell Research, "ISSCR Guidelines for Stem Cell Research and Clinical Translation" (2021), online: <www.isscr.org/docs/default-source/all-isscr-guidelines/2021-guidelines/isscr-guidelines-for-stem-cell-research-and-clinical-translation-2021.pdf?sfvrsn=979d58b1_4> [ISSCR, "2021 Guidelines"]. These Guidelines outline specific recommendations regarding requirements for stem cell based medical innovation (i.e. scientific rationale and justification, pre-clinical proof-of-principle evidence of safety and efficacy, procedure details, follow-up plan, peer review, etc.). See 3.5.2.

[106] The URL for this service was: www.closerlookatstemcells.org. This service was quickly closed following threats of litigation.

[107] The ISSCR has often had Canadian membership, including representation on the authorship groups for the Guidelines. See e.g. the 2021 Task Force membership, ISSCR, "2021 Guidelines", *supra* note 105 at 56.

[108] First established in 2001 as part of the Network of Centres of Excellence Program, the SCN is now a national non-profit organization, funded primarily by the federal government, that funds and advocates for stem cell and regenerative medicine research and medicine in Canada. See Stem Cell Network, "About us" (last visited 27 May 2022), online: <stemcellnetwork.ca/about-us/>.

[109] Lori Knowles, "Stem Cell Hype and the Dangers of Stem Cell 'Tourism'" (2014) *Stem Cell Network*, online: <www.stemcellnetwork.ca/index. php?page=patientbooklet&hl=eng>.

[110] Zubin Master & Timothy Caulfield, "Patient Booklet: What you need to know about stem cell therapies" (2014), online (pdf): <oirm.ca/wp-content/uploads/2018/07/sc_patient_booklet_feb_2014.pdf>.

Canadian not-for-profit organization that was established in 2014 as part of the Government of Canada's Networks of Centers of Excellence), has a "What you need to know" section on its website that covers basic information about cell therapies and clinical translation. This section includes a warning to "Beware of unproven therapies", with information on "How can you recognize frauds?".[111] And as another example, *CanChild (*a non-profit research and educational centre at McMaster University) published an information document titled "Current State of Stem Cell Treatments for Cerebral Palsy: A Guide for Patients, Families, and Service Providers".[112] A section on "Stem Cell Tourism" emphasized potential risks and urged caution.[113]

Some patient advocacy and consumer protection groups have issued similar cautions using information instruments. For example, the Parkinson Society of Canada released a statement in 2009 describing the state of stem cell research and its potential for treating Parkinson's. This statement included a section about "stem cell treatments available on the internet", cautioning that stem cell treatments must be approved by Health Canada to be used in a treatment context, and explaining that many treatments advertised online are unsupported by clinical evidence.[114] In 2016, the Saskatchewan Lung Association released a statement addressing Idiopathic Pulmonary Fibrosis (IPF) and Stem Cell based Therapies.[115] This statement clarified that stem cell therapies for IPF are still in early stages of clinical research, and that participation in clinical trials is the only access option available to patients. Cansumer, an independent online product recommendation service,[116] issued a notice on "Stem Cell Therapy in Canada", which provided basic information on what stem cell therapy is, what types of therapies are available, and questions that should be asked about "unapproved therapies".[117]

In addition to these organizational governance actors, a less readily identifiable yet still potentially influential set of actors has played a role in disseminating information about the market for unproven stem cell interventions. These actors include "experts" and members of research communities from varied fields including stem cell science, medicine, law, ethics, and policy, among others.[118] Although I did not undertake a comprehensive media analysis, I gathered and reviewed a sample of media coverage relating to unproven stem cell interventions

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[111] CellCAN Regenerative Medicine and Cell Therapy Network, "What you need to know" (last visited 24 May 2022), online: <www.cellcan.com/en/index.aspx?id=25>.
[112] Stephanie Beldick & Michael G. Fehlings, "Current State of Stem Cell Treatments for Cerebral Palsy: A Guide for Patients, Families, and Service Providers" (January 2017), online (pdf): *CanChild* <www.canchild.ca/system/tenon/assets/attachments/000/001/944/original/Stem_Cells_Update-Fehlings-Final.pdf>.
[113] *Ibid* at 5.
[114] Parkinson Society of Canada, "Stem Cell Research and Parkinson's Disease" (2009), online (pdf): <www.parkinson.ca/wp-content/uploads/stem-cells-Pamphlet-en.pdf>.
[115] Saskatchewan Lung Association, Breath, "Idiopathic Pulmonary Fibrosis (IPF) and Stem Cell based Therapies" (6 July 2016), online: <www.lungsask.ca/about-us/news-room/news/2016/07/idiopathic-pulmonary-fibrosis-ipf-and-stem-cell-based-therapies>.
[116] Cansumer, "What is Cansumer?" (last visited 24 May 2022), online: <cansumer.ca/>.
[117] Cansumer, "Stem Cell Therapy in Canada", (last modified 11 February 2021), online: <cansumer.ca/stem-cell-therapy-in-canada/> [Cansumer, "Stem Cell Therapy in Canada"].
[118] "Experts" is placed in quotation marks to acknowledge that expertise can be a contested concept and subject to various critiques including those related to allegations of bias and conflict of interest. For the purpose of the discussion in this chapter, individuals may fall within the category of "expert" if they are represented in a public forum (often a media article) as having special insight or experience that is framed as adding legitimacy to their perspectives.

available in Canada.[119] I identified three primary ways in which the media has been used as a vehicle by such actors to disseminate information to the public. First, groups of experts and members of research communities have shared their perspectives regarding the current state of stem cell research, concerns about unproven stem cell interventions, and recommendations for improved oversight. For example, one story highlighted the work of "a small group representing scientific communities from Canada and the U.S., as well as the government", led by Canadian stem cell scientist Dr. Fabio Rossi and Dr. Judy Illes, Professor of Neurology and Canada Research Chair in Neuroethics at the University of British Columbia. This group proposed development of a stem cell provider registry with requirements that enrolling clinics adhere to specific medical and ethical principles, including informed consent from patients to share their data for research.[120] Second, individual experts have used research results and other information to urge caution and highlight risks of unproven stem cell interventions.[121] For example, in response to Health Canada's initial enforcement efforts (discussed below), Timothy Caulfield, Canada Research Chair in Health Law and Policy, was quoted as suggesting there is a need for "careful oversight by the regulatory bodies, like the colleges of physicians and surgeons" as well as public support for enforcement efforts, including by submitting complaints to the Competition Bureau or through political advocacy.[122] Third, providers of unproven stem cell interventions have used media to promote their services and to advocate for access to unproven stem cell interventions in Canada. For example, Dr. Scott Barr, an Ontario physician and stem cell intervention provider, emphasized that stem cells should not be treated as drugs, arguing that plastic surgeons have been doing fat cell transfers for decades with a strong history of safety and efficacy.[123]

In contrast to the liberation therapy case study, I found few examples of organized advocacy surrounding access to unproven stem cell interventions. The Adaptive Canuck ALS Society is one group that used the media as well as political appeals via letters to MPs to advocate for access by way of both expanded clinical trials for stem cell treatments for ALS as well as introduction of "Right-to-Try" legislation.[124] Rights framing has also been used by some providers of unproven stem cell interventions to argue in favour of unrestricted access. In

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[119] For more detail on methods including data collection, see Chapter 3, Section 3.2.2.2, *above*.

[120] Fabio Rossi & Judy Illes, "Consensus is building on stem-cell therapies; Provider registry program and set of ground rules would further research, say Dr. Fabio Rossi and Dr. Judy Illes", *The Vancouver Sun* (11 October 2018), A.11.

[121] See e.g. Tom Blackwell, "Calls for crackdown on stem-cell therapy", *The National Post* (4 July 2017) A.1 [Blackwell, "Calls for crackdown"]; see also Brittany Flaherty, "Canada case highlights possible long-term risks of experimental stem cell therapy", *StatNews* (11 July 2019), online: <www.statnews.com/2019/07/11/canada-case-long-term-risks-experimental-stem-cell-therapy/>; see also Sheryl Ubelacker, "Gordie Howe's stem cell therapy raises concerns", *CTV News* (29 January 2015), online: <www.ctvnews.ca/health/gordie-howe-s-stem-cell-therapy-raises-concerns-among-medical-experts-1.2211179>.

[122] Sharon Kirkey, "Regulation of stem cell therapies urged", *The Sudbury Star* (7 August 2019) A.7. Caulfield is one of several high-profile researchers who have been featured in numerous media articles.

[123] Carol Mulligan, "Sudbury doc defies Health Canada order to stop performing stem cell treatment" (17 July 2019), online: <www.sudbury.com/local-news/sudbury-doc-defies-health-canada-order-to-stop-performing-stem-cell-treatment-1589149>.

[124] Ontario, *Journals of the Legislative Assembly*, 41-2 (29 March 2017) (Hon. Mr. Jeff Yurek). See also Joanne Laucius, "Terminally ill seek 'right to try' unofficial drugs", *Ottawa Citizen* (4 November 2016), A.3. Right to Try frameworks have also been used in the United States in connection with efforts to expand access to unproven stem cell treatments. See David T. Harris, ""My Right to Try": The Dangers of Unregulated Stem Cell Clinics" (2016) 8 Cell & Tissue Transplantation & Therapy 1 at 1.

response to a cease-and-desist letter from Health Canada, Dr. Barr was quoted as arguing that stem cell treatments are a patients' rights issue, suggesting that, "[o]nly the patient manufactures and owns the cells in their body, so the patient should have the right to decide what to do with them. No one else should have the right to deny them the use of their own property to alleviate pain or improve the quality of their life".[125] I also identified some forms of advocacy in favour of limiting access to unproven stem cell interventions. One notable example was a letter sent by the ISSCR to the federal Minister of Health, asking Health Canada to take steps to "rein in unscrupulous clinics marketing unproven therapies as stem cell treatments".[126] The information-based activities of individual members of the scientific research community discussed above could also arguably be considered a form of advocacy.

Spending is another instrument that regulatory and governance actors have used to limit access to unproven stem cell interventions in Canada. Unproven stem cell interventions available in Canada are not funded under provincial or territorial health insurance programs. Individuals who pursue these treatments are generally required to pay out-of-pocket, and the costs are often considerable. One Canadian clinic's website indicates that stem cell injections cost $8,500; this website clearly advises patients that treatments are not covered under the provincial health plan.[127] Out-of-country unproven stem cell interventions are also generally ineligible for provincial or territorial funding under their respective programs for health coverage outside Canada. As discussed below, funding denials for such interventions have typically been upheld on appeal. There is however a suggestion that some individuals may have received a form of government subsidy for the costs of pursuing unproven stem cell interventions out-of-country, by way of claiming those costs as a medical expense on their tax returns.[128] Other governance actors, such as the Stem Cell Network, have used research funding to advance knowledge about this issue and to encourage dissemination of that knowledge to relevant stakeholder groups, including via engagement with government, professional regulatory bodies, clinicians, patient representatives, and the public more broadly.[129] It is likely that this funding has helped develop the community of researchers from varied disciplines who have engaged in the information-based governance activities discussed above.

Operating at a higher level of coerciveness, all provincial colleges of physicians and surgeons across Canada have policies and practice standards that, though not specific to these interventions, are relevant to the marketing and provision of unproven stem cell interventions, such as rules regarding advertising, participation in research, and complementary and alternative medicine. Some of these existing policies and standards appear to permit physicians to provide

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[125] Mulligan, *supra* note 123. It is not clear that individuals have property rights in their cells and tissues. For a more in-depth discussion of the complexity of the law surrounding property rights and the body, see Erin Nelson, "Law and the Body" in Joanna Erdman, Vanessa Gruben & Erin Nelson, eds. *Canadian Health Law and Policy,* 5th ed (LexisNexis Canada, 2017) 427.

[126] International Society for Stem Cell Research, "Letter to the Honourable Ginette Petitpas Taylor, minister of health" (2018), online: <www.isscr.org/docs/ default-source/policy-documents/isscr-letter-re-canada's-regulation-of-celltherapies-june-2018.pdf?sfvrsn=2>, cited in Caulfield & Murdoch, *supra* note 89.

[127] Trimetrics, "kinetix" (last visited 27 May 2022), online: <www.trimetricsphysio.com/kinetix-prp-stem-cell-treatment-information/>.

[128] Tom Blackwell, "Unproven treatments get indirect subsidies; Tax credits given for foreign health procedures", *National Post* (29 November 2010) A.1.

[129] In the interest of transparency, I acknowledge that I have previously received research funding from the Stem Cell Network.

unproven stem cell interventions in some circumstances or, at the very least, create ambiguity in this domain.[130] The College of Physicians and Surgeons of Alberta has stem cell-specific standards. The College of Physicians and Surgeons of Alberta issued Stem Cell Regenerative Therapy Standards in November, 2017 to supplement the College of Physicians and Surgeons of Alberta standards for *Non-Hospital Surgical Facilities,* and to operate alongside Health Canada requirements for cell therapy products.[131] These standards specify that physicians are only permitted to provide services involving Adipose-Derived Stem/Stromal Cells (considered to be a type of liposuction surgical procedure) and Bone Marrow Aspirate Concentrate (considered to be a type of bone marrow biopsy surgical procedure) in a non-hospital facility in Alberta that is accredited by the College of Physicians and Surgeons of Alberta, while noting that accreditation does not imply College of Physicians and Surgeons of Alberta-endorsement of the therapy. Physicians providing regenerative therapies must be "licensed to practice medicine in Alberta, be a certified specialist with training in regenerative therapy, and have evidence of appropriate and sufficient training with experience that is suitable to the Registrar".[132] Only minimally manipulated autologous cells can be used, they cannot be compounded or administered with other substances, and the entire procedure (stem cell collection, separation and administration) must occur in the operating room, with the patient present, and within 3 hours of collection.[133] In September 2018, the Council of the College of Physicians and Surgeons of Saskatchewan approved a related policy on performing office-based non-insured procedures, which may include "Peripheral stem cell injection as approved by Health Canada". This policy requires physicians to obtain college approval for the appropriate scope of practice; it also states that "Physicians are expected to practise evidence-based medicine, and to maintain a level of understanding of the available evidence supporting the procedure as it evolves".[134]

Legislation is often situated at the top of the responsive regulation pyramid for its coercive power, particularly when accompanied by criminal sanctions.[135] Canada has an extensive regulatory regime governing drug therapies and the use of human cells which operates under the legislative authority of the federal *Food and Drugs Act*, with its *Food and Drug Regulations, Safety of Human Cells, Tissues and Organs for Transplantation Regulations,* and *Medical Devices Regulations.*[136] There is a rich body of work addressing the nuances of how this regime applies to different forms of cell therapies, including stem cell interventions, and exploring important questions regarding its limitations and the merits of alternative approaches.[137] Health Canada itself has acknowledged that the individualized nature of

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[130] Carly Weeks, "Stem-cell clinic plans to defy Health Canada order to stop offering injections to patients", *The Globe and Mail (*10 July 2019), A.1.
[131] College of Physicians and Surgeons of Alberta, "Stem Cell Regenerative Therapy Standards" (30 November 2017), online (pdf): <httcpsa.ca/wp-content/uploads/2020/06/Stem-Cell-Regenerative-Therapy-Standards.pdf>.
[132] *Ibid* at 2.1, 2.5, 2.7.
[133] *Ibid* at 11.
[134] College of Physicians and Surgeons of Saskatchewan, "Policy: Performing Office-based Non-insured Procedures" (approved September 2008, amended September 2019), online: <www.cps.sk.ca/imis/CPSS/CPSS/Legislation__ByLaws__Policies_and_Guidelines/Legislation_Content/Policies_and_Guidelines_Content/Performing_Office-based_Non-insured_Procedures.aspx>.
[135] Braithwaite, *supra* note 91 at 117-118.
[136] *Food and Drugs Act*, RSC 1985, c F-27; *Food and Drug Regulations*, CRC, c 870; *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, SOR/2007-118; *Medical Devices Regulations*, SOR/98-282.
[137] See e.g. Sowmya Viswanathan & Tania Bubela, "Current practices and reform proposals for the regulation of advanced medicinal products in Canada" (2015) 10:5 Regenerative Medicine 647.; Barbara von Tigerstrom,

autologous cell therapy products presents a regulatory challenge.[138] Comparative international work has offered particular value in efforts to identify potential lessons for Canada in how we might move forward with regulatory reform.[139] As part of broader reform initiatives started in 2017,[140] Health Canada has been engaged in regulatory review processes including development of a new regulatory pathway to enable "advanced therapeutic products", defined as "drugs or devices that our current regulations were not designed to handle because they're so novel, complex and distinct".[141] Although this work is relevant to the research presented in this thesis, my focus is on understanding regulatory and governance responses to unproven stem cell interventions that are provided outside or in contravention of the existing regime.

One of the critiques levied against Canada's existing oversight regime was that it created a gap or, at the very least, ambiguity regarding oversight of autologous, minimally manipulated

"Product Regulation and the Clinical Translation of Stem Cell Research" (2009) 5 Stem Cell Rev 135; Anthony Ridgway, "The regulation of cell therapy products in Canada" (2015) 43 Biologicals 406; Anthony Ridgway et al, "Regulatory Oversight of Cell and Gene Therapy Products in Canada" (2015) in M.C. Galli & M. Serabian, eds, *Regulatory Aspects of Gene Therapy and Cell Therapy Products, Advances in Experimental Medicine and Biology* 871, doi 10.1007/978-3-319-18618-4_3; Tania Bubela et al, "Bringing regenerative medicines to the clinic: the future for regulation and reimbursement" (2015) 10:7 Regenerative Medicine 897. Bubela et al. discuss the potential in novel adaptive licensing practices.

[138] With such interventions, it is suggested that "the process is the product". See Health Canada, "Position Paper", *supra* note 44.

[139] For a comparison and critique of regulatory approaches in the United States, Canada, Japan, Australia, and Europe, see Barbara von Tigerstrom, "New Regulatory Pathways for Stem Cell-Based Therapies: Comparison and Critique of Potential Models" in Phuc Van Pham & Achim, eds, *Safety, Ethics and Regulations; Stem Cells in Clinical Applications* (Springer, 2017) 173; for a discussion of potential lessons Canada could draw from regulatory approaches in Australia and Europe, see Barbara Von Tigerstrom, "Revising the Regulation of Stem Cell-Based Therapies: Critical Assessment of Potential Models" (2015) 70:2 Food & Drug LJ 315. For a comparison of the EU with nine additional countries, see Tingting Qiu et al, "Regenerative medicine regulatory policies: A systematic review and international comparison" (2020) 124 Health Policy 701. See also Tamra Lysaght et al, "Ethical and Regulatory Challenges with Autologous Adult Stem Cells: A Comparative Review of International Regulations" (2017) 14 Bioethical Inquiry 261. Lsaght et al. review the regulatory systems in Australia, Japan, Singapore, the United Kingdom, and the United States. See also Anjali Nagpal et al, "Stem cell therapy clinical research: A regulatory conundrum for academia" (2017) 122 Advanced Drug Discovery Reviews 105. Anjali et al. review the regulatory pathways in the US, the EU, Japan, Canada, and Australia.

[140] See Health Canada, "Health and Biosciences: Targeted Regulatory Review – Regulatory Roadmap" (last modified January 2021), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review/roadmap.html> [Health Canada, "Regulatory Roadmap"]. 2017 marked the launch of "R2D2", Health Canada's Regulatory Review of Drugs and Devices, with the goal of developing a regulatory system "that provides greater and faster access to therapeutic products that are better aligned with healthcare system needs".

[141] Government of Canada, "Regulatory innovation for health products: Enabling advanced therapeutic products" (last modified 2 February 2021), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/strategies-initiatives/health-products-food-regulatory-modernization/advanced-therapeutic-products.html>.

cell products,[142] intended for homologous use.[143] In the position paper noted above,[144] Health Canada clarified that autologous cell therapies are considered to be drugs and subject to both the clinical trial and new drugs requirements of the *Food and Drugs Act*.[145] In what was described in media as a "crackdown", Health Canada also sent cease-and-desist warning letters to clinics treating patients in Canada with unauthorized stem cell interventions.[146] Though details on individual cases are not publicly available, media reports covering these developments cited Health Canada representatives discussing use of "site visits, public communications, recalls, and seizing products and advertising materials" and potential charges under the *Food and Drugs Act*.[147] Responses to these enforcement activities and how they relate to regulatory legitimacy are discussed further below, in Section 7.2.3.

As was discussed in Chapter 5, courts and tribunals play an important role in interpreting and applying the law. Through my data collection, I identified two notable lines of jurisprudence affecting access to unproven stem cell interventions: questions of funding under different regimes, and professional discipline. Some of these cases involve unproven stem cell interventions offered outside Canada. However, they are relevant to this work insofar as they impact domestic regulation and governance activity, and where they contribute to how evidence is constructed and interpreted in this domain.

Funding for unproven stem cell interventions has been sought as part of damage claims in negligence lawsuits. The reasonableness of damage claims for stem cell treatments has only been considered in a handful of Canadian tort cases.[148] In *Morrison v. Greig*[149], the Plaintiff suffered spinal cord injury from a car accident. The court awarded $74,714 in special damages for a stem cell treatment in Portugal, finding that it was a "reasonably foreseeable procedure with a

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[142] Cells are minimally manipulated when "the processing does not alter the biological characteristics that are relevant to their claimed utility". Health Canada, "Clinical Trial Guidance", *supra* note 6.
[143] Homologous use is when the "cell, tissue or organ performs the same basic function after transplantation". *Ibid*. For discussion of the noted gap or ambiguity, see Jolene Chisholm, Crystal Ruff & Sowmya Viswanathan, "Current state of Health Canada regulation for cellular and gene therapy products: potential cures on the horizon" (2019) 21 Cytotherapy 686 at 687; see also Ridgway, *supra* note 137 at 408. It is noteworthy that at the time of writing, Ridgway was with the Biologics and Genetic Therapies Directorate, Health Products and Foods Branch, Health Canada; see also Anthony Ridgway et al, *supra* note 137.
[144] Health Canada, "Position Paper", *supra* note 44.
[145] Part C, Divisions 5 and 8, respectively. See also Health Canada, "Clinical Trial Guidance", *supra* note 6.
[146] Health Canada, "Advisory", *supra* note 9. For media coverage of this 'crackdown', see Avis Favaro, Elizabeth St. Philip & Nicole Bogart, "Debate over Health Canada crackdown on stem cell therapies", *CTV News* (13 July 2019), online: <www.ctvnews.ca/health/debate-over-health-canada-crackdown-on-stem-cell-therapies-1.4507220>; see also Carly Weeks, "Health Canada in 'overdue' crackdown on unproven stem-cell based treatments", *The Globe and Mail* (7 July 2019), online: <www.theglobeandmail.com/canada/article-health-canada-in-overdue-crackdown-on-unproven-stem-cell-based/>.
[147] Mia Jensen, "City doctor, Health Canada at odds; 'Stem cells are safe. We've done over 150 treatments and we've never had an adverse event'", *Sudbury Star* (12 July 2019), A.1. Health Canada representatives cited in media reports suggested case-specific information could not be shared when investigations were ongoing. See Sharon Kirkey, "Canada slow to act against shoddy stem cell therapies, new paper argues", *The National Post* (6 August 2019), online: <nationalpost.com/news/canada-slow-to-act-against-shoddy-stem-cell-therapies-new-paper-argues>.
[148] Research published in 2018 exploring the use of civil litigation as a means for patients harmed by unproven stem cell interventions to seek redress similarly identified only a handful of lawsuits (nine individual and class action lawsuits in total). See Claire Horner et al, "Can civil lawsuits stem the tide of direct-to-consumer marketing of unproven stem cell interventions" (2018) 3:1 NPJ Regenerative Medicine 1.
[149] [2007] OJ No 225 (SC).

reasonable likelihood of success".[150] The court was satisfied that the plaintiff's subsequent ability to crawl was due to the stem cell therapy. The court's reasons do not explain why the court was persuaded that the stem cell treatment would have a reasonable likelihood of success, notwithstanding the lack of expert evidence regarding the stem cell treatment, or why the plaintiff's improvements should be attributed to it as opposed to the intensive rehabilitation program he also completed. *Morrison v. Greig* is an anomaly in the jurisprudence on this issue.

In subsequent decisions, courts were less inclined to accept the reasonableness of unproven stem cell treatments. In *Sturgess v. McIntyre*[151], an application for summary judgment regarding damages following a motor vehicle injury that included $100,000 for two stem cell treatments in Panama, the court held that the "reasonableness and likelihood of these items should be the subject of oral evidence and tested by cross-examination".[152] *Kirby v. Loubert*[153] was another claim for damages for personal injuries following a motor vehicle accident. The plaintiff had pursued "extreme measures" including stem cell treatments in Mexico.[154] The court found that the stem cell therapy proved unhelpful, and did not allow the claim for related expenses.[155] Finally, in *Qiao v. Owners, Strata Plan LMS 3863*[156], the Plaintiff suffered injury following an incident with a security guard and pursued a stem cell treatment in China, at a cost of $100,000. A medical expert in physical medicine and rehabilitation testified that the stem cell therapy "either had no proven use or provided only short term use benefits in treating chronic pain, neurological disorders and/or musculoskeletal soft tissue disorders".[157] The court refused the Plaintiff's claim for damages of over $6 million for future stem cell therapy costs, holding that it was unsupported by any evidence, that there was no medical justification for such a course of treatment, and the claim was unreasonable.[158]

In a different funding context, courts have considered appeals from denials of provincial coverage for out-of-country stem cell treatments. As discussed in Chapters 4 and 5, these decisions are made pursuant to provincial legislation which establishes criteria for funding eligibility.[159] For example, *AD v The General Manager, Ontario Health Insurance Plan*[160] was an appeal from a decision of the General Manager of the Ontario Health Insurance Plan (OHIP) denying funding for an out-of-country stem cell treatment for advanced neuroblastoma, a rare cancer that was resistant to standard therapy. Medical experts testified in favour of this treatment, which was approved in Europe and provided at the Children's Hospital of Philadelphia. The appeal board found that the treatment was not considered experimental in Ontario; it was accepted for someone in the appellant's condition, but was not available in the province. Accordingly, the treatment was eligible for provincial funding pursuant to the legislation and the

[150] *Ibid* at para 109.
[151] [2016] S.J. No. 210 (Q.B.).
[152] *Sturgess v McIntyre*, [2016] S.J. No. 210 (Q.B.) at para 72.
[153] [2018] B.C.J. No. 565 (S.C.).
[154] *Ibid* at para 18.
[155] *Ibid* at para 184.
[156] 2020 BCSC 818 (S.C.).
[157] *Ibid* at para 269.
[158] *Ibid* at para 376.
[159] See discussion on Ontario, Ministry of Health and Long-Term Care, "Ontario Health Insurance Plan; Out of Country Prior Approval Program" (last modified 13 November 2018), online: <www.health.gov.on.ca/en/public/programs/ohip/outofcountry/prior_approval.aspx>.
[160] 2005 CanLII 76941.

appeal board ordered OHIP to provide funding. This case serves as an example of the approach taken for treatments that, while not available in a Canadian province, do not fall into the 'unproven' category considered in this research because they are accepted as standard of care.

By way of contrast, in *E.T. v. The General Manager, Ontario Health Insurance Plan*[161], the Appellant sought stem cell therapy in Germany for congestive heart failure and ischemic cardiomyopathy. The ON HSARB accepted expert submissions that this treatment is not generally accepted in Ontario as appropriate in the Appellant's circumstances. It held that the stem cell treatment is not an insured service and denied the appeal.[162] Under the Ontario legislative framework, the OHIP bears the burden of establishing on a balance of probabilities that a treatment is experimental. A treatment is not experimental when "the effects of that treatment [are] known and understood …. [it] is accepted within the medical community and is proven to induce a clinical benefit".[163] Where there is conflicting expert opinion indicating the question is a matter of contention, it is unlikely that burden will be satisfied.[164]

The question of coverage for stem cell treatments has also been considered under Worker's Compensation regimes. Similar to the jurisprudence reviewed thus far, the weight of evidence and expert opinion played a determinative role in the decisions I reviewed. For example, the Appeals Commission for Alberta Workers' Compensation considered whether a worker was entitled to funding for stem cell therapy to treat a knee injury, including the costs of an initial consultation,[165] The Appeals Commission found that "the weight of medical evidence indicates that stem cell treatment is non-standard, not generally accepted and experimental medical aid".[166] In so finding, the Appeals Commission considered evidence from the treating surgeon that the stem cell therapy was experimental and not standard practice in Alberta. The WCB does cover non-standard, not-generally accepted, and experimental treatments if certain criteria are met. Here, it was not clear that all conventional medical treatments had been tried or were not medically appropriate, "and there was insufficient evidence to indicate the proposed intervention has a positive effect or can be expected to produce the intended effects in this particular case".[167]

A similar result was reached in another appeal before the Appeals Commission for Alberta Workers' Compensation where an injured worker sought coverage for stem cell and platelet-rich plasma (PRP) treatment.[168] A physician and an orthopedic specialist gave evidence that PRP and stem cell injections are experimental or unproven. The panel concluded that the worker was not entitled to compensation.[169] Conversely, funding for both "bone marrow stem cell regeneration procedure" and PRP to treat a knee injury and aggravation to pre-existing osteoarthritis was awarded in a funding denial appeal before the British Columbia Worker's

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[161] 2009 CanLII 85019 (ON HSARB).
[162] *E.T. v The General Manager, Ontario Health Insurance Plan*, 2009 CanLII 85019 (ON HSARB) at paras 1-3.
[163] *S.C.W. v The General Manager, The Ontario Health Insurance Plan*, 2008 CanLII 87348 at 7 [*S.C.W.*]; see also *R.E. v The General Manager, The Ontario Health Insurance Plan*, 2016 CanLII 20524 (ON HSARB).
[164] *S.C.W., supra* note 163 at 21.
[165] *2017-0202 (Re)*, 2017 CanLII 21761 (AB WCAC).
[166] *Ibid* at para 19.
[167] *Ibid* at paras 22-24. The appeal was denied; subsequent application for reconsideration was also denied. *2017-0640 (Re)*, 2017 CanLII 81204 (AB WCAC).
[168] *2019-0001 (Re)*, 2019 CanLII 30462 (AB WCAC) at para 8.
[169] *Ibid* at paras 13-15.

Compensation Appeal Tribunal.[170] The treatment was acknowledged as experimental by the worker's general practitioner, who nonetheless recommended it noting that it holds promise for soft tissue repair. The guiding policy directs the Board to consider scientific evidence regarding treatment effectiveness as part of its approval decisions,[171] and the policy regarding Conflict of Medical Opinion directs that where there are differences of medical opinion or conflicts of medical evidence, the Board must analyze them and determine where it thinks the preponderance of evidence lies.[172]

There are few publicly available professional discipline decisions addressing provision of unproven stem cell interventions. Practice restrictions were imposed by way of undertaking and consent on at least one physician in Ontario following allegations of professional misconduct and/or incompetence in his practice of family and complementary medicine. The physician undertook to "cease to engage in the practice of stem cell therapy" and to post a visible sign in his offices stating that "Dr. Hui must not engage in the practice of stem cell therapy. Further information may be found on the College of Physicians and Surgeons of Ontario website at www.cpso.on.ca".[173] No details are available on the specifics of the complaint. In *Krause (Re)*[174], Dr. Krause was found to have demonstrated incapacity or unfitness to practice medicine through her involvement in recruitment and treatment of patients using a combination of liberation therapy and stem cell injections. Treatment was provided in India under the auspices of a clinical research study. As noted in Chapter 5, this decision emphasizes the importance of physicians distinguishing between research and treatment, and of meeting the standards of practice for managing conflicts of interest as well as for providing non-traditional therapies.

In addition to requirements regarding the care that is provided, physicians also have obligations with respect to the location of care. In *Ontario (College of Physicians and Surgeons of Ontario) v. Bélanger*[175], a family physician provided pain management treatments to patients at a clinic that was not an approved outside hospital premises location, as required under the regulation pursuant to the *Medicine Act, 1991*. Dr. Bélanger agreed to the facts and admitted professional misconduct. The Committee awarded a 5-month suspension, and specifically highlighted its goal of deterrence, of protecting the public, and of maintaining the integrity of the profession and public confidence in the College's ability to regulate in the public interest.[176] Although not addressing stem cell treatments, this decision may be instructive precedent for physicians who provide unproven stem cell treatments in unlicensed clinics.

Overall, as found with respect to liberation therapy, my review of relevant jurisprudence in this case study indicates that courts and administrative tribunals have generally approached issues related to unproven stem cell interventions in a consistent manner, following past precedent and the principles of statutory interpretation. In so doing, they have relied to a large extent on the testimony of medical experts, particularly with respect to whether the treatments at

[170] *A1700807 (Re)*, 2018 CanLII 74791 (BC WCAT). This was an appeal by rehearing.
[171] *Ibid* at para 45.
[172] *Ibid* at para 48.
[173] College of Physicians and Surgeons of Ontario, "Hui, Frederick", CPSO#:31602 (last visited 27 May 2022), online: <doctors.cpso.on.ca//Doctor-Details-Print.aspx?view=5&id=31602&ref-no=0026779>.
[174] *Krause (Re)*, 2019 LNMBCPS 1 (Manitoba College of Physicians and Surgeons). This case was discussed in more detail in Chapter 6.
[175] 2018 ONCPSD 18.
[176] *Ibid*.

issue were experimental or a generally accepted form of treatment. This was true even where the treatment was supported by the patient's regular physician.[177] This finding runs contrary to the concern that without appropriate policies and regulations, policy will be developed by the courts which may have "a propensity to be swayed by persuasive and emotional arguments", rather than scientific expertise.[178] Although *Morrison v. Greig* may stand as one example of this concern, in general it was not borne out by the data in this case study.

7.2.2 Clarity of purpose

As with the previous two case studies, a central aspect of my analysis of regulation and governance of access to unproven stem cell interventions in Canada involved considering the prevailing purposes or goals that appear to have motivated or driven the exercise of influence by different actors. I identified three primary goals or purposes underlying regulatory and governance responses to unproven stem cell interventions in Canada: (i) promotion and protection of health, with the sub-goal of risk mitigation or avoidance, (ii) education and empowerment of patients, and (iii) promotion of research and clinical innovation.

For example, Health Canada's mission and vision include "helping the people of Canada maintain and improve their health".[179] Health Canada's responsibilities include ensuring the safety, efficacy and quality of drug products and medical devices before they are authorized for sale in Canada. This focus on safety, efficacy and quality is emphasized in public-facing forums such as Health Canada's website,[180] and in informational materials including the stem cell-specific instruments reviewed above.[181] Health Canada further emphasized its focus on mitigating risk to patients in media statements regarding its enforcement actions against clinics that advertise and sell unproven stem cell interventions.[182] There is also some evidence to suggest that promoting safety and mitigating risk are drivers supporting the broader mandate of medical regulatory bodies to act in the public interest. In *Ontario (College of Physicians and Surgeons of Ontario) v. Bélanger*, the Discipline Committee acknowledged that provision of healthcare in clinics and private facilities is increasing, and suggested that "[i]t is in the public interest, and that of physicians, that there be no question that wherever that care is provided the requisite standards are established, monitored and maintained".[183] When discussing penalty, the Committee emphasized the importance of maintaining "the integrity of the profession and public confidence in the College's ability to regulate in the public interest".[184] Although this emphasis on protection and promotion of health, including via managing risks, is laudable, other aspects of

[177] See e.g. *S.C.W.*, *supra* note 163.
[178] Kirsten Matthews & Ana S. Iltis, "Unproven stem cell–based interventions and achieving a compromise policy among the multiple stakeholders" (2015) 16 BMC Medical Ethics 75 [Matthews & Iltis, "Compromise policy"].
[179] Health Canada, "About Mission, Values, Activities" (last modified 12 October 2011), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/mission-values-activities.html>.
[180] See e.g. Health Canada, "Drug products" (last modified 2 March 2022), online: <www.canada.ca/en/health-canada/services/drugs-health-products/drug-products.html>.
[181] Health Canada, "Position Paper", *supra* note 44.
[182] Jensen, *supra* note 147.
[183] *Ontario (College of Physicians and Surgeons of Ontario) v Bélanger*, 2018 ONCPSD 18 at para 8. As noted earlier, this case concerned provision of care in non-licensed facilities and did not include stem cell interventions. It is however instructive precedent given that many unproven stem cell interventions are provided in the kind of treatment context addressed in this case.
[184] *Ibid* at para 30.

regulatory and governance responses, including timing, instrument selection and enforcement, suggest different priorities may have played a larger role in guiding some responses.

Many information-based regulatory and governance instruments were focused on educating their audiences about stem cell research realities and the risks of unproven interventions, with the apparent goals of empowering people to make informed decisions and managing expectations.[185] For example, the Parkinson Society of Canada's information booklet stated that it "has been prepared to help you become more informed about stem cell research. It is designed to answer questions about the status of stem cell research in relation to Parkinson's disease and what is currently known about therapies".[186] Another Patient Booklet explained that it was designed to answer questions about stem cell research and unproven treatment options to help readers "make more informed decisions".[187] A guide tailored to parents of children with cerebral palsy explained the key hurdles that need to be overcome in order to develop safe and effective stem cell treatments, including avoiding the risk of tumour formation and improving cell survival and differentiation after transplantation.[188] It emphasized the importance of managing "expectations of stem cell therapies" and being patient with the research process.[189]

Two unstated assumptions seem to underpin this focus on education and empowerment. The first is that people will continue to have unsanctioned private market options available, whether domestically or internationally. Though pragmatic, this assumption risks being taken as acceptance that regulatory and governance efforts to reduce or eliminate such markets will prove unsuccessful. Second, the goal rests in part on a type of information deficit model, which presumes that if people have deeper understandings about the science, the outstanding questions about interventions being offered, and about their risks, they will be disinclined to pursue them. However, the limits of assumptions based on information deficit models of this nature are increasingly emphasized in health and science communication.[190] There is also a growing body of work that looks at the power of hope as a motivating force behind pursuit of unproven interventions, one that is not necessarily impacted by traditional forms of evidence.[191]

Finally, there have also been innovation-based imperatives at play, meaning the desire to promote development of new and improved therapeutic alternatives. For example, in relation to

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[185] See e.g. Cansumer, "Stem Cell Therapy in Canada", *supra* note 117. This consumer information emphasized that there are many questions to consider when thinking about stem cell therapy and suggested: "It is important for the patient to have all of the information and understand the risks involved with the procedure when speaking with their doctor." See also Saskatchewan Lung Association, Breath, *supra* note 115. This document explains the need for further research to determine both benefits and risks of stem cell therapies for idiopathic pulmonary fibrosis.
[186] Parkinson Society of Canada, *supra* note 114.
[187] Master & Caulfield, *supra* note 110 at 4. This booklet also included information about questions to ask regarding unproven interventions, understanding the role of patient testimonials in promoting or advertising unproven interventions, identifying potential risks, and common misunderstandings (e.g. regarding safety of cells from one's own body).
[188] Beldick & Fehlings, *supra* note 112 at 5.
[189] *Ibid* at 7-8.
[190] See e.g. Brianne Suldovsky, "In science communication, why does the idea of the public deficit always return? Exploring key influences" (2016) 25:4 Public Understanding Science 415.
[191] Alan Petersen & Kate Seear, "Technologies of hope: techniques of the online advertising of stem cell treatments" (2011) 30:4 New Genetics and Society 329; see also Charles Murdoch & Chris Scott, "Stem cell tourism and the power of hope" (2010) 10:5 American J Bioethics 16; see also Julie Robillard et al, "Fueling hope: stem cells in social media" (2015) 11:4 Stem Cell Revs & Reports 540; see also Petersen, Seear & Munsie, *supra* note 31.

the regulatory review process discussed earlier, Health Canada emphasized the dual goals of protecting the health and safety of Canadians while also supporting regulation that allows for "the adoption of promising new therapies" and does not "stifle innovation that could improve the health of Canadians".[192] The question of unproven stem cell interventions does not appear to have made it onto political agendas to any widespread degree and there were few relevant discussions in Hansard records.[193] However, there were discussions regarding the potential and value of stem cell research more broadly, both in therapeutic and economic terms.[194] These comments from the Ontario Hansard serve as one example:

> Stem cell research is laying a pathway towards better therapies and the cures for chronic diseases. Just recently, I was in the Ontario Institute for Regenerative Medicine, where I announced a $25-million investment by our government in support of research in treatments and therapies for chronic diseases such as multiple sclerosis, cancer and diabetes. This funding will support the institute in revolutionizing treatments and making Ontario a global leader in commercialization of stem cell-related products and services. With advances in stem cell therapy, one day we could fix damaged cells in the heart, we will be able to restore vision and we will be able to activate the immune system to fight cancer. We will continue investing in research and innovation, which will be the foundation of our economic growth for tomorrow"[195]

There is a potential tension between innovation-based priorities, and goals or purposes that focus on protection of health through risk mitigation. When viewed against the backdrop of enthusiasm for the future potential of stem cell research discussed earlier in this chapter, these innovation-based imperatives may help explain why access to unproven stem cell interventions has expanded over time in Canada notwithstanding the varied concerns and potential risks which were also discussed above.

7.2.3 Legitimacy

As outlined in the conceptual framework I presented in Chapter 2, legitimacy is an important feature of regulation and governance that captures elements including matters of jurisdiction, influences on decision-making, procedural considerations, and questions of compliance and enforcement. Collaboration and engagement with key stakeholders can serve to strengthen the perceived legitimacy of regulation and governance.[196] Their expertise and experiences can inform instrument selection and design, and their buy-in may foster more

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[192] Health Canada, "Regulatory Roadmap", *supra* note 140.

[193] Those I did find touched on the topic only generally or in passing, such as a mention of having attended a local event to raise funds in support of an individual pursuing a stem cell treatment in the US. See Newfoundland and Labrador, *Journals of the Legislative Assembly*, 48, No. 20 (2 May 2016) (Hon. Ms Perry).

[194] See e.g. Ontario, *Journals of the Legislative Assembly*, 42-1 (15 May 2019) (Hon. Catherine Fife). The Hon. C. Fife was critical of the Ford government's cuts to research organizations that "drive research and innovation", such as the Ontario Institute for Regenerative Medicine.

[195] Ontario, *Journals of the Legislative Assembly* 41-1 (22 October 2015) at 1140 (Hon Reza Moridi). For similar examples, see Ontario, *Journals of the Legislative Assembly* 41-2 (26 October 2017); see also Ontario, *Journals of the Legislative Assembly* 39-1 (9 March 2009).

[196] Shawn HE Harmon, Graeme Laurie & Gill Haddow, "Governing risk, engaging publics and engendering trust: New horizons for law and social science?" (2013) 40:1 Science & Public Policy 25. Harmon et al. focus on public engagement, but I would argue the same principle extends to other stakeholders as well.

successful enforcement and compliance.[197] Collaboration may be particularly valuable for enhancing regulatory legitimacy in complex fields involving highly specialized knowledge, such as with stem cells.[198] The data in this case study indicate that there have been several clear efforts by regulators and governance actors to collaborate with stakeholders, both with respect to development and updating of oversight mechanisms, as well as with enforcement activities related to unproven stem cell interventions. There are potential advantages with this approach but also, as will be discussed below, questions and additional opportunities that could be explored.

As part of its regulatory reform efforts, Health Canada has indicated its intent to work with key stakeholders including "regulated parties, health care professionals, patients, medical colleges, researchers, environmental stakeholders, health technology assessment and reimbursement bodies, other governments, and health care system planners and decision-makers to develop the appropriate requirements that would enable industry to market advanced therapeutic products in Canada".[199] Similar sentiments were emphasized in Health Canada's Policy Position Paper on Autologous Cell Therapy Products, including a commitment to take a collaborative approach with "cell therapy sponsors, medical specialists, provincial governments" and the international cell therapy community, to support development of "safe and effective innovative products".[200] Health Canada's Cell Therapy Stakeholder Group (CTSG) also engages in bilateral dialogue regarding regulatory gaps, development of guidelines, and assessment of quality and regulatory challenges for cell therapy in Canada.[201] For example, at its 2018 bi-annual meeting, the CTSG heard from a representative of the International Society for Cell & Gene Therapy about its Presidential Task Force on the Use of Unproven Cellular Therapies.[202] Health Canada has also signalled a willingness to engage with members of the research community by sending representatives to act as observers of workshops and related events addressing issues related to unproven stem cell interventions.[203]

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[197] Ortwin Renn, "Stakeholder and Public Involvement in Risk Governance" (2015) 6 Intl J Disaster Risk Science 8 at 13. Renn suggests that appropriate forms of stakeholder involvement vary with the complexity, uncertainty, and ambiguity of the risks at issue.

[198] Sarah Devaney, *Stem Cell Research and the Collaborative Regulation of Innovation* (London and New York: Routledge, 2014) at 66-67.

[199] Government of Canada, "Health and Biosciences: Targeted Regulatory Review – Program and Policy and Initiatives and Novel Regulatory Approaches" (last modified 27 May 2021), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review/policy-program-initiatives-novel-regulatory-approaches.html>; see also Ridgway, *supra* note 137 at 408. Ridgway (who at the time of publication of this article was employed with Health Canada) discussed Health Canada's interest in working with regulatory partners on harmonization, and pointed to its participation on related initiatives including the Cell Therapy Working Group, under the umbrella of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

[200] Health Canada, "Position Paper", *supra* note 44.

[201] CellCAN Regenerative Medicine and Cell Therapy Network, "Health Canada Cell Therapy Stakeholder Group (CTSG)" (last visited 24 May 2022), online: <www.cellcan.com/129/Health_Canada_Working_Group.cellcan>.

[202] CellCAN Regenerative Medicine and Cell Therapy Network, "CTSG April 2018 Update" (April 2018), online: <www.cellcan.com/en/index.aspx?id=1217>. For information on the ISCT Task Force, see International Society for Cell and Gene Therapy Committee on the Ethics of Cell and Gene Therapy (formerly known as the ISCT Presidential Task Force on the Use of Unproven and/or Unethical Cell and Gene Therapies), "About us" (2019), online: <www.isct-unprovencellulartherapies.org/>.

[203] See e.g. Amy Zarzeczny et al, "Call for Clarity", *supra* note 16; see also Timothy Caulfield, Amy Zarzeczny & the Toronto Stem Cell Working Group, "Stem Cell Tourism and Canadian Family Physicians" (2012) 58:4 Canadian Family Physician 365.

These examples of collaboration and engagement reflect opportunities for knowledge exchange between regulators and communities of experts, including from different jurisdictions. However, appropriate resources and will are required to mobilize information into regulatory or governance response. The extent to which, if at all, the collaborations and engagement activities described above impacted government responses to unproven stem cell interventions is not clear from the data in this case study. There is also limited publicly available information regarding engagement between medical regulators and their members about this issue. One example was in June 2018, when the College of Physicians and Surgeons of Saskatchewan opened a draft of its new policy on performing office-based non-insured procedures for stakeholder consultation, which explicitly addressed peripheral stem cell injection and PRP. This policy was adapted from similar guidance from the United Kingdom's General Medical Council and the College of Physicians and Surgeons of Manitoba, which serves as an example of collaboration of a different form.[204]

Several regulatory and governance actors have also sought to engage and collaborate with the public with respect to monitoring and enforcement activities for unproven stem cell interventions. For example, Health Canada's 2019 advisory statement about "unauthorized cell therapy treatments" included the following statement:

> Health Canada encourages Canadians to report the potential non-compliant sale or advertising of unauthorized cell therapies by submitting a complaint to Health Canada using its online complaint form. Canadians can also report any adverse events from health products, including unauthorized cell therapies, to Health Canada by calling toll-free at 1-866-234--2345, or by reporting online, by mail or by fax.[205]

Similar urging has come from experts in media articles addressing concerns with the growing market in Canada for unproven stem cell interventions.[206] Other information-based instruments, including from Health Canada and AHS, have also recommended that patients investigate the legitimacy of stem cell interventions, have directed people to clinical trials databases, and have provided suggested questions for people to ask providers.[207]

Involving the public with regulation and governance of access in this manner is a strategy with some advantages. It diffuses the burden of monitoring, which is helpful given the reality of limited regulatory resources and the fast-moving nature of this field. It could also be seen as a mechanism to empower individuals who stand to be directly affected by potentially unsafe and ineffective interventions and may promote the goals of education and empowerment. However, it also presumes a fairly sophisticated level of understanding to identify problematic treatments, as well as awareness of reporting options and the capacity to take advantage of them. Further, it risks shifting the burden of responsibility away from regulators to individuals, many of whom are interested in these interventions because they are facing unmet medical needs and challenging health circumstances. Accordingly, the reasonableness of this shift is a question that

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[204] College of Physicians and Surgeons of Saskatchewan, "Policy, Standard and Guideline Updates" (2018) 5:3 *DocTalk* 21, online: <www.cps.sk.ca/imis/CPSS/DocTalk_Newsletter/Newsletters/CPSS/fdrPublications/Publications.aspx?PublicationsCCO=3&hkey=f3a340af-d4d7-4dfb-b646-cc7bdd712dfb>.

[205] Health Canada, "Advisory", *supra* note 9.

[206] See e.g. Kirkey, *supra* note 147.

[207] Health Canada, "Advisory", *supra* note 9; see also Alberta Health Services, "Osteoarthritis", *supra* note 99.

should be considered, and the approach one that should likely only be used strategically and in a complementary way with other enforcement activities.

Compliance with rules, policies and standards can be another important element of legitimacy.[208] In this case, levels of compliance with Health Canada's enforcement efforts seem to have been mixed among providers of unproven stem cell interventions in Canada. Several providers published public statements on their websites confirming that they would be acting in compliance with Health Canada's regulatory framework. For example, a statement in the Stem Cell Therapy section of Inovo Medical's website, accessed October 29, 2020, indicated the following: "IMPORTANT NOTICE: In accordance with Health Canada's compliance laws, we do not offer any stem cell therapy services".[209] The Vancouver Regenerative Health and Wellness Centre, an affiliate of the Cell Surgical Network, also addressed Health Canada's enforcement activities in a web post dated July 2020.[210] It indicated that it received a cease and desist letter in May 2019 from Health Canada requiring the clinic to cease operations until they received a No Objection Letter for Clinical Trial Application. They described their practices as having included adipose-derived autologous stem cell treatments and HcPRP for musculoskeletal or joint issues and other various conditions, and indicated they had taken early steps to apply for a clinical trial.[211] Another provider was quoted as expressing his intent to comply with Health Canada and stop offering stem cell therapies, while indicating his concern that "enforcing strict policies may prevent patients from getting safe access to treatment".[212]

However, compliance was not universal and at the time of writing, there are still clinics offering stem cell interventions seemingly without approval from Health Canada. One provider of stem cell treatments in Ontario was quoted in multiple media reports stating that stem cells are surgical procedures and not drugs, and indicating his intent to continue providing stem cell treatments.[213] He also asserted that the College of Physicians and Surgeons of Ontario had advised him in 2017 that providing stem cell interventions was a matter of clinical discretion under the College's policy on complementary and alternative medicine.[214] Public attention to Health Canada's enforcement efforts through this type of media coverage may have helped advance its perceived legitimacy as a regulator in this space, insofar as it was seen to be taking action. Conversely, the associated public debates may have contributed to mixed understandings about the validity of unproven stem cell interventions available in the Canadian market, particularly when provided by physicians who are members of a regulated profession.

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[208] Fiona Haines, *The paradox of regulation: what regulation can achieve and what it cannot* (United Kingdom: Edward Elgar Pub, 2013) at 29. Haines discusses compliance as linked to the regulatee's perceptions of legitimacy of the regulator.

[209] Inovo Medical, "Stem Cell Therapy" (last visited 29 October 2020), online: <inovomedical.ca/education/stem-cell-therapy>, emphasis removed.

[210] Vancouver Regenerative Health and Wellness Centre; an affiliate of the Cell Surgical Network, "Clinical Trial Applications" (July 2020, last visited 28 October 2020), online: <https://vanstemcell.com/cta/>; note: as of June 16, 2021, the site is accessible by member log-in only.

[211] As of June, 2021, the site was accessible by member-only login.

[212] Favaro, St. Philip & Bogart, *supra* note 146.

[213] Jensen, *supra* note 147.

[214] Weeks, *supra* note 130. This article includes a statement from the CPSO that it would "need to consider what steps to take to ensure that the public is not being put at risk" if a physician was not complying with a specific directive from Health Canada.

On the whole, the provincial colleges of physicians and surgeons have not taken a strong public position regarding provision of unproven stem cell interventions by their members, nor did my data collection identify many related professional disciplinary decisions. Without drawing conclusions regarding the robustness of their internal regulatory and governance activities, this minimal public response begs the question of whether it is important for such bodies to be 'seen to be acting', to foster public trust and enhance their legitimacy as regulator. Similar questions could be asked regarding the Competition Bureau which has also been largely silent on this issue, notwithstanding pressure from the research community for it to take action against false or misleading marketing claims about stem cell interventions.[215] Although it is admittedly a complex concept involving multiple factors,[216] I would argue that compliance and, in its absence, robust enforcement, are relevant factors when considering the quality of regulation and governance.

7.2.4 Responsiveness and adaptability

As discussed in Chapter 2, there is a persuasive argument that responsiveness and adaptability are qualities of strong regulation and governance, particularly when looking at complex and evolving fields. In evaluating responsiveness and adaptability of regulatory and governance responses to unproven stem cell interventions in Canada, I have considered questions of timing, flexibility, and evidence of learning. On the whole, regulation and governance responses to the growing availability of unproven stem cell interventions in Canada have been largely reactive. This was not a case where regulatory and governance actors were called to respond rapidly to an unforeseen or quickly emerging phenomenon. Academic literature documenting related developments in other countries goes back to 2008.[217] With the subsequent growth of markets for unproven stem cell interventions in jurisdictions with similar regulatory regimes and cultural contexts to Canada, including Australia and the United States, it was arguably foreseeable that a domestic market could emerge here as well.

A small number of governance actors in Canada, including patient advocacy and support organizations and some researchers, acted early with information-based strategies. These responses focused on warning Canadians about the risks of interventions available in other jurisdictions,[218] and on raising awareness among healthcare providers.[219] I did not find similar examples of proactive responses from Health Canada, provincial and territorial governments, or the colleges of physicians and surgeons. To the contrary, although Canada had the advantage of watching and learning from other jurisdictions, it seems the development of comparable markets in other jurisdictions may have been a missed opportunity from regulatory and governance perspectives. A domestic market for unproven stem cell interventions grew in Canada over several years before there was any official public response from Health Canada or medical

[215] See e.g. Caulfield & Murdoch, *supra* note 89.
[216] See Christine Parker & Vibeke Lehmann Nielsen, "Compliance: 14 Questions" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 217. Parker and Nielsen discuss different meanings of compliance and the broad array of factors – individual and collective, or organizational – that may influence compliance behaviours. They offer a series of "compliance questions" that direct attention to different facets of compliance behaviour including: economic, social, and normative motives; characteristics and capacities of the target population; and deterrence factors.
[217] Darren Lau et al, *supra* note 55.
[218] See e.g. Parkinson Society of Canada, *supra* note 114.
[219] See e.g. Caulfield & Zarzeczny, *supra* note 203.

regulatory bodies. Members of the research community were the actors that documented and brought public attention to the size and scope of the growing Canadian market for unproven stem cell interventions. Specifically, Turner's 2018 publication was a catalyzing event for regulatory response.[220] His findings received considerable media attention and were credited with prompting Health Canada's enforcement letter campaign.[221]

This lack of proactive response may be explained in part by key regulatory actors including Health Canada and the colleges of physicians and surgeons using complaint-driven processes.[222] It appears there were few if any early public complaints regarding unproven stem cell interventions in Canada. The appropriateness of a complaint-driven approach is an important question meriting future consideration, particularly where regulatory bodies have expressed a commitment to act for the safety and well-being of Canadians or in the public interest. This issue will be discussed in more detail in Chapter 8.

Important regulatory actors demonstrated some adaptability in their responses to the changing context underpinning this case study. For example, as noted earlier, experts identified gaps and ambiguities regarding the regulation of minimally manipulated cells intended for autologous use in several academic publications.[223] Providers of unproven stem cell interventions in Canada arguably took advantage of this lack of clarity by offering this type of intervention on a direct-to-consumer basis. Health Canada then responded with its Policy Position Paper on Autologous Cell Therapy Products, which clarified that these products are considered drugs and are governed by the *Food and Drugs Act*.[224] Health Canada also initiated work to address challenges with meeting regulatory requirements for the manufacturing and sale of autologous cell therapy products, including those prepared at the bedside.[225] Another example of regulatory responsiveness, this time on the part of a medical regulatory body, is when the College of Physicians and Surgeons of Saskatchewan updated its policy on "Performing Office-based Non-Insured Procedures" with reference to Health Canada regulations in relation to stem cell treatments and platelet rich plasma treatments.[226] However, these examples of adaptability must be viewed in the larger context, recognizing that overall there have been relatively few regulatory and governance responses to access to unproven stem cell interventions in Canada.

7.3 Key lessons and future priorities

The market for unproven stem cell interventions in Canada shared key features with chelation therapy and liberation therapy. They are interventions that promised to address unmet medical need(s) and thus engaged the power of hope for patients and their loved ones, which can be a strong motivator in favour of access. Each received attention in news and social media,

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[220] Turner, "Marketing by Canadian businesses", *supra* note 72.
[221] John McFee, "Research questions marketing of treatment", *Halifax Chronicle-Herald Cape Breton* (27 September 2018) A9.
[222] Blackwell, "Calls for crackdown", *supra* note 121; see also Pamela Fayerman, "Researcher skeptical of stem cell clinics", *The Vancouver Sun* (6 October 2018), A.11.
[223] For leading work on this topic, see Jolene Chisholm et al, "Workshop to address gaps in regulation of minimally manipulated autologous cell therapies for homologous use in Canada" (2017) 19:12 Cytotherapy 1400.
[224] Health Canada, "Position Paper", *supra* note 44.
[225] *Ibid*, at Statement 3. This work builds on Health Canada's earlier guidance regarding clinical trials using cell therapies in humans. See Health Canada, "Guidance Document", *supra* note 6.
[226] College of Physicians and Surgeons of Saskatchewan, *supra* note 101 at 11. For the revised policy, see College of Physicians and Surgeons of Saskatchewan, *supra* note 134.

sometimes accompanying advocacy efforts. They all prompted some degree of scientific uncertainty and conflicting professional views, and a diverse set of actors has exercised influence over all three areas. Nonetheless, there were also important differences in how access to these unproven medical interventions in Canada has unfolded, and in the associated regulation and governance responses. My analysis of regulation and governance of access to unproven stem cell interventions in Canada has highlighted three notable insights.

First, collaborative governance involving government regulators, professional regulatory bodies, and leaders in clinical and research communities, can help leverage and maximize resources, expertise, reach, and impact. Responsibility and influence over access to unproven stem cell interventions in Canada has been distributed between several key regulatory and governance actors. As already discussed, Health Canada has jurisdiction over the safety, quality, and efficacy of products considered to be drugs, cells, or tissues for transplantation, and medical devices. Responsibility over activities falling under the practice of medicine, including surgical innovation, fall under provincial authority and have been delegated to the colleges of physicians and surgeons. The colleges also have standards regarding their members' advertising activities, which may also be subject to oversight by the Competition Bureau. Finally, though in a less official and more diffuse capacity, members of research communities have influence in defining the scope of the field, monitoring developments, and identifying emerging issues.

This form of distributed governance[227] over new and unproven medical interventions, such as stem cell interventions, offers potential advantages insofar as it presents the opportunity to share the demands of regulation and governance amongst different actors as well as to draw on their respective and varied strengths, including reach and expertise. When the science and related clinical practices are complex, as is the case with stem cells, engaging deliberately with researchers and other relevant experts can help regulators augment their own knowledge and buttress limited regulatory resources.[228] Doing so via transparent and accessible processes may help avoid triggering critiques about procedure and legitimacy concerns. Engaging with diverse stakeholders, including providers of unproven stem cell interventions, may also create an opening for enhanced understanding about their respective motivations, priorities, and interests, as well as potential opportunities for reconciling existing obstacles to compliance.[229]

However, maximizing the opportunities of distributed governance over unproven medical interventions, such as stem cell treatments, requires deliberate and systematic collaboration and role clarity. My analysis suggests there is room for improvement in this area, particularly between Health Canada and the colleges of physicians and surgeons. The evolution of the market for unproven stem cell interventions in Canada illustrates how 'grey areas' in oversight (e.g. when there is a lack of clarity regarding whether an intervention should be classified as a drug or as falling under the practice of medicine) can be used to facilitate early access, even though

[227] This concept is discussed in Chapter 2. See also Mark Bevir, "Governance as Theory, Practice and Dilemma" in Mark Bevir, ed, *The Sage Handbook of Governance* (SAGE Publications Ltd: 2011) at 11-12.
[228] Daniel Weiss et al, "Medical societies, patient education initiatives, public debate and marketing of unproven stem cell interventions" (2018) 20 Cytotherapy 165. Weiss et al. make a similar argument, suggesting that medical communities should draw on the expertise of stem cell scientists, bioethicists, and experts in public policy and regulatory science when developing clinical guidelines for stem cell interventions. They point to the work of the ISCT Presidential Task Force on the Use of Unproven Cellular Therapies as an instructive example of this type of collaboration.
[229] Matthews & Iltis, "Compromise policy", *supra* note 178.

important questions remain regarding the safety, efficacy, and quality of the intervention. Inconsistent responses or lack of public-facing responses by medical professional regulatory bodies can create further ambiguity, which may fuel interest in access by both patients and providers. As others have argued, there is a space for medical regulators and professional societies to take a larger role in raising awareness with both patients and providers,[230] and a more proactive stance in monitoring and investigating provision of questionable stem cell interventions.[231] Inconsistencies among colleges of physicians and surgeons' policies regarding provision of non-standard of care interventions, and the obligation for physicians to practice evidence-based medicine, are a related point of challenge that has further complicated oversight for unproven stem cell interventions. Clarifying physicians' professional responsibilities with respect to unproven medical interventions, and what regulating in the public interest requires of medical professional bodies in this context, would be a valuable priority for ongoing and future professional regulatory reform efforts.[232] Given that medical regulatory bodies act under delegated authority, it would be reasonable for provincial governments to play a role in ensuring the colleges are meeting their mandates to regulate in the public interest.

Second, this case highlights the importance of health and science communication, and of productive engagement with the public and other key stakeholder groups, including patient communities and health care providers.[233] The years of enthusiastic portrayals about the potential of stem cell research have created a context of expectation and a confusing information environment regarding the legitimacy of stem cell interventions available on the direct-to-consumer market.[234] As discussed above, different actors have used information-based instruments targeted at the public, patients, and physicians to raise awareness about this market and its attendant concerns, which could be seen as a strength in the regulation and governance of this field. However, these efforts have been sporadic, and there is considerable room for more coordinated strategies going forward, including regarding how research results are promoted by the scientific community.[235] For example, research with Canadian parents of children with

[230] Weiss et al, *supra* note 228.
[231] Bowman et al, *supra* note 50 at 1345.
[232] See e.g. Government of British Columbia Steering Committee on Modernization of Health Profession Regulation, "Recommendations to modernize the provincial health profession regulatory framework" (August 2020), online (pdf): <www2.gov.bc.ca/assets/gov/health/practitioner-pro/professional-regulation/recommendations-to-modernize-regulatory-framework.pdf>. BC's regulatory modernization project follows a review of the provincial regulatory framework for health professionals that was initiated by the BC Ministry of Health. This review identified concerns including governance issues, lack of transparency, lack of public trust, and promotion of the interests of the profession over the interests of the public. See also British Columbia Health Regulators, "Regulatory Modernization" (last visited 22 May 2022), online: <bchealthregulators.ca/health-regulation-in-bc/regulatory-modernization/>.
[233] For more in-depth discussion, see Alan Regenberg & Theodore Schall, "Outreach and Engagement: Evolving Media and the Public Obligations of Stem Cell Science" (2015) 1 Current Stem Cell Reports 219 at 219. Regenberg and Schall observe that the complexity of stem cell science, along with its fast-moving nature and controversial past, require effective outreach and engagement to foster public trust, but also make doing so particularly challenging. They also note that the stem cell field is not alone in facing these challenges.
[234] Timothy Caulfield, "Unproven stem-cell treatments can be dangerous. The hype needs to stop", *The Globe and Mail* (13 July 2019), online: <www.theglobeandmail.com/opinion/article-unproven-stem-cell-treatments-can-be-dangerous-the-hype-needs-to-stop/>.
[235] See e.g. Moses Fung et al, "Responsible Translation of Stem Cell Research: An Assessment of Clinical Trial Registration and Publications" (2017) 8 Stem Cell Reports 1190 at 1190. The authors evaluated "the extent to which the publication of clinical trial results of innovative cell-based interventions reflects ISSCR best practice guidelines."

cerebral palsy or autism spectrum disorder suggests that although the internet is a common source of information about what unproven stem cell interventions are available, parents also express high levels of trust in information received from science journals, researchers, physicians, allied health professionals, and other parents of children with similar health issues.[236] Other research with Canadian MS patients found that the study participants had a limited understanding of the time required to move stem cell research to the clinic, and a desire to know more about the clinical translation process.[237]

Given the evolution and current state of the market for unproven stem cell interventions, it seems unlikely that one-way communication via information-based instruments will be sufficient to curb access demands and to meet the informational needs of patients and their supporters. Although valuable for providing clarity about why these interventions are potentially problematic, it would be prudent for information-based approaches to be part of broader engagement strategies.[238] As a starting point, these engagement strategies might focus on a two-fold exchange. Clinicians and other experts could promote "informed hope" for patients and their loved ones through education about research and clinical translation processes, including attendant challenges.[239] At the same time, regulatory and governance actors could also focus on deepening their understanding about different stakeholders' priorities and views about risk, including both patients and providers, to inform their overall approach and instrument selection.[240]

This understanding is arguably a necessary element of achieving balance between fostering safe and effective medical innovation in the stem cell field, while protecting against premature access that may threaten both individual patients and the long-term health of the field.[241] It would also partly answer the call for a greater emphasis in governance on the

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See also Zubin Master et al, "Stem cell tourism and public education: the missing elements" (2014) 15:3 Cell Stem Cell 267.

[236] Kimberly Sharpe et al, "A Dichotomy of Information-Seeking and Information-Trusting: Stem Cell Interventions and Children with Neurodevelopmental Disorders" (2016) 12 Stem Cell Revs & Reports 438 at 442; see also Datta, "Emerging dynamics", *supra* note 19 at 359. Datta analyzed social media discussions in online patient communities, including Facebook, and observed high levels of trust in basic research results as well as in personal experiences (i.e. anecdotes), but not in provider-constructed interpretations of research (e.g. warnings, etc.).

[237] Shelly Benjaminy et al, "Perspectives About Time Frames in Stem Cell Research for Multiple Sclerosis" (2019) 21:4 International J of MS Care 185.

[238] Findings from a recent evaluation of regenerative medicine consultation services provided by the Mayo Clinic suggest that provider-patient consultations are one way of engaging patients who are otherwise struggling to navigate the complex health information context surrounding regenerative medicine. See Smith et al, *supra* note 37.

[239] Benjaminy et al, *supra* note 237 at 192.

[240] See e.g. Brian Kwon et al, "Expectations of benefit and tolerance to risk of individuals with spinal cord injury regarding potential participation in clinical trials" (2012) 29 J Neurotrauma 2727. For work exploring the role of public and stakeholder participation in policy-making, see Margot Hurlbert & Joyeeta Gupta, "The split ladder of participation: A diagnostic, strategic, and evaluation tool to assess when participation is necessary" (2015) 50 Environmental Science & Policy 100.

[241] Kirsten Matthews & Ana Iltis, "Unproven Stem Cell–Based Interventions: Advancing Policy through Stakeholder Collaboration" (2017) 44:3 Texas Heart Institute J 171. See also Edna Einsiedel & Hannah Adamson, "Stem Cell Tourism and Future Stem Cell Tourists: Policy and Ethical Implications" (2012) 12:1 Developing World Bioethics 1471. Einsiedel and Adamson's research – now almost a decade old but still relevant – with healthy Canadians suggested that people were sympathetic to the drivers of hope and desperation and might be inclined to pursue unproven stem cell interventions where there are few or no alternative treatments available.

consumer demand side of access to unproven stem cell interventions.[242] Social media has been promoted as one potentially valuable tool for public and patient engagement strategies in the realm of stem cell interventions, with many arguing that scientists and health care providers will need to play important roles in these communication efforts.[243] Social media is already used as a "connecting platform for many voices and as a key tool for the dissemination of information about stem cells".[244] However, the use of social media for this purpose is not uncomplicated, and more work needs to be done to understand how to capture and, to some extent, control its potential if it is to be used as an instrument of deliberate engagement.[245]

The third priority identified through this case study analysis is the need to consider what counts as "evidence" for different actors, and how the way in which evidence is constructed and assessed factors into the regulation and governance of a particular intervention. This priority is an overarching one that influences the setting of regulatory and governance priorities and instrument selection. It is also tied to authority and influence, expertise, and legitimacy. What constitutes sufficient evidence of safety and efficacy to permit access, and who is empowered to make that assessment, are contested questions in the stem cell field.[246] For example, crowdfunding campaigns have been identified as spaces where a "politics of evidence" plays out, in that different parties (including providers of unproven interventions and recipients, among others), present narratives "as 'truth' about the potential efficacy of SCIs [stem cell interventions] for various conditions".[247] In other realms, actors emphasize biomedical models with clinical research standards. One study noted that Facebook users "stepped beyond the boundaries of 'unproven' to evaluate the trustworthiness and credibility of evidence", and that while they exhibited distrust in processes, actors, and institutions underpinning scientific evidence, particularly where there were commercial linkages, that distrust did not extend to the scientific evidence itself.[248] Questions about different forms of evidence are tied to broader debates about both evidence-based medicine and evidence-based policy. This theme resonates across all three case studies and will be discussed in more detail in the following chapter.

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[242] Brian Salter, Yinhua Zhou & Saheli Datta, "Governing new global health-care markets: the case of stem cell treatments" (2017) 22:1 New Political Economy 76 at 77. Salter et al. frame their arguments using the language of political economy and suggest that regulation, governance, and scientific models of biomedical innovation have traditionally focused on addressing the supply side (i.e. restricting the activities of providers).

[243] See e.g. Sharpe et al, *supra* note 236; see also Regenberg & Schall, *supra* notre 233 at 224. Regenberg and Schall discuss several strengths of social media in this context, including that it is inexpensive, broadly accessible, and facilitates real-time exchange.

[244] Robillard et al, *supra* note 191.

[245] Some of my own previous research on the use of Twitter as a public information campaign mechanism demonstrates the challenge of achieving reach and engagement. See Kathleen McNutt & Amy Zarzeczny, "Leveraging social media in the stem cell sector: exploring Twitter's potential as a vehicle for public information campaigns" (2017) 12:7 Regenerative Medicine 753.

[246] See e.g. Datta, "Emerging dynamics", *supra* note 19 at 360; see also Karen Maschke & Michael Gusmano, "Evidence and Access to Biomedical Interventions: The Case of Stem Cell Treatments" (2016) 41:5 J Health Politics, Policy & L 918 at 920, 921.

[247] Claire Tanner et al, "The politics of evidence in online illness narratives: An analysis of crowdfunding for purported stem cell treatments" (2019) 23:4 Health 436 at 453-454.

[248] Datta, "Emerging dynamics", *supra* note 19 at 356.

CHAPTER 8: LESSON DRAWING & LOOKING FORWARD

8.1 A brief review

In this research I used case studies to explore what we can learn from current and past regulation and governance of access to unproven medical interventions in Canada, with the goal of informing and strengthening future strategies. The second objective of this work was to develop insights into what regulation and governance offer as frameworks to analyze and deepen understanding about complex and multifaceted policy issues, such as questions of access to unproven medical interventions. The three cases I studied included chelation therapy for applications other than treating heavy metal toxicity, liberation therapy as a treatment for MS, and unproven stem cell interventions. The need to analyze and learn from these kinds of past experiences was identified by the CIHR Scientific Expert Working Group tasked with reviewing evidence and providing advice regarding liberation therapy,[1] and has been echoed by scholars working in related areas.[2]

These cases had several features in common. They each involved a new or non-standard of care medical intervention (defined in Chapter 1 as an unproven medical intervention) that promised to address unmet medical need(s). They each received public attention and prompted political pressure or advocacy in news and social media. They each involved some degree of scientific uncertainty and conflicting professional opinions about the merits of the intervention. Finally, each case involved a diverse set of actors with influence and authority over questions of access. The insights drawn from these case studies will likely be most relevant to future cases that share similar features.

I developed a conceptual framework to guide my analysis, drawing on the fields of both regulation and governance scholarship. I revised the conceptual framework in an iterative manner throughout my data analysis by adjusting how I approached different features of regulation and governance, their relationship to one another, and their key elements or considerations, in response to what I found in the data. In the sections that follow, I first present results from my cross-case synthesis of the three cases studied. I then outline what I see as key features of the Canadian context that need to be accounted for in regulation and governance of access to unproven medical interventions in Canada, and offer strategies for strengthening future approaches, based on my findings from the case study analyses. I next reflect on how my

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[1] Canadian Institutes of Health Research, "Highlights from the March 7, 2017 CIHR Scientific Expert Working Group on Multiple Sclerosis and Chronic Cerebrospinal Venous Insufficiency Meeting" (30 March 2017), online: *Government of Canada* <cihr-irsc.gc.ca/e/50159.html> [CIHR, "Expert Working Group March 2017 Meeting"].

[2] See e.g. Jeremy Snyder et al, "'I knew what was going to happen if I did nothing and so I was going to do something': Faith, hope, and trust in the decisions of Canadians with multiple sclerosis to seek unproven interventions abroad" (2014) 14:445 BMC Health Services Research www.biomedcentral.com/1472-6963/14/445 at 9; Ari Green, Hooman Kamel & Andrew Josephson, "Combating the Spread of Ineffective Medical Procedures A Lesson Learned From Multiple Sclerosis" (2018) 75:2 J American Medical Assoc Neurology 15 at 17; S. Michelle Driedger, Ebenezer Dassah & Ruth Ann Marrie, "Contesting Medical Miracles: A Collective Action Framing Analysis of CCSVI and Venous Angioplasty ("Liberation Therapy") for People With Multiple Sclerosis in News and Social Media" (2018) 40:4 Science Communication 469 at 492; Judy Illes, Anthony Traboulsee & Shelly Benjaminy, "Science and society must collaborate; Civic engagement vitally important, write Judy Illes, Anthony Traboulsee and Shelly Benjaminy", *The Vancouver Sun* (18 March 2017) G.4.

conceptual framework served this research and consider related theoretical insights for future regulation and governance scholarship. Following that discussion, I highlight some important limitations to this research and conclude by considering implications for further research.

8.2 Cross-case synthesis

There are different approaches to presenting a cross-case synthesis. At its core, this term describes a strategy in case study research of first analyzing each case individually and then together, to draw important observations, comparisons, or other notable findings from the cases collectively.[3] I presented the individual case study results in Chapters 5-7 of this thesis. In this section, I reflect on the findings from the three case studies to answer my primary research question for this project, which was: *What can we learn from current and past practices to inform and improve future strategies for regulation and governance of access to unproven medical interventions in Canada?*[4] I originally parsed this overarching question into the following three sub-questions:

> (1) How can we characterize different examples (past and present) of regulation and governance of access to unproven medical interventions provided by physicians in Canada, and what lessons or principles can we draw from these examples?
>
> (2) What is the role of law in setting the parameters within which regulation and governance of access to medical interventions take place, and as an instrument of regulation and governance?
>
> (3) What features of regulation and governance of access to unproven medical interventions are particularly important for effective oversight in the Canadian context?

Rather than being distinct areas of enquiry, these sub-questions helped frame the boundaries of my data collection and focus my analysis, including by informing the development of my conceptual framework (see Chapter 2, Section 2.5). In the sections that follow, I use the structure of my conceptual framework to discuss key findings from the cross-case synthesis, starting with addressing actors and instruments, then moving to consider purposes or objectives, legitimacy, and responsiveness and adaptability.

8.2.1 Actors and instruments – reflections and challenges

My first step in analyzing examples of regulation and governance of access to unproven medical interventions provided by physicians in Canada involved identifying regulatory and governance actors that exerted influence over access to unproven medical interventions in Canada and exploring the instruments that they used to do so. Regulation and governance of access to chelation therapy, liberation therapy, and unproven stem cell interventions from physicians in Canada has involved a multitude of state and non-state actors. Federal, provincial, and territorial governments have all been engaged in these issues, as have colleges of physicians and surgeons, medical and scientific associations, patient advocacy groups, and the courts. Collectively, these actors used an assortment of

[3] See R.K. Yin, *Case study research: design and methods*, 4th ed (California: Thousand Oaks Sage, 2009).
[4] My research questions were presented and discussed in Chapters 1 and 3, *above*.

instruments with varying degrees of coerciveness, ranging from light-touch, information-based approaches, to funding-based approaches, to legislation with criminal law sanctions.[5]

Information-based strategies were particularly common among many actors, including governments. Their appeal is understandable. They can be faster and less costly to implement and update than other instruments such as legislation or programming. Importantly, they can also be used to support or empower individual decision-making which, as seen in the case studies, can be a compelling narrative surrounding questions of access to unproven medical interventions. As will be discussed below, information-based responses to such issues could perhaps be strengthened with enhanced collaboration and coordination, and with updated strategies that respond to today's online information environment. Given the prominence of information-based strategies in regulatory and governance responses to the unproven medical interventions studied here, these investments seem worthwhile.

In all three cases, provincial and territorial governments withheld funding under provincial health insurance systems, which is one way of limiting access.[6] Spending can be an important regulatory and governance instrument for controlling access to medical interventions. Approximately 75% of healthcare in Canada is publicly funded, while the other approximately 25% is funded by a combination of private insurance and out-of-pocket payments by individuals.[7] Withholding public funding for an unproven medical intervention is one way for governments to limit or at least discourage access by imposing financial barriers. However, several provincial and territorial governments also allocated public funds for research as a means of facilitating access to liberation therapy, albeit a far more limited form of access than would have been available via its adoption in publicly funded healthcare systems.[8]

Legislation was also an important instrument of regulation and governance of access in all three of the cases studied. With chelation therapy, provinces and territories used legislation to drive expanded access, sometimes in opposition to recommendations from members of the medical community. In the case of liberation therapy, high-profile but ultimately unsuccessful private members bills reflected the tense political debates associated with access demands for this intervention. With unproven stem cell interventions, legislation (more specifically, the *Food and Drugs Act*) was used to provide an oversight framework for autologous cell therapy products.[9] Failure to comply with the

[5] See Chapter 5, 5.2.1, Chapter 6, 6.2.1, and Chapter 7, 7.2.1, *above*.
[6] See e.g. *F.D.E. v Ontario Health Insurance Plan (General Manager)*, 2011 CanLII 101469.
[7] Canadian Institute for Health Information, "Health Expenditure Data in Brief" (November 2021), online (pdf): <www.cihi.ca/sites/default/files/document/health-expenditure-data-in-brief-en.pdf>.
[8] See e.g. Government of Saskatchewan, "Province of Saskatchewan Slates $5 Million for MS Liberation Clinical Trials" (19 October 2010), online: <www.saskatchewan.ca/government/news-and-media/2010/october/19/province-of-saskatchewan-slates-$5-million-for-ms-liberation-clinical-trials>.
[9] Health Canada, "Health Canada Policy Position Paper – Autologous Cell Therapy Products" (last modified 17 January 2020), online: *Government of Canada* <www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/cell-therapy-policy.html> [Health Canada, "Position Paper"].

provisions of this legislation or its regulations could result in the potential for both fines and imprisonment.[10]

Unsurprisingly, the ways in which legislation was used in these case studies emphasized its ability to control the conditions of access to unproven medical interventions (although enforcement remains a separate issue). The case studies also demonstrated the potential for legislation to serve as a vehicle for political pressure and as a catalyst for policy debate. In particular, the legislative debates that surrounded proposed legislation in both the chelation therapy and liberation therapy case studies reflected considerable influence from political advocacy, including through personal appeals for access to these unproven medical interventions which drew heavily on individual anecdotes. As will be discussed further in Section 8.2.3 below, although not unique to these case studies, these findings raise legitimacy-based questions about decision-making processes that control access to unproven and potentially harmful medical interventions, particularly where the evidence surrounding the intervention is complex, evolving, or contested. Overall, the use of legislation to control access to the unproven medical interventions studied here affirmed the central role of government in this context, notwithstanding the other forms of influence that were used by broader networks of non-state actors.

Colleges of physician and surgeons were another important actor in all three case studies. Several colleges used information as an instrument or tool by providing updates and guidance to their members.[11] Others engaged in political processes, including by attempting to influence the crafting of legislation and bylaws.[12] Some used instruments such as professional guidelines and practice standards to direct the conduct of their members and to establish expectations in relation to these unproven interventions.[13] In several instances, breaches of these standards were addressed through professional discipline processes.[14] Other notable actors included professional medical and scientific organizations which leveraged their reach and expertise to disseminate information about the interventions, often including information about the potential risks.[15] Patient-focused and advocacy groups of varied forms also featured in all three case studies. These actors used information-based instruments and political pressure or advocacy to promote access,

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[10] *Food and Drugs Act*, RSC 1985, c F-27 at s 31.

[11] See e.g. College of Physicians and Surgeons of Saskatchewan, "Stem Cell Therapies – Health Canada Requirements" (2019) 6:2 *DocTalk* 11, online (pdf): <www.cps.sk.ca/iMIS/Documents/Newsletters/DOCTALK%20Vol%206%20issue%201.pdf>.

[12] See e.g. *The Medical Profession Act, 1981, Bylaw 52 – College of Physicians and Surgeons of Saskatchewan Standards for Performance of Chelation Therapy*, (1997) S Gaz I, 93:7, 128.

[13] See e.g. College of Physicians and Surgeons of Alberta, "Stem Cell Regenerative Therapy Standards" (30 November 2017), online (pdf): <cpsa.ca/wp-content/uploads/2020/06/Stem-Cell-Regenerative-Therapy-Standards.pdf>.

[14] See e.g. *Krause (Re),* 2019 LNMBCPS 1.

[15] See e.g. G.B. John Mancini et al, "Canadian Cardiovascular Society Guidelines for the Diagnosis and Management of Stable Ischemic Heart Disease" (2014) 30 Canadian J Cardiology 837; see also Suresh Vedantham et al, "Interventional Endovascular Management of Chronic Cerebrospinal Venous Insufficiency in Patients with Multiple Sclerosis: A Position Statement by the Society of Interventional Radiology, Endorsed by the Canadian Interventional Radiology Association" (2010) 21 J Vascular & Interventional Radiology 1335; see also Lori Knowles, "Stem Cell Hype and the Dangers of Stem Cell 'Tourism'" (2014) *Stem Cell Network*, online: <www.stemcellnetwork.ca/index. php?page=patientbooklet&hl=eng>.

seek funding, empower individuals to make more informed decisions, dissuade individuals from pursuing the intervention, or to influence physicians' professional practices.

Together, the approaches utilized by the different actors in these case studies reflected a plurality of instruments used to shape or otherwise influence regulation and governance of access to the three unproven medical interventions studied, but notably few examples of formal or express coordination or collaboration. One marked example of productive collaboration among different actors in the regulation and governance of access to the unproven medical interventions studied here was the work of the CIHR Scientific Expert Working Group with liberation therapy,[16] but this was an exception in my data rather than the norm. I also found instances of contradictory approaches among comparable actors. For example, for a short time New Brunswick subsidized patients who received liberation therapy outside Canada, other provinces funded research to learn more about the intervention, still others warned patients against pursuing it, and yet others do not appear to have taken a public position. Different objectives and priorities coupled with other factors such as resource constraints may explain some of these inconsistencies. However, as will be discussed later in this chapter, there are likely valuable opportunities to be explored with respect to collaboration and coordination among such actors going forward.

Identifying and exploring the involvement of diverse actors was an important aspect of understanding the regulation and governance landscape in these case studies. However, it is also important to note that this identification and exploration does not necessarily capture potentially important nuances including varying degrees of involvement, or the absence of some actors in public-facing activities. For instance, although the Competition Bureau has the mandate and jurisdiction to exert influence over how unproven medical interventions are marketed to the public,[17] I did not find evidence to suggest that it played a prominent role in any of these three case studies.[18] In addition, the engagement of some actors such as AHS in providing public-facing information,[19] or the College of Physicians and Surgeons of Saskatchewan in providing clarification to their members about provision of unproven stem cell interventions,[20] was not

[16] Canadian Institutes of Health Research, "Scientific Expert Working Group" (last modified 30 March 2017), online: *Government of Canada* <cihr-irsc.gc.ca>. The creation and composition of this group reflected a degree of collaboration or coordination between different actors including the federal government, the MS Society, and individual "experts". Some of the group's activities also reflected a cooperative approach, such as when it provided an update to colleges of physicians and surgeons regarding its recommendation against the use of liberation therapy to treat or manage MS. See CIHR, "Expert Working Group March 2017 Meeting", *supra* note 1; see also College of Physicians and Surgeons of Saskatchewan, "Executive Summary of the June 16 & 17, 2017 Council Meeting" (last visited 23 May 2022), online: <www.cps.sk.ca>.

[17] See Ubaka Ogbogu, "Combatting Unlicensed Stem Cell Interventions through Truthful Advertising Law: A Survey of Regulatory Trends" (2015-2016) 9 McGill JL & Health 311; see also Barbara von Tigerstrom, "Regulating the advertising and promotion of stem cell therapies" (2017) 12:7 Regenerative Medicine 815.

[18] It is possible that my search strategies simply did not capture its activities. Limitations to this project are outlined in Section 8.6, *below*.

[19] For chelation therapy, see Alberta Health Services, "Chelation FAQ" (last visited 22 May 2022), online (pdf): <www.albertahealthservices.ca/assets/healthinfo/Padis/hi-padis-faq-chelation.pdf>; for liberation therapy, see Alberta Health Services, "Alberta Health Services Statement on Venous Imaging and Venous Angioplasty in Multiple Sclerosis (MS)" (16 February 2010), online: <www.albertahealthservices.ca/news/features/2010/Page1409.aspx>; for unproven stem cell interventions, see Alberta Health Services, "Stem Cell Treatment for Osteoarthritis" (last modified 27 Feb 2020), online: *MyHealth.Alberta* <myhealth.alberta.ca/Alberta/Pages/stem-cell-treatment-for-osteoarthritis.aspx>.

[20] College of Physicians and Surgeons of Saskatchewan, *supra* note 11 at 11.

necessarily mirrored by companion organizations in other provinces and territories. Among other things, these divergences potentially signal lost opportunities for lesson drawing and collaboration, which will be discussed in Section 8.4.1 below.

8.2.2 Clarity of purpose – observations and tensions

The second step in my analysis of these cases was to identify and explore the purposes (goals or objectives) that were used to frame, or which appeared to drive, actors' regulatory and governance activities. In all three cases, some version of protecting and promoting health stood out as a strong priority or imperative in the regulation and governance of access to the unproven interventions studied. This purpose underpinned a wide variety of government responses, including some that facilitated access to the intervention (e.g. legislative amendments that expanded access to chelation therapy), others that controlled it (e.g. by using public funds to support research into liberation therapy, where access would only be provided in the context of approved research protocols), and yet others that restricted it (e.g. by deeming stem cell interventions to be drugs that cannot be offered without approval under the *Food and Drugs Act*).

These varied outcomes could be interpreted to indicate that protecting and promoting health may legitimately require different measures in different circumstances, including the state of knowledge and evidence regarding the risks and benefits of the intervention as well as of its alternatives. However, these case studies also suggest that the broad goals of protecting and promoting health can be malleable and used to justify or support different courses of action in the same circumstances, on the same available evidence. To some extent, this observation also reflects the power of discourse and framing, meaning the way in which one message which holds general appeal – here, promotion and protection of health - can be used to serve different purposes in regulation and governance. Encouraging greater transparency and nuance regarding the specific ideas or content that support broad and laudable goals, such as promoting health and well-being, would aid efforts to subsequently evaluate whether regulatory and governance activities are successful in protecting or advancing their stated priorities.

Within the context of health promotion and protection objectives in the different cases, there was sometimes a discernible tension between access-related imperatives focused on freedom of individual choices with respect to health, and an emphasis on risk avoidance or mitigation. The former was particularly prominent in the legislative debates surrounding chelation therapy,[21] while the latter was emphasized in several outward facing government communications regarding liberation therapy.[22] Individual freedom or autonomy-based rationales appear to have been particularly compelling to elected officials when presented in relation to a sense of unmet medical needs or urgency.[23] For example, Hansard records from both the chelation therapy and liberation therapy case studies included passionate appeals from elected

[21] See discussion in Chapter 5, 5.2.2, *above*.
[22] See discussion in Chapter 6, 6.2.2, *above*. For example, AHS's position was that liberation therapy would not be supported as standard practice until it was established that its benefits outweighed its risks. See Alberta Health Services, *supra* note 19.
[23] The liberation therapy case study was particularly notable for this theme. See e.g. Government of Saskatchewan, "Saskatchewan entering partnership to advance MS research" (23 September 2011), online: < www.saskatchewan.ca/government/news-and-media/2011/september/23/saskatchewan-entering-partnership-to-advance-ms-research>.

officials using language such as "right to choose"[24] or "freedom" to make medical decisions,[25] and referencing advocacy from patients and their families as a reason to facilitate access.[26] The influence of advocacy and individual experiences or anecdote on decision-making regarding access to unproven medical interventions will be discussed in Section 8.2.3, below.

One objective or priority sometimes used to counterbalance freedom of choice narratives and support limiting or restricting access to an unproven medical intervention is the desire to avoid or manage risks. Risk mitigation often features as a central role in regulation.[27] However, risk-related considerations were far from straightforward in these case studies. To some extent, the narratives captured in these case study data reflected a lack of consensus about risk thresholds as well as shifting perceptions of, and responses to, different kinds of risks as they relate to unproven medical interventions. For example, a precautionary approach seems to have guided decisions to restrict access to liberation therapy in the absence of sufficient evidence establishing that it was safe and effective.[28] Regulation and governance of access to unproven stem cell interventions in Canada has fallen somewhere in the middle. Health Canada's decision to treat autologous stem cells as drugs subject to the authority of the *Food and Drugs Act* is arguably a precautionary approach that requires clinical trial evidence of safety and efficacy before access is permitted. However, the persistence of a private market (albeit small as compared to other countries such as the United States) offering treatments or services that seemingly contravene Health Canada's regulations, without public evidence of a robust enforcement response from either Health Canada or the colleges of physicians and surgeons, raises questions about how committed regulatory and governance actors are to a precautionary approach in this case.

In contrast, there was a strong push from proponents of chelation therapy to permit access to it in the absence of evidence that it is harmful, or more harmful than current standard of care treatments. As discussed in Chapter 5, several provinces passed legislated "negative proof" provisions, which protect physicians from findings of unprofessional or unbecoming conduct solely for providing chelation therapy (or in some cases CAM generally) unless there is demonstrable harm. These provisions embedded this permissive type of approach to access, where access is permitted unless and until there is evidence of harm, into the regulatory frameworks of several Canadian jurisdictions. Some advocates of this approach pointed to the historical reality that many medical and surgical advancements have evolved outside the context of formal research environments, via off-label prescription drug uses and practice innovations, and thus have been introduced into medical practice without evidence of safety and efficacy.

The reality that many well established standard of care treatments still carry risk and can be potentially harmful (e.g. all surgeries have risk, chemotherapy and radiation can be very harmful and risky and yet are still standard of care treatments for many cancers, etc.) was a related rationale used to suggest that access to chelation therapy should not be restricted simply because it may have risks. As these arguments used in relation to chelation therapy highlight, the

[24] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-2 (26 April 1994) at 1460 (Hon. Mr. Yankowsky).
[25] See e.g. Alberta, *Journals of the Legislative Assembly*, 23-4 (27 March 1996) at 875 (Hon. Mr. Langevin).
[26] See e.g. *House of Commons Debates*, 41-1, vol 146, No 63 (8 December 2011) at 1839 (Hon. Kirsty Duncan).
[27] See related discussion in Chapter 2, 2.1.2, *above*.
[28] As already discussed, some governments directly allocated funding for research to pursue answers to these questions about safety and efficacy.

realities of medicine can make it challenging to draw lines or distinctions when it comes to making access decisions about unproven medical interventions based on potential risk. In many respects, questions surrounding risk avoidance or mitigation are tied to concepts of evidence, which has its own complexities, as will be discussed in greater detail in the next section.

8.2.3 Legitimacy – reflections and questions

The third step of characterizing and analyzing the case studies was to consider questions of regulatory and governance legitimacy, which in my conceptual framework accounts for several features including jurisdiction, influences on decision-making, process, compliance, and enforcement. The element of legitimacy that stood out most prominently in this cross-case analysis was that of influence or, in other words, what shapes or impacts decision-making. As outlined in my conceptual framework, analyzing influence includes considering the role that expertise, evidence, political priorities, and advocacy play in decision-making. Although all of these considerations were relevant to one or more of the case studies, evidence and advocacy appear to have been particularly influential in regulatory and governance decisions about access.

In all three cases, there was a notable emphasis on evidence-based or evidence-informed decision-making in statements made by regulatory and governance actors, particularly within governments. However, all three cases also illustrated that evidence is a contested concept with multiple meanings in different contexts. The liberation therapy case study presented particularly poignant examples of some of the complexities that surround how evidence is defined, framed, interpreted, and applied. For example, elected officials routinely drew on personal stories and anecdote as a form of evidence that influenced their approaches or perspectives regarding the need to advance access to this intervention, including both by way of research and more direct clinical avenues.[29] In contrast, other actors such as the Ontario Health Technology Advisory Committee, the Ontario Health Quality Council, and the Canadian Agency for Drugs and Technologies in Health emphasized the need for rigorous scientific study in their assessments of the intervention.[30] The Traboulsee clinical trial, which was randomized, double-blind and placebo controlled, reflected an approach often characterized as the 'gold standard' of clinical research evidence. Several governance actors in the liberation therapy case study, including scientific and medical experts, prioritized this type of evidence in their public-facing communications about the intervention. In a different vein, and as would be expected in judicial and quasi-judicial processes, courts and administrative tribunals in all three case studies generally focused on expert testimony as the key source of evidence to assess the reasonableness of a particular intervention and its acceptance within the medical community.

To some extent, these varied views and the accepted uses of different kinds of information as evidence reflect debates taking place between and within different fields regarding how data and evidence are defined, constructed, and interpreted.[31] Resolving these debates goes well beyond the scope of this research. However, a key lesson from these case studies is that one cannot assume there is consensus regarding the meaning and implications of

[29] See Chapter 6, 6.2.3, *above*.
[30] See Chapter 6, 6.2.1, *above.*
[31] See e.g. Norman Denzin, "The elephant in the living room: or extending the conversation about the politics of evidence" (2009) 9:2 Qualitative Research 139; see also Sarah Devaney, *Stem Cell Research and the Collaborative Regulation of Innovation* (London and New York: Routledge, 2014) at 70-71, wherein Devaney discusses the "social construction of science for regulation".

"evidence" when discussing its role in and influence on decision-making. Rather, there is the potential for multiple perspectives and constructions to be operating simultaneously not only across different contexts and among different actors, but also within specific decision-making spheres. As will be discussed below, acknowledging that evidence is a contested concept is vital for strong regulation and governance, particularly when decisions are framed within an "evidence-based" or "evidence-informed" context. Engaging in reflective practice to assess and evaluate what forms of evidence are appropriate for different decision-making contexts or, at the very least, to identify the strengths and limitations of different kinds of evidence, would strengthen the legitimacy and credibility of decision-making processes regarding access to unproven medical interventions.

The role of advocacy was evident in the cross-case analysis as a prominent element in regulatory and governance decisions regarding access to the unproven medical interventions studied here. The chelation therapy and liberation therapy case studies in particular suggest that advocacy and political pressure had considerable influence in political forums and debates regarding access to these unproven medical interventions in Canada. Hansard records reflected combinations of organized lobbying (e.g. from chelation associations), petitions to legislative assemblies, public rallies, and direct personal appeals from constituents that appear to have resonated with some elected officials and motivated support for varied forms of access to these interventions. As discussed in Chapter 2, stakeholder engagement and public consultation can enhance the quality and credibility of regulation and governance, while also potentially encouraging greater levels of compliance.[32] However, the informal and opaque processes by which stakeholder perspectives were heard in these two case studies, including via political advocacy by well-organized patient and provider groups, seem unlikely to advance those benefits. To the contrary, such processes raise questions of fairness and mandate, as well as regarding potential bias and regulatory capture. The influence of advocacy is perhaps unsurprising in the political sphere. It nonetheless requires transparent assessment, particularly in relation to the use of evidence and other influences on decision-making regarding access to medical interventions, as these are important considerations in the legitimacy and credibility of those decisions. I will discuss the merits of prioritizing fairness and transparency in processes of stakeholder engagement in future strategies regarding regulation and governance of access to unproven medical interventions in Section 8.4.3.

8.2.4 Responsiveness and adaptability – limitations and potential

The final consideration in the characterization of these past examples of regulation and governance of access to unproven medical interventions provided by physicians in Canada was the degree to which they reflected responsiveness and adaptability.[33] As set out in my conceptual framework, these features of regulation and governance include the elements of timing of response or interventions, flexibility (i.e. shifts in approaches, generally in response to changing context, new information, or emerging evidence), and evidence of learning. Different actors in the case studies used a variety of instruments or approaches, with varying levels of coerciveness,

[32] See e.g. John McMillan & Jeanne Snelling, "Equality: Old Debates, New Technologies" in Roger Brownsword, Eloise Scotford & Karen Yeung, eds, *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) 69 at 70.

[33] For a discussion of these concepts and their connection to evaluating regulation and governance, see Chapter 2, 2.1.3 and 2.2.2, *above*.

and intervened at various points in time. Sometimes, these different strategies seemed to be used by actors concurrently or independently, without regard to levels of compliance or other external circumstances. The merits of graduated regulatory responses that begin with less intrusive options such as information or incentives and escalate to more coercive approaches such as legislated sanctions only as necessary are a focus in scholarship regarding responsive and smart regulation.[34] The central argument flowing from this body of work is that responsiveness and adaptability are features of good or strong regulation and governance.

I found some evidence of responsiveness and adaptability in regulatory and governance activities in the case studies. For example, regulation and governance of access to chelation therapy in Canada appears to have evolved largely in response to the considerable advocacy efforts advanced in favour of access towards elected officials. However, this status quo now appears to be well entrenched. Chelation therapy has been studied for over fifty years but this research has still not established that it is a safe and effective treatment for conditions other than those related to heavy metal toxicity. Nonetheless, I did not find evidence in my data to suggest that, for example, changes to the negative proof legislative regimes in place in several provinces are likely to be forthcoming anytime soon.[35]

In contrast to chelation therapy, the regulatory and governance activities surrounding access to liberation therapy evolved rapidly with considerable momentum, but also resolved relatively quickly. After initially responding with combinations of information-based and funding instruments, governments and other regulatory and governance actors shifted their responses over time, including by stepping away from engaging in rigorous debate on the topic (e.g. in legislative and parliamentary assemblies), after emerging evidence, including the Traboulsee trial, largely discredited the intervention.[36] With respect to the case study regarding unproven stem cell interventions in Canada, Health Canada arguably missed an opportunity from a timing perspective to take early leadership and provide clarity regarding unproven stem cell interventions in Canada when growing markets in other international jurisdictions signalled the likely development of this issue domestically. However, it demonstrated responsiveness when it published a Policy Position Paper to clarify ambiguities in its regulatory regime that had been identified by scholars and scientists as creating a form of loophole for provision of specific kinds of unproven stem cell interventions in Canada.[37] Although events are still unfolding, the tenor of current regulatory reform efforts under way with respect to regenerative medicine also arguably signal that improving responsiveness and adaptability are a focus or goal of these initiatives.[38]

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[34] John Braithwaite, "Types of responsiveness" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 117 at 117-118; see also Julia Black & Robert Baldwin, "Really Responsive Risk-Based Regulation" (2010) 32 L & Policy 181; see also Neil Gunningham & Darren Sinclair, "Smart regulation" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 133.

[35] See discussion in Chapter 5, 5.1.1, *above*.

[36] Anthony Traboulsee et al, "Safety and efficacy of venoplasty in MS A randomized, double-blind, sham-controlled phase II trial" (2018) 91 Neurology e1660. doi :10.1212/WNL.0000000000006423.

[37] Health Canada, "Position Paper", *supra* note 9.

[38] See Government of Canada, "Regulatory innovation for health products: Enabling advanced therapeutic products" (last modified 2 February 2021), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/strategies-initiatives/health-products-food-regulatory-modernization/advanced-therapeutic-products.html>.

With respect to evidence of learning, it remains to be seen whether and to what extent regulation and governance of access to future unproven medical interventions that enter the public stage will reflect learnings from past experiences, such as from the events of these three case studies. I found very few examples in these case study data of actors referencing past experiences in relation to the current questions about access that they were facing.[39] Brown and Beynon-Jones discuss the limitations of a temporal reflex in regulation, which describes a focus on present and near-term opportunities and consequences rather than a longer-term view or an emphasis on building from past lessons.[40] My data will not have captured the full picture of decision-making in these case studies. However, public-facing information from these cases arguably reflected a strong temporal reflex with limited evidence of learning as an influence on how regulatory and governance actors approached decisions about access to these three unproven medical interventions. Interestingly, and as noted above, actors in the liberation therapy case study including the Scientific Expert Working Group did recommend that it be studied and the resulting lessons used to inform future strategies in similar situations.[41] As discussed below, one of the goals of this doctoral research is to help identify lessons from these three case studies that can be used to strengthen learning for the benefit of future regulation and governance. In the next sections, I draw on my findings from the case studies to discuss key features in the Canadian context that have important implications for future regulation and governance of access to unproven medical interventions, and then offer suggestions regarding priority areas for future development in this field.

8.3 Key features in the Canadian context and implications for future regulation and governance

In Chapter 4, I briefly mapped the relevant legal and policy landscape for this research, including the roles and sources of authority for regulatory and governance actors that featured prominently in the case studies. In my cross-case analysis, I built on that foundation to identify what I suggest are particularly important features of the Canadian context that future regulation and governance of access to unproven medical interventions will need to account for to be successful. These features include our decentralized healthcare system, the importance of medical professional regulation, and our judicial and quasi-judicial processes with an independent judiciary.

8.3.1 A decentralized healthcare system

Healthcare in Canada is highly decentralized and, as reflected in these case studies, involves a large network of actors with influence over access to medical interventions including all levels of government, healthcare institutions, healthcare professionals and their regulatory bodies, patient representatives, advocacy groups, and industry (e.g. pharmaceutical companies, medical device manufacturers, etc.), among others. As was discussed in Chapter 4, health is an area of shared jurisdiction under Canada's Constitution, meaning federal, provincial, and

[39] In hindsight, liberation therapy has been described by some commentators as a "lesson to the medical community". See Lindsay Machan, Kieran Murphy & Tony Traboulsee, "Multiple Sclerosis and Venous Abnormalities: Medicine in the Age of Social Media" (2012) 63 Canadian Assoc Radiologists J S2 at S2-S3.
[40] Nik Brown & Sianm Beynon-Jones, "Reflex regulation: an anatomy of promissory science governance" (2012) 14 Health Risk & Society 223
[41] CIHR, "Expert Working Group March 2017 Meeting", *supra* note 1.

territorial governments are limited in the extent to which they are able to control access to unproven medical interventions by way of legislation.

The federal government has several options available when seeking to establish a national approach to an issue such as access to a particular unproven medical intervention. Most importantly in the context of this research, these options include jurisdiction over criminal law and drugs, and its spending powers. The regulation of autologous stem cell interventions under the *Food and Drugs Act* is an example of how the federal government has used its criminal law powers to establish national standards and processes governing access to unproven medical interventions that are deemed to be drugs.[42] However, the chelation therapy case study demonstrates some of the limitations of this form of federal oversight. With chelation therapy, the federal government has authority to approve chelating drugs. However, once approved those drugs can be used off-label, as has been the case with non-standard of care applications of chelation therapy. These unproven applications fall within the scope of the practice of medicine and are under provincial authority. Canada's constitutional division of powers affords provinces and territories jurisdiction over much of healthcare and the practice of medicine. Within this arrangement, provinces and territories have considerable independence and thus it is not uncommon to see variation across Canada in how they respond to similar issues, including the unproven medical interventions studied here. As was discussed in Chapter 5, several provinces and territories have legislated permissive regimes for CAM that include unproven applications of chelation therapy.

Together, these three case studies reflect varying levels and forms of federal, provincial, and territorial engagement in regulation and governance of access to the unproven medical interventions studied. At times, there have been notable tensions between a desire for national consistency or coordination, and the individual interests and priorities of provinces and territories. The liberation therapy case study provides a useful illustration of this tension. Against an early backdrop of public statements from representatives of provincial and territorial governments regarding their interests in a coordinated national approach to addressing the scientific questions and access demands surrounding liberation therapy,[43] different jurisdictions took varied approaches. None of the unproven medical interventions in these three case studies, including liberation therapy, were made available in publicly funded healthcare systems in Canada. However, several provinces and territories including Saskatchewan, Manitoba, and Yukon facilitated access to liberation therapy by way of committing public funding for research, while New Brunswick briefly provided a subsidy for individuals who received the intervention out of country.[44] This variation may be explained in part by different priorities and imperatives, including the level of public pressure and advocacy levied towards elected officials.[45] It also might be argued that it reflects the flexibility inherent in decentralization (also referred to as regionalization in the context of health system reforms), which – at least in theory - permits

[42] Health Canada, "Position Paper", *supra* note 9.
[43] See e.g. Government of Newfoundland and Labrador, "Federal, Provincial and Territorial Health and Healthy Living / Wellness Ministers Agree on Ways to Strengthen the Health of Canadians" (14 September 2010), online: *Health and Community Services* <www.releases.gov.nl.ca/releases/2010/health/0914n11.htm>.
[44] Canadian Agency for Drugs and Technologies in Health, "An Update on the Investigation of Chronic Cerebrospinal Venous Insufficiency for the Treatment of Multiple Sclerosis; Environmental Scan" (4 May 2011), online (pdf): <www.cadth.ca/sites/default/files/pdf/MS_Liberation_Update_es-20_e.pdf> at 3.
[45] See e.g. Chapter 6, Section 6.2.3, *above*, which includes examples of political advocacy in favour of access to liberation therapy.

jurisdictions to tailor their activities (priorities, budget allocations, etc.) to their unique needs and circumstances.[46]

The decentralization of healthcare in Canada means that distributed governance is embedded within our healthcare systems.[47] Distributed governance describes the devolution and power of public sector responsibilities and activities, such as program or service delivery, management, and administration, to arms-length and non-government entities.[48] Working effectively within a distributed governance framework is arguably necessary for regulatory and governance actors to advance or achieve their objectives with respect to managing access to unproven medical interventions. Doing so not only requires governments to act within the bounds of their constitutional authority,[49] but also that both government and non-government actors collaborate or coordinate where there is an interest in advancing shared goals or objectives, such as protecting and promoting health. I will speak again to the matter of collaboration in Section 8.4.1 below as part of the discussion regarding priorities and strategies for future regulation and governance of access to unproven medical interventions in Canada.

8.3.2 The importance of medical professional regulation

The second feature that stood out in my cross-case analysis is the critical role that medical professional regulation plays in the regulation and governance of access to unproven medical interventions in Canada. I have already addressed the context for medical professional self-regulation in Canada and the functions and responsibilities of the colleges of physicians and surgeons in Chapter 4 and will not revisit those points here. Instead, I will highlight four areas where my analysis of the case studies indicates they have particularly important influence over whether and under what conditions physicians can provide an unproven medical intervention.

First, the colleges of physicians and surgeons provide critical oversight of physicians who provide unproven medical interventions lawfully, but outside publicly funded healthcare systems in Canada. For example, as noted above, although provinces and territories have limited access to unproven applications of chelation therapy by withholding public funding, there is nothing legally preventing physicians from using Health Canada approved chelating drugs off-label on a private market basis. However, as members of a self-regulating profession, physicians are bound by their professional standards and obligations regardless of whether they are providing care in a public or private system. Accordingly, the colleges of physicians and surgeons have the authority and the responsibility to ensure that their members who provide lawful unproven medical

[46] For example, a 2004 issue of *Healthcare Papers* included a series of essays that explored different aspects of regionalization in Canadian healthcare systems, including its potential and associated challenges. See Peggy Leatt, "Editorial: Notes from the Editor-in-Chief" (2004) 5:1 *Healthcare papers* doi:10.12927/hcpap..16835.

[47] See e.g. Carey Doberstein, *Distributed Democracy; Health Care Governance in Ontario* (Toronto: University of Toronto Press, 2020). Doberstein presents an analysis of health care governance in Ontario's Local Health Integration Networks through a distributed democracy framework and, in so doing, highlights the importance of accountability in distributed governance models.

[48] Samuel Wells & Karl Salgo, *The Changing Nature of Public Sector Governance; A qualitative review of distributed governance in Canada* (Ottawa, ON: Institute on Governance, 2019) at 3. Wells and Salgo suggest that distributed governance is an established feature of public sector governance in Canada.

[49] As discussed in Chapter 4, the *AHRA Reference* case highlighted the constitutional risks when the federal government goes too far and encroaches on provincial jurisdiction over regulation of the practice of medicine or related areas. See *Reference re Assisted Human Reproduction Act*, 2010 SCC 61.

interventions in the private market are meeting their professional standards. As will be discussed below, the extent to which they are fulfilling this responsibility is a matter of some debate.

Second, the colleges of physicians and surgeons can play an important role in setting out professional expectations regarding new and emerging unproven medical interventions that might otherwise trigger ambiguity and uncertainty regarding their appropriateness as a treatment option. The liberation therapy case study serves as a useful example here. As discussed in Chapter 6, unlike some other jurisdictions including the United States, Canada did not see a notable domestic private market develop for liberation therapy, despite the considerable public interest that surrounded this intervention. This result may be attributed in part to a lack of support from the colleges of physicians and surgeons.[50]

Third, the colleges of physicians and surgeons can help resolve ambiguities in how unproven medical interventions are classified. Important definitional challenges associated with unproven medical interventions, including managing distinctions between research and medical or surgical innovation, were discussed in Chapter 1. Some of these challenges are evident in how unproven stem cell interventions have been characterized in Canada. As discussed in Chapter 7, even after Health Canada attempted to resolve potential regulatory ambiguities surrounding autologous stem cell interventions by clarifying that they are drugs and subject to the requirements of the *Food and Drugs Act*, there was some public pushback from providers who objected to that approach and argued they should be considered part of surgical practice and not under the regulatory purview of Health Canada.[51] Although the colleges of physicians and surgeons are well placed to take a public stand on these debates, they have been largely silent.[52]

Finally, the colleges of physicians and surgeons have valuable professional expertise to offer government decision-makers who are faced with challenging questions about access to unproven medical interventions. The value of this professional expertise to inform standards and evaluate the conduct of members of the profession is one of the rationales often used to support the model of professional self-regulation.[53] It can also potentially provide a counterbalance to the influence of advocacy and political pressure on elected officials. As noted above, the chelation therapy case study served as a particularly poignant example of the impact of these pressures on governments' decisions about access. However, it also highlighted the complexities of the relationship between provincial governments and the colleges of physicians and surgeons when,

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[50] For example, the Collège des médecins du Québec exhibited early leadership in 2010 by announcing that in Quebec, testing or treatment for CCSVI should only be provided in approved research trials. Canadian Institutes of Health Information, *Canadian Multiple Sclerosis Monitoring System: Environmental and Technical Scan* (Ottawa, Ontario: CIHI, 2012) at 21.

[51] See e.g. Carol Mulligan, "Sudbury doc defies Health Canada order to stop performing stem cell treatment" (17 July 2019), online: <www.sudbury.com/local-news/sudbury-doc-defies-health-canada-order-to-stop-performing-stem-cell-treatment-1589149>.

[52] The College of Physicians and Surgeons of Saskatchewan in one exception. It provided clarification to its members about the need for Health Canada approval for stem cell therapies in its newsletter. See College of Physicians and Surgeons of Saskatchewan, *supra* note 11 at 11. The College of Physicians and Surgeons of Alberta is another exception with its stem cell-specific practice standards. See College of Physicians and Surgeons of Alberta, *supra* note 13.

[53] Ontario Bar Association, "The regulation of health professionals and professional discipline" (April 2018), online: <www.oba.org/Sections/Health-Law/Resources/Resources/The-Regulation-of-Health-Professionals-and-Profess>; see also Trudo Lemmens & Kanksha Mahadevia Ghimire, "Regulation of Health Professions in Ontario: Self-Regulation with Statutory- Based Public Accountability" (2019) 9:3 Revista de direito sanitário 124 at 130.

in some jurisdictions, governments moved to expand access notwithstanding the lack of support from their respective college.

This discussion regarding the important roles that colleges of physicians and surgeons have in the regulation and governance of access to unproven medical interventions should not be taken as a suggestion that they have successfully fulfilled these roles or that the approaches they have taken are without critique. To the contrary, these case studies raise questions about whether the current medical professional self-regulatory approach is sufficient to safeguard the public interest in the context of unproven medical interventions. If not, the provinces arguably have not only the power but also the responsibility to intervene. It has been argued elsewhere that self-regulation works best in the "shadow" of government, and that past regulatory failures illustrate that government cannot "abdicate its responsibilities to self-regulators".[54] Although the provinces have largely delegated their authority over regulation of the medical profession to the colleges of physicians and surgeons, they are still a form of meta-regulator in so far as they have the authority to monitor and set standards and expectations for the colleges' activities.[55] There are important and currently unanswered questions about the future of medical professional self-regulation in Canada, including what it means for the colleges of physicians and surgeons to act in the public interest with respect to unproven medical interventions. These questions will be addressed below in Section 8.4.3.

8.3.3 Judicial and quasi-judicial processes, and our independent judiciary

The role of judicial and quasi-judicial processes with an independent judiciary was the third feature that stood out in the case studies as an important element of the legal context within which regulation and governance of access to unproven medical interventions in Canada takes place. I will address two particularly notable aspects of their involvement in this section, the first of which is more concrete, while the second operates at a broader level of influence.

First, courts and administrative tribunals served as actors that directly addressed questions of access to chelation therapy, liberation therapy, and unproven stem cell interventions in specific cases and, in so doing, played a role in setting standards for evidence in these contexts. For example, courts and tribunals were called upon to adjudicate appeals over denials of coverage under provincial health insurance statutes, and to consider the eligibility of related medical expenses as part of damage claims in all three case studies. In most of these cases, courts and tribunals did not find in favour of the individuals seeking coverage or compensation for the unproven interventions. Notably, political pressure and advocacy did not have the same degree of prominence or influence in courts and tribunals as they did in other forums. Rather, the judicial and quasi-judicial decisions I reviewed in these case studies generally reflected measured approaches based on precedent, with a strong emphasis on evidence. The opinion of medical experts was often highly persuasive to decisions about whether an intervention was reasonable and medically justified or experimental. This finding, though not unexpected, is relevant to the broader theme surrounding different interpretations of evidence that is addressed in Section 8.4.4 below.

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[54] Margot Priest, "The Privatization of Regulation: Five Models of Self-Regulation" (1997-1998) 29 Ottawa L Rev 233 at 239.

[55] Peter Grabosky, "Meta-regulation" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 149 [Grabosky, "Meta-regulation"].

Second, and more broadly, the potential for individuals to seek recourse for unfavourable access-related issues via judicial and quasi-judicial proceedings arguably plays an important role in framing the boundaries for what is acceptable conduct on the part of regulatory and governance actors. As we have seen in other areas, courts have extensive power under the *Charter* to impact laws regarding access to medical interventions when they find that an individual's *Charter* rights (typically s. 7 or s. 15) are violated in a manner that cannot be justified in a free and democratic society.[56] I did not identify any *Charter* claims specific to the medical interventions in these case studies and to date, these are not areas where the courts have exerted direct influence via constitutional rights-based access claims.[57] Nonetheless, *Charter* jurisprudence provides some guidance to governments regarding whether, how, and to what extent they can limit individual freedoms with respect to choice of medical interventions, and the potential for *Charter* challenges may provide some incentive to stay within those bounds.

In a related vein, individuals who are harmed by an unproven medical intervention have the option of suing the provider in tort law for negligence. As discussed in Chapter 4, previous negligence cases have established standards of care that are highly relevant to the provision of unproven medical interventions, including regarding informed consent. I did not find many medical negligence cases addressing the specific interventions in these case studies and can only speculate why that might be. It is possible that not many individuals have been harmed by these interventions, or not harmed seriously enough to prompt legal action. It may also be the case that the more systemic limitations of tort law as an oversight mechanism, including the burden it places on patients and its evidentiary challenges, particularly where there are stark asymmetries in knowledge between patients and providers, have played a role in limiting lawsuits in this area.[58] In any event, similar to the ways in which the potential for *Charter* challenges may influence government regulation of access to unproven medical interventions, the potential for legal liability in negligence may have some bearing on the actions of physicians with respect to whether and how they provide unproven medical interventions. It is beyond the scope of this research to offer conclusions about the strength of those relationships, but it is clear that judicial and quasi-judicial processes are an important part of the context for regulation and governance of access to unproven medical interventions in Canada.

8.4 Proposed areas of focus in future strategies for regulation and governance of access to unproven medical interventions in Canada

The three case studies analyzed in this research are not unique phenomena. They are not the first instances of debates regarding access to unproven medical interventions,[59] nor will they

[56] For example, courts can strike down or read down legislation that violates the *Charter*, sever unconstitutional sections, provide constitutional exemptions, read in for laws that are underinclusive, and suspend declarations of invalidity, among other possibilities. For a discussion of *Charter* remedies, see Kent Roach, "Enforcement of the Charter – Subsections 24(1) and 52(1)" (2013) 62 SCLR (2d) 473.

[57] As discussed in Chapter 4, *above*, abortion, Medical Assistance in Dying, use of medical marijuana, and supervised safe injection facilities for intravenous drug use are areas where courts have done so. See *R. v. Morgentaler*, [1988] 1 SCR 30; *Carter v. Canada (Attorney General)*, 2015 SCC 5; *R v. Smith*, 2015 SCC 34; *Canada (Attorney General) v. PHS Community Services Society* 2011 SCC 44.

[58] For a related discussion in the US context, see e.g. Claire Horner et al, "Can civil lawsuits stem the tide of direct-to-consumer marketing of unproven stem cell interventions" (2018) 3:1 NPJ Regenerative Medicine 1.

[59] See e.g. Kirsten Matthews & Ana Iltis, "Unproven stem cell–based interventions and achieving a compromise policy among the multiple stakeholders" (2015) 16 BMC Medical Ethics 75 at 3-4. Matthews and Iltis draw

likely be the last. They do however provide fertile ground for drawing lessons and identifying priorities that may help strengthen regulatory and governance responses to similar issues as they arise in future. Different individuals and stakeholder groups including governments, healthcare providers, the scientific community, and patients, among others, will inevitably vary with respect to how regulatory and governance activities are evaluated, and how different factors such as individual liberty, economic implications, risk management, transparency, and timeliness are prioritized. Similarly, resolving questions about what instruments and processes are acceptable and appropriate in different contexts can be anticipated to be challenging. Widespread agreement regarding what priorities or objectives should drive regulation and governance is also unlikely.

I propose the following priorities for future regulation and governance of access to unproven medical interventions in Canada: (i) facilitating responsible research as well as scientific and clinical innovation, including access to therapies in contexts that support safe, effective, and good quality interventions;[60] (ii) limiting premature or inappropriate use of unproven medical interventions outside such contexts;[61] (iii) promoting trust in the research enterprise through responsible and transparent use of public research funds and related resources.[62] The strategies I present in this section focus on areas that may help further these objectives and support regulation and governance approaches that seek to mitigate risks to individuals from unproven interventions as well as the longer-term, more amorphous risks to

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comparisons between unproven stem cell interventions, HIV activism in the 1980s, and breast cancer advocates seeking access to HDC/ABMT in the 1990s.

[60] This approach echoes Health Canada's existing priorities for regulating health products, which include protecting the public from unsafe products, and maintaining "appropriate and proportional regulatory oversight". See Health Canada, "Health Products and Food Regulatory Modernization" (last modified 18 February 2021), online: <www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/strategies-initiatives/health-products-food-regulatory-modernization.html>. It also captures the public interest in benefiting from science and research that has the potential to identify safe and effective therapies. See Tracey Evans Chan, "Legal and regulatory responses to innovative treatment" (2013) 21 Med L Rev 92 at 121. Some scholars go so far as to look to Article 27 of the *Universal Declaration of Human Rights*, GA Res 217A (III), UNGAOR, 3rd Sess, Supp No 13, UN Doc A/810 (1948) 71, as grounding a human right to benefit from scientific advancements, including biomedical research. For example, see Bartha M. Knoppers et al. "A human rights approach to an international code of conduct for genomic and clinical data sharing" (2014) 133:7 Human Genetics 895.

[61] This proposal builds on the work of others who have discussed the role of regulation in ensuring safe, effective, and high-quality therapies, while avoiding unnecessary restrictions on research or clinical practice. See Barbara von Tigerstrom, Thu Minh Nguyen & Bartha Martha Knoppers, "Regulation of Stem Cell-Based Therapies in Canada: Current Issues and Concerns" (2012) 8 Stem Cell Revs & Reports 623 at 623; see also von Tigerstrom & Schroh, *supra* note 2 at 181. It also responds to the concern that adverse events following premature use of an unproven medical intervention may damage public trust and support for promising fields of research. As noted earlier, a caution along these lines was issued to the field of stem cell research, suggesting it should learn from the history of gene therapy trials – see James Wilson, "A History Lesson for Stem Cells" (2009) 324:5928 Science 727.

[62] For example, the diversion of public funds to research liberation therapy was criticized by both patients and some researchers for the opportunity cost implications (i.e. the idea that funds used to research this intervention were then not available for other avenues of research or treatment). See e.g. Shelly Benjaminy, "Resilience, trust, and civic engagement in the post-CCSVI era" (2018) 18:366 BMC Health Services Research https://doi.org/10.1186/s12913-018-3130-x; see also Michael Hutchinson, "Funding CCSVI research is/was a waste of valuable time, money and intellectual energy: Commentary" (2013) 19:7 Multiple Sclerosis J 861 at 861 & 862. A related concern is that loss of public trust in the research enterprise would be to the detriment of future patients as well as healthcare providers and funders who rely on research evidence to make clinical and health system-level decisions about new treatment options. These kinds of concerns are sometimes raised with respect to "Right-to-Try" legislation. See e.g. Rebecca Dresser, "First-in-Human Trials Participants: Not a Vulnerable Population, but Vulnerable Nonetheless" (2009) J L Med & Ethics 38.

future patients and healthcare systems that can follow premature applications of unproven interventions (including those that are potentially promising).[63] These proposals are grounded in today's current reality of limited public funds and other resource constraints, stressed healthcare systems, and the ever-shifting online information environment.

I will discuss the value of collaborative, distributed governance, the need for an emphasis on the public interest in renewal of medical professional regulation, the importance of fairness and transparency in stakeholder engagement practices, the need for clarity and nuance in discussions about evidence, and the importance of strong science and health communication practices that respond to the realities of today's online information environment. There are a few important caveats that must accompany this discussion. These strategies should not be viewed as a comprehensive menu or map for future regulation and governance, and there is naturally room for debate about their respective merits and practical utility. I also want to emphasize that each of the topics identified below are nuanced areas and the subjects of both scholarship and policy attention. The modest purpose of this discussion is merely to highlight how, because of my findings in this case study research, I see these areas as being particularly important for future regulation and governance of access to unproven medical interventions in Canada. Finally, it is also important to note that while my research has focused on provision of unproven medical interventions in Canada (and that is the focus of this discussion), future strategies for regulation and governance will also need to account for the influences of the global medical marketplace and its digital ecosystem.

8.4.1 An emphasis on collaborative, distributed governance

The research I have presented in this thesis highlights the potential value of collaborative, distributed governance in responding to unproven medical interventions. Among other things, collaborative governance can involve "shared, negotiated, and deliberative consultation and decision-making".[64] It can also extend into sharing resources, instruments, and enforcement activities. Each case studied here involved a range of different actors who exerted varied forms of influence over access to the unproven medical interventions studied. As already discussed, in addition to governments and professional regulatory bodies, notable actors included medical and scientific organizations (e.g. the Canadian Medical Association, the Stem Cell Network), and advocacy groups (e.g. the MS Society). These varied actors offer expertise in different areas, command different spheres of influence, and have different resources at their disposal. However, the regulatory and governance activities of these actors in relation to the unproven medical interventions studied were often uncoordinated and inconsistent.

Federal, provincial, and territorial government collaboration can play an important role in achieving some level of national consistency or a coordinated strategy in relation to new unproven medical interventions, while avoiding constitutional challenges based on division of powers concerns. Coordinating responses (e.g. via development of shared policy statements or linked information campaigns) may also offer the potential to leverage resources and expertise,

[63] For a discussion using a similar balancing approach, see Barbara von Tigerstrom, "New Regulatory Pathways for Stem Cell-Based Therapies: Comparison and Critique of Potential Models" in Phuc Van Pham & Achim, eds, *Safety, Ethics and Regulations; Stem Cells in Clinical Applications* (Springer, 2017) 173 at 191.
[64] Lisa Bingham, "Collaborative Governance" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 386 at 388.

which is important in situations where both may be in limited supply. It also provides the potential to reach larger and more diverse audiences than any one actor can easily do on their own, including those that may have greater trust in some actors than others. For example, research suggests public trust may be higher for stem cell researchers working in publicly funded universities than in private settings.[65] Other research on social media users discussing unproven stem cell interventions pointed to complex perspectives about evidence, with some Facebook users exhibiting trust in basic scientific evidence but also in individual experience, coupled with distrust of some institutions, processes, and actors that underpin or seek to interpret evidence.[66] Accordingly, collaborative approaches that engage university researchers along with informed patient representatives in communication strategies regarding the potential risks of a particular unproven medical intervention that use different mechanisms, including social media, may find a more receptive audience among patients and their families who might be considering that intervention.

The Scientific Expert Working Group convened by CIHR and the MS Society of Canada to make recommendations on CCSVI and liberation therapy is one example from this research of collaborative, distributed governance that appears to have had some success in bridging governments, scientific and medical experts, and a prominent patient advocacy organization, with the common goal of promoting evidence-informed decision-making regarding the use of liberation therapy.[67] Although it was not without its critics,[68] the recommendations from this group appear to have played a significant role in shaping decisions regarding access to liberation therapy in Canada. Governments are particularly well-placed to lead coordinated efforts of this nature, including with other non-state actors, by virtue of the resources at their disposal including their financial resources, the considerable administrative infrastructure they command which includes strong channels for public communication, and the legitimacy that follows an electoral mandate.[69] However, resource and attention constraints, along with political factors, may limit governments' willingness or ability to do so. Accordingly, it is important that other actors, including professional regulatory bodies and professional associations, not rely solely on government leadership when issues arise with respect to access demands for unproven medical interventions. The value of a proactive response from such actors is discussed in the following section.

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[65] See Christine Critchley, "Public opinion and trust in scientists: the role of the research context, and the perceived motivation of stem cell researchers" (2008) 17 Public Understanding Science 309. In the context of a different emerging biotechnology, genomic medicine, research found that in Canada and the United Kingdom, non-profit researchers and physicians were the most influential and trustworthy social actors studied. See Sarah Savić-Kallesøe et al, "Public trust and genomic medicine in Canada and the UK" (2021) 6 Wellcome Open Research doi: 10.12688/wellcomeopenres.16831.2.

[66] Saheli Datta, "Emerging dynamics of evidence and trust in online user-to-user engagement: the case of 'unproven' stem cell therapies" (2018) 28:3 Critical Public Health 352 at 356, 359-360.

[67] Canadian Institutes of Health Research, *supra* note 16.

[68] See Chapter 6, Section 6.2.3, *above*.

[69] For a more in-depth discussion of these "tools" of government, also referred to as the powers of treasury and nodality, see Christopher Hood, *The Tools of Government* (London: The MacMillan Press Ltd, 1983).

8.4.2 Renewed focus on the public interest and the role of professional regulation

Medical professional regulatory bodies are key actors in the governance of unproven medical interventions in Canada by virtue of their technical expertise, credibility among many healthcare professionals, and the regulatory authority that has been delegated to them by the provinces and territories. However, my analysis of their involvement in these case studies raises questions regarding whether they are fulfilling their mandates to act in the public interest with respect to how they approach unproven medical interventions. As discussed in Chapter 4, medicine is currently a self-regulated profession in Canada. The colleges of physicians and surgeons across Canada operate under delegated provincial authority, in some cases with an explicit legislative mandate to act in the public interest.[70] Conceptions of what is in the "public interest", and whether or how it is served by professional self-regulation, are contested ideas that have changed over time.[71] There are initiatives underway in Canada to explore challenges and concerns with current medical self-regulation models,[72] and these activities may create a policy window to take a renewed look at what is expected of professional self-regulatory bodies with respect to unproven medical interventions.[73] My findings in these case studies point to three issues that I suggest would be particularly important in such future efforts to strengthen professional regulation with respect to unproven medical interventions.

The first question that bears consideration is whether and to what extent the public interest is served when medical professional regulatory bodies take reactive rather than proactive approaches. For example, does serving the public interest require colleges of physicians and surgeons to use information-based instruments to provide early advice and guidance to members in the face of an emerging issue such as a new unproven medical intervention that is getting public attention? As already noted, there was not a notable private market for liberation therapy within the Canadian medical profession, perhaps in part because colleges of physicians and surgeons did not publicly support use of this intervention outside approved research contexts. In contrast however, colleges of physicians and surgeons have faced criticism about their relative public silence regarding provision of unproven stem cell interventions.[74]

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[70] See e.g. Ontario's *Regulated Health Professions Act, 1991*, SO 1991, c18 at s 3, which provides "It is the duty of the Minister to ensure that the health professions are regulated and co-ordinated in the public interests".

[71] See Tracey L. Adams, "Professional Self-Regulation and the Public Interest in Canada" (2016) 6:3 Professions & Professionalism https://journals.hioa.no/index.php/pp/article/view/1587; see also Priest, *supra* note 54.

[72] See e.g. British Columbia Steering Committee on Modernization of Health Profession Regulation, "Recommendations to modernize the provincial health profession regulatory framework" (August 2020), online (pdf): <www2.gov.bc.ca/assets/gov/health/practitioner-pro/professional-regulation/recommendations-to-modernize-regulatory-framework.pdf>. Similar work is underway in the United Kingdom. See Department of Health and Social Care, "Regulating healthcare professionals, protecting the public" (2021), online (pdf): <assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978833/Regulating_healthcare_professionals__protecting_the_public.pdf>.

[73] The concept of a policy window is generally attributed to John Kingdon who suggested that when problem, policy, and political streams align, a policy window of opportunity opens for public policy agenda setting. John Kingdon, *Agendas, Alternatives and Public Policies* (Boston: Little, Brown and Company, 1984).

[74] Timothy Caulfield, Blake Murdoch & Michael Rudnicki, "Medical colleges: Tell your members to stop providing unproven stem cell therapies" (2019) Healthy Debate https://healthydebate.ca/2019/03/topic/unproven-stem-cell-therapies/.

In another vein, does serving the public interest permit (or perhaps even require) professional regulatory bodies' professional discipline processes to respond when information becomes available regarding potentially problematic conduct of regulated members who are providing unproven medical interventions, or is it sufficient to rely on complaint-driven processes, which often (though not necessarily) involve some type of adverse event(s) suffered by a patient? The data from these case studies suggest colleges of physicians and surgeons have largely adopted a reactive approach to the oversight of members' conduct, whereby they generally only address potential violations of professional ethics or other practice standards in the face of a traditional complaint. This approach places a considerable burden on patients and their families, particularly given the asymmetries in knowledge and resources often found in the doctor-patient relationship which are arguably only exacerbated with respect to unproven medical interventions that are often characterized by scientific uncertainty and complex or evolving evidence.[75]

Professional regulatory bodies have considerable power over the conduct of their members by virtue of their authority to set and enforce standards of practice with respect to unproven medical interventions, but it is not clear from the case studies that these powers have been used proactively, or to their full potential. These questions may not have easy answers but are worth exploring in future professional regulatory reform efforts. Maintaining broad public trust in the medical profession, and its privilege to self-regulate, may require more proactive leadership from the colleges of physicians and surgeons when tensions and conflicts arise regarding new unproven medical interventions that stir public interest in access, with the potential to prompt new private markets.

The second topic worth exploring is how medical professional regulatory bodies approach the question of evidence-based practice,[76] including the extent to which they are consistent between the standards they establish and the practices that they permit. The Canadian Medical Association Code of Ethics, which has been adopted by colleges of physicians and surgeons across Canada, includes the obligation to recommend "evidence-informed treatment options".[77] The policies and practice standards of individual colleges also generally emphasize the importance of evidence-based care. For example, the Ontario College of Physicians and Surgeons' Practice Guide provides that "physicians should provide medical care based on objective evidence wherever possible".[78] On their face, these standards and expectations do not necessarily appear to be consistent with the provision of unproven medical interventions which, by definition, lack evidence of safety and efficacy. Developing a deeper understanding of the expectations for physicians with respect to evidence-based care and understanding the potential

[75] See Tamra Lysaght, Bernadette Ricards & Anantharaman Muralidharan, "Exploring the boundaries of autonomy and the 'right' to access innovative stem cell therapies" (2017) 9 Asian Bioethics Rev 45 at 50-51. Lysaght et al. also note the added vulnerabilities associated with suffering from terminal and chronic illness.
[76] It is important to emphasize that evidence is a contested topic and will be discussed in Section 8.4.4, *below*.
[77] Canadian Medical Association, *CMA Code of Ethics and Professionalism* (2018), online (pdf): <policybase.cma.ca/documents/policypdf/PD19-03.pdf>.
[78] College of Physicians and Surgeons of Ontario, "The Practice Guide; Medical Professionalism and College Policies" (2007, last modified 2021), online (pdf): <www.cpso.on.ca/admin/CPSO/media/Documents/physician/polices-and-guidance/practice-guide/practice-guide.pdf> at 8.

implications of any current inconsistencies would be valuable. Doing so could facilitate efforts to align these standards more closely across practice areas.[79]

Finally, there are also important considerations regarding the degree to which medical professional regulatory bodies are equipped and enabled to provide expert input into government decisions regarding access to new and unproven medical interventions. One way in which professional regulatory bodies can potentially strengthen governance of unproven medical interventions is by bringing that expertise to serve as a form of check and balance to the public pressure and political advocacy that can motivate government responses. However, putting aside the question of their own vulnerability to different forms of pressure, advocacy, or stakeholder capture (discussed more in Section 8.7), fulfilling such a role requires a certain degree of influence and potentially cooperation between professional self-regulatory bodies and government. The debates about chelation therapy from the 1980-1990s and associated legislative activity, where access to chelation therapy and other forms of CAM moved forward notwithstanding initial opposition from several colleges,[80] reflect the complexities of these relationships and point to potential merits of exploring stronger collaboration between governments, professional regulatory bodies, and professional medical associations such as the Canadian Medical Association and its provincial equivalents.

Professional medical associations have established advocacy roles and may be particularly well-placed to engage with governments on issues related to access to unproven medical interventions. For a recent example, the Canadian Medical Association has been very active in advocacy with respect to virtual care in Canada following the COVID-19 pandemic. It has collaborated with the Royal College of Physicians and Surgeons of Canada and the College of Family Physicians of Canada to produce recommendations regarding national standards, legislation, and policies that should shape the provision of virtual care in Canada. It has also advocated with governments regarding national fee codes for physician billing.[81] Although my data did not capture much involvement from these actors in the case studies, they stand to make an important contribution to future governance of access to unproven medical interventions.

8.4.3 Fairness, transparency, and processes of stakeholder engagement

Developing or utilizing processes of stakeholder engagement that prioritize fairness and transparency in decisions (including government decisions) regarding access to unproven medical interventions is a third priority that this case study research indicates could help strengthen future strategies. As already discussed, there was considerable advocacy and political pressure surrounding demands for access to the unproven medical interventions studied in this research, especially chelation therapy and liberation therapy. Hansard records of legislative debates from various jurisdictions across Canada suggest these pressures resonated with elected officials who then supported different forms of expanded access even in the absence of strong endorsement from scientific and medical communities.

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[79] It is worthwhile to note that some of these practices including regarding the provision of unproven applications of chelation therapy and other forms of CAM, for example, are protected in legislation or college bylaws. Accordingly, updating or revising the current status quo may not be uncomplicated processes.

[80] See Chapter 5, 5.2.1 and 5.2.2, *above*.

[81] See Canadian Medical Association, "Advocacy – Virtual Care" (last visited 24 May 2022), online: <www.cma.ca/virtual-care>.

The power of public opinion and political influence is certainly not unique to the realm of government decisions regarding access to medical interventions. However, the scientific complexities and potential risks (both individual and collective) that are often at play in these contexts raise important questions about participatory processes that primarily account for the perspectives of those who are sufficiently well resourced and politically savvy to mount an effective advocacy effort.[82] Public and stakeholder engagement can potentially strengthen decision-making by offering diverse perspectives and insights informed by lived experience and professional expertise, and by enhancing legitimacy and trust in those decisions and resulting frameworks.[83] However, for the most part the cases studied here did not reflect a balanced, deliberate, or equitable process of consultation or engagement. Accordingly, there would be merit in exploring how more transparent and systematic processes could be used to support engagement of the public and key stakeholders, including patients, healthcare providers, and scientists, in political-level decision-making regarding access to unproven medical interventions.[84]

8.4.4 Nuanced discussions about how evidence is constructed, interpreted, and utilized

The complexities surrounding how evidence is understood and interpreted by different actors, and in different contexts, was a strong theme that cut through each of the case studies. There were marked differences in how actors, both within and across different contexts, approached issues of evidence. For example, political advocacy efforts in support of expanded access to the unproven medical interventions studied here often included personal anecdotes about individuals who sought or had received the intervention. These lived experiences were framed and treated as a form of evidence that persuaded some officials regarding the need for and benefits of the intervention.[85] In contrast, other actors focused on the importance of rigorous clinical research to develop evidence regarding the safety and efficacy of these different interventions.[86] In other words, types of information ranging from individual experiences to double-blind, placebo-controlled clinical trials were all framed as forms of "evidence" by different regulatory and governance actors in these case studies. Notwithstanding the stark

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[82] See e.g. Albert Weale, "New Modes of Governance, Political Accountability and Public Reason" (2011) 46:1 Government & Opposition 58 at 62.

[83] See e.g. Shawn HE Harmon, Graeme Laurie & Gill Haddow, "Governing risk, engaging publics and engendering trust: New horizons for law and social science?" (2013) 40:1 Science & Public Policy 25. See also Andy Stirling, "Opening up the politics of knowledge and power in bioscience" (2012) 10:1 Plos Biol e1001233. Stirling discusses public engagement in bioscience governance and emphasizes the value of inclusive participation.

[84] See e.g. Ortwin Renn, "Stakeholder and Public Involvement in Risk Governance" (2015) 6 Intl J Disaster Risk Science 8 at 13; see also Roger Brownsword, "Responsible Regulation: Prudence, Precaution and Stewardship" (2011) 62 N. Ir. Legal Q. 583; see also Harmon, Laurie & Haddow, *supra* note 83.

[85] For example, the following quote from New Brunswick Premier David Alward was first presented in Chapter 6, Section 6.2.3: "What continues to buoy my sense that this is the right thing to do is when you meet people like Tim [an MS sufferer who received liberation therapy in New York] or the others who have received the positive benefits". See Kevin Bissett, "MS patients who had liberation therapy call on Canada, provinces to support it", *The Canadian Press* (5 May 2011), online: <www.theglobeandmail.com/life/health-and-fitness/ms-patients-call-on-canada-provinces-to-support-liberation-therapy/article4262321/>.

[86] For example, CIHR President Alain Beaudet testified before the Senate Standing Committee regarding the regarding the uncertain state of the evidence regarding the safety of liberation therapy. Bill S-204, *An Act to establish a national strategy for chronic cerebrospinal venous insufficiency (CCSVI)*, Standing Senate Committee on Social Affairs, Science and Technology, *Evidence*, 41-1 (4 October 2012) (Senator Verner & Dr. Alain Beaudet).

differences between these different sources of information or "evidence", the malleability of the concept was generally not explicitly acknowledged.

As regulation and governance scholarship and practice evolve, including with respect to managing access to unproven medical interventions, encouraging greater nuance and transparency in how evidence is framed and interpreted would be valuable. More specifically, regulatory and governance actors could be encouraged to be more specific about what they mean by "evidence", how it differs from other types of information, and how it relates to their objectives or priorities. Different situations may call for different standards of evidence, and consensus regarding what counts as legitimate forms of evidence may not be feasible across the varied actors and stakeholders who have interests and influence with respect to unproven medical interventions.[87] For example, it is not clear that the randomized clinical trial model is an appropriate standard for all medical interventions.[88] As Maschke and Gusmano argue, "it is also important not to overlook how the intersection of values, interests, politics, and contexts frames and shapes disputes about evidence, influences policy initiatives about evidentiary standards, and plays a role in regulatory decision making about the safety and effectiveness of new biomedical technologies".[89] Providing a specific definition of evidence for use in access decisions is well beyond the scope of this work and indeed may be neither feasible nor appropriate as a goal for work of this nature. However, encouraging greater transparency and critical reflection regarding the features of acceptable evidence in different contexts and their implications for decision-making about access may help strengthen the credibility of regulatory and governance actors, and the instruments they employ.

8.4.5 Advancing science and health communication practices

Developing and honing effective science and health communication practices that reflect the changing realities of social media and today's complex online information (and misinformation) environment is another critically important area that regulation and governance scholars and actors will need to consider when framing responses to future unproven medical interventions. Information-based instruments were a prominent tool used by regulatory and governance actors in all three cases, but approaches were inconsistent (e.g. between different provincial and territorial governments[90]) and relatively static (e.g. a statement on a website, or an update in a newsletter). At the same time, public demand for access to each of the unproven interventions studied here appears to have been fueled in part by online information of varied forms, including social media. Mainstream media also played a role in framing the issues in these case studies and in disseminating information, including from or about different regulatory and governance actors. For example, media stories highlighted advocacy activities that promoted access to chelation therapy, spoke to government funding announcements for liberation therapy, and provided a platform for "experts" to share their views regarding unproven stem cell interventions. Going forward, regulatory and governance actors may be able to expand their

[87] For a more in-depth discussion about standards of clinical evidence from a bioethics perspective, see Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics*, 7th ed (Oxford: Oxford University Press, 2012) at 332.
[88] Miriam Solomon, *Making Medical Knowledge* (Oxford, UK: Oxford University Press, 2015).
[89] Karen J. Maschke & Michael K. Gusmano, "Evidence and Access to Biomedical Interventions: The Case of Stem Cell Treatments" (2016) 41:5 J Health Politics, Policy & L 918 at 929.
[90] For example, Alberta Health Services stood out among other government actors with its efforts to provide clear and publicly accessible guidance on each of the case studies via its websites.

spheres of influence and increase their resonance, particularly when using information-based instruments, by exploring new ways to engage with their target audiences.

There is a growing area of scholarship and practice in the fields of health and science communication that could support these efforts, including recent work in response to what has been termed an "infodemic" in the context of the COVID-19 pandemic.[91] For example, initiatives such as #ScienceUpFirst are focused on countering the spread of misinformation with strong science, shared in creative ways.[92] It may be helpful for regulatory and governance actors, including governments, professional regulatory bodies, and medical and scientific actors to use this emerging knowledge to inform their practices for sharing information about future unproven medical interventions that draw public attention. These different actors have unique strengths, including varied spheres of influence and trust among different audiences. Sharing current, accurate information in accessible formats that are appropriately tailored to different audiences may help support informed decision-making by patients, healthcare providers, and policymakers alike. In this way, information can be a powerful instrument in the regulatory and governance toolbox. However, maximizing its potential will require strategies that reflect and respond to the evolving realities of the information environment.[93] This is also an area where coordinated responses, such as consistent messaging between governments and other influential regulatory and governance actors, may help counter misinformation about unproven medical interventions.

Risk communication is a particularly important aspect of health and science communication in the context of unproven medical interventions. It is also an integral element of risk management, which is often framed as a central part of governments' regulatory roles and responsibilities.[94] The nature of unproven medical interventions often means that evidence about risk is either not yet available or is contested. Relevant risks may change over time, as there is more experience with an intervention, or as there is more available research addressing its safety and efficacy. There can also be a plurality of perspectives about risk and varying risk tolerances. For example, as was particularly notable in the chelation therapy case study, the reality that most medical interventions come with at least some degree of risk can complicate communications about the risks of unproven medical interventions, particularly where those risks are largely theoretical. Taking these complexities and evolving ideas and understanding about risk, including regulation of risk and risk governance, into account may strengthen future efforts to

[91] See e.g. Arunima Krishna & Teresa L. Thompson, "Misinformation About Health: A Review of Health Communication and Misinformation Scholarship" (2021) 65:2 American Behavioural Scientist 316; see also Wen-Ying Sylvia Chou, April Oh & William M.P. Klein, "Addressing Health-Related Misinformation on Social Media" (2018) 320:23 J American Medical Assoc 2417; see also Nathan Walter et al, "Evaluating the Impact of Attempts to Correct Health Misinformation on Social Media: A Meta-Analysis" (2021) 13 Health Communication 1776; see also Nour Mheidly & Jawad Fares, "Leveraging media and health communication strategies to overcome the COVID-19 infodemic" (2020) 41 J Public Health Policy 410.

[92] See ScienceUpFirst, "Together Against Misinformation" (last visited 24 May 2022), online: <www.scienceupfirst.com/>.

[93] For example, research shows that relying on emotion increases people's belief in fake news. See Cameron Martel, Gordon Pennycook & David G. Rand, "Reliance on emotion promotes belief in fake news" (2020) 5:47 Cognitive Research: Principles & Implications doi.org/10.1186/s41235-020-00252-3. Other research shows that false news spreads more quickly than accurate reports. See Soroush Vosoughi, Deb Roy & Sinan Aral, "The spread of true and false news online" (2018) 359:6380 Science 1146.

[94] See e.g. Health Canada, "Strategic Risk Communications Framework; For Health Canada and the Public Health Agency of Canada" (2006), online (pdf): <www.canada.ca/content/dam/hc-sc/migration/hc-sc/ahc-asc/alt_formats/pacrb-dgapcr/pdf/pubs/ris/ris-comm-eng.pdf>.

manage or mitigate the risks of unproven medical interventions as they emerge in different contexts.

8.5 Theoretical insights - reflections on the conceptual framework

In addition to addressing the research questions set out above, one of the core objectives of this doctoral project was to develop and contribute theoretical insights regarding the use of regulation and governance as frameworks for understanding complex and multifaceted health policy issues, using access to unproven medical interventions in Canada as the context for this work. There is much valuable work to be done with theory development in relation to regulation and governance,[95] particularly with respect to how these bodies of scholarship can be used to understand real-life practice and, conversely, how these 'on the ground' realities can help enrich theoretical understandings in these fields.[96] As Bevir observes, "the interaction of theory and practice continues apace: changes in the theories challenge our established ways of doing things, prompting us to adopt new actions in an attempt to remake the world, and changes in the practices often require us to rethink our beliefs and theories so as to make sense of the new worlds in which we find ourselves".[97] Recognition of this interaction between theory and practice is embedded within much of the work done in the fields of regulation and governance.[98] Utilizing regulation and governance theories to their full advantage, including to enhance current practices and inform future strategies, requires continued work to improve conceptual clarity regarding their respective interpretations and how they relate to one another. Indeed, leading regulatory and governance scholars have suggested this work is needed but is currently underexplored.[99]

I developed a conceptual framework that incorporated concepts from the fields of both regulation and governance that were relevant to my research questions. My original conceptual framework can be found in the Appendix. In that original conceptual framework, I separated the concepts of regulation and governance and identified key features of each. I provided descriptions of those features and identified elements or considerations that I saw as particularly significant and relevant to this research. I used this framework as a starting point and guide to help understand, organize, and analyze the data. However, as my research and analysis evolved, it became clear that separating my data between regulation and governance was not useful to advancing an in-depth understanding of the complexities and relations at play both between these

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[95] The need for work of this nature to advance theoretical understandings of regulation and governance has been acknowledged by various scholars working in these fields. For e.g. see Andreas Duit & Victor Galaz, "Governance and Complexity - Emerging Issues for Governance Theory" (2008) 21:3 Governance: An Intl J Policy, Administration & Institutions 311 at 329.

[96] For example, see Braithwaite, *supra* note 34 at 129. Braithwaite suggests that the concept of responsive regulation includes the idea "that wisdom grounded in practice leads theory; then that theory provides better lenses through which to see and transform practice." Gunningham and Sinclair similarly observe that "while there has been considerable progress in the development of smart regulation as a theoretical construct, its attempted translation into regulatory policy and practice has been mixed". Gunningham & Sinclair, *supra* note 34 at 145.

[97] Mark Bevir, "Governance as Theory, Practice and Dilemma", in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 1 at 11.

[98] Drahos and Krygier suggest that a responsive attitude to regulation requires that we study processes in our world so that we can then intervene to improve them. See Peter Drahos & Martin Krygier, "Regulation, institutions and networks" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 1 at 18.

[99] Grabosky, "Meta-regulation", *supra* note 55 at 157-158.

fields of scholarship and in relation to the data I was exploring. There may be avenues of work where those demarcations would be important and helpful. However, in the context of this research, forcing distinctions between the roles of different actors, instruments, and features with a largely parallel analysis between regulatory and governance activities increasingly seemed artificial and was not serving the larger objectives of this project. Accordingly, I revisited and adjusted the conceptual framework in an iterative manner throughout my data analysis. In so doing, I considered how I could bridge the fields of regulation and governance scholarship in a way that supported a richer analysis and deeper understanding of the case studies. My revised conceptual framework was presented at the end of Chapter 2, in Table 1. In this revised version, I merged the key features analysis into one joint framework that incorporated concepts, including important elements and considerations for each feature, from both regulation and governance scholarship.

This process led me to revisit a question I first raised in Chapter 2, that is, whether it is helpful to use the concepts of both regulation and governance when seeking to understand responses to, and oversight of, access to medical interventions, or whether one or the other would suffice. As discussed in Chapter 2, much of the work in the fields of regulation and governance scholarship appears to have evolved in parallel with limited connections between them. Regulatory and governance scholars writing from different disciplinary perspectives often use different terms to explain similar concepts, and the connections between the fields are arguably underexplored. To some extent, my research in this doctoral project served to test and experiment with these concepts by exploring their utility in providing structure to an analysis of oversight and influence in real-world contexts.

How one defines regulation and governance, respectively, is critically important to answering the question posed above, and to the potential value of these concepts for advancing understanding in applied contexts. For example, it remains unclear to me after this analysis that there are fundamental differences in substance between broad views of regulation that account for the engagement of diverse institutional actors such as government, industry, and professional regulation on the one hand,[100] and narrower approaches to understanding governance on the other which also consider the same types of actors.[101] However, governance scholarship offers valuable insights that one would not want to lose by only looking at the field of regulation. Similarly, drawing exclusively on governance scholarship risks losing valuable insights found in the rich history of regulatory scholarship. By way of brief reminder, I adopted the following definitions early in this research:

[100] See e.g. Grabosky, "Beyond Responsive Regulation", *supra* note 22 at 120. As discussed in Chapter 2, Gunningham and Sinclair's version of "smart regulation" is another pluralistic framing of regulation that gives space for varied actors and instruments to exert influence. See Gunningham & Sinclair, *supra* note 34. Similarly, concepts of meta-regulation also include many parallels to the literature on governance, particularly where the focus is on the potential influence of non-state actors. See e.g. Grabosky, "Meta-regulation", *supra* note 55 at 155.

[101] Some approaches to governance focus on broader forces including market influences and cultural practices; see e.g. Rod Rhodes & Mark Bevir, "The Stateless State" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 203. Others take a more focused approach that aligns more closely with regulatory scholarship in considering the relationships between the role of the state and other actors. See e.g. Bingham, *supra* note 64.

Regulation: an intentional, goal-oriented, state-driven activity, potentially involving varied policy instruments and the participation of non-state actors when they are acting under the state's ultimate authority.

Governance: how the interactions of multiple actors (both state and non-state) serve to influence activity in a particular domain, potentially via a wide variety of instruments.

This approach provided clarity in the relationship between these two concepts for the purpose of this work and, in so doing, justified the use of both fields in developing my conceptual framework. After completing this research, I continue to see value in looking at regulation as a component or facet of governance.[102] Although there is considerable room to debate the nuances, the pragmatic merits of using an approach along these lines is that it creates space to draw on insights from the wealth of scholarship in both fields while working within long-standing terminology and associated theoretical constructs. For example, although related concepts appear in governance scholarship, including with respect to risk governance, there is a particularly strong and well developed body of work in the field of regulation looking at risk in regulation. Among other things, this research addresses the complexities of defining, measuring, and controlling for risk in complex contexts that may include different perspectives about risk as well as fast-moving technologies that present evidentiary challenges.[103] This body of work in regulatory scholarship helped inform my analysis of the role that controlling or mitigating risks played as an objective for some regulatory and governance actors in the case studies. As another example, using the definitions outlined above also allowed me to acknowledge the inextricable connection between regulation and governance, while giving government-led regulation a privileged position within the broader sphere of influence captured by governance.[104] Although all three case studies included a variety of influential actors, governments unquestionably held that privileged position and at times used, or debated using, the power of their legislative authority to make definitive decisions about access, even where doing so potentially ran counter to the efforts of other influential actors.[105]

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[102] For similar approaches, albeit including those that take a hard law approach to regulation which may not necessarily extend to use of instruments such as information, see Marian Döhler, "Regulation" in Mark Bevir, ed, *The SAGE Handbook of Governance* (London: SAGE Publications Ltd, 2011) 518 at 531; Graeme Laurie, Shawn Harmon & Fabiana Arzuaga, "Foresighting Futures: Law, New Technologies, and the Challenges of Regulating for Uncertainty" (2012) 4:1 L, Innovation & Technology 1 at 14; Gregory Mandel, "Regulating Emerging Technologies" (2009) 1:1 L, Innovation & Technology 75 at 78.

[103] See e.g. Fiona Haines, *The paradox of regulation: what regulation can achieve and what it cannot* (Cheltenham, UK: Edward Elgar Pub, 2011) at 232; see also Brownsword, *supra* note 84 at 574; see also Harmon, Laurie & Haddow, *supra* note 83.

[104] As already noted, there are branches in both modern regulatory and governance scholarship that take a similar approach. For an example from regulatory scholarship, see e.g. Grabosky, "Beyond Responsive Regulation", *supra* note 22; for an example using a governance framing, see Cameron Holley & Clifford Shearing, "A nodal perspective on governance: Advances in nodal governance thinking" in Peter Drahos, ed, *Regulatory Theory: Foundations and Applications* (Acton, Australia: ANU Press, 2017) 163.

[105] One example of this dynamic in the chelation therapy case study was when some provincial governments used legislation to permit access (i.e. via the "negative proof" provisions discussed in Chapter 5, Section 5.2.1, *above*), notwithstanding concerns from some members of the medical profession including representatives from colleges of physicians and surgeons.

Overall, my experience through this case study analysis suggests that regulation and governance are useful, if not uncomplicated, frameworks for understanding how governments and other actors respond to the multifaceted tensions and uncertainties that can surround unproven medical interventions. I found that combining and applying regulation and governance constructs can be a messy process, and that using these frameworks together as a lens for understanding complex spheres of action, decision-making, and influence is far from straightforward. For example, one of the strengths of a governance analysis is that it acknowledges and seeks to account for the many different actors who can exert influence over particular issues and practices. However, the more inclusive the approach one takes for identifying actors, and the broader the scope one uses to identify types and ranges of influence, the more difficult it is to analyze key features of effectiveness. In other words, when looking at a multitude of actors with different spheres of influence, it can be very difficult to identify, understand, and reconcile the many different purposes, instruments, and processes used. It is also equally challenging to ascertain what makes different governance approaches "effective", or even what "effectiveness" means in such diverse contexts, particularly given the plurality of perspectives that different actors are likely to hold on this question.

Notwithstanding these and other challenges, the conceptual framework I developed using concepts from both regulation and governance scholarship ultimately provides a systematic approach to identifying and analyzing the field of influence over a particular issue. Although my work in this thesis focused on access to unproven medical interventions that are provided by physicians in Canada, this conceptual framework could be used in future research studying regulation and governance in other contexts. The construct of this framework could help individual actors such as governments, regulatory bodies, or professional associations, strengthen their approaches and strategize accordingly, including by evaluating the merits of different instruments, identifying who to partner with, where coordination or collaboration might be particularly helpful or impactful, and what might enhance (or threaten) their credibility or legitimacy. In so doing, it responds to the calls noted above for work that uses regulation and governance theory to inform and strengthen practice, and vice versa.[106]

8.6 Limitations

There are several limitations to this research. As outlined in Chapter 3, I relied on publicly available information including Hansard records, legislation and regulations, case law, professional regulatory decisions, policy documents and other public-facing information presented on the websites of regulatory and governance actors and available in library databases, media articles obtained through internet searches and library databases, and public information about advocacy activity on social media sites. Purposeful sampling of this nature is common in case study research, and where saturation may not be possible, ensuring data adequacy and seeking confirmation across different types or sources of data is the goal.[107] Given the broad scope of this data collection, and the long time frame covered by the case studies (for example, the chelation therapy case study spanned decades), I cannot assert that my data collection was comprehensive. My search strategies may have failed to capture some relevant material. It is also probable that there are, or would previously have been, relevant documents held internally by

[106] See e.g. Drahos & Krygier, *supra* note 98 at 18; see also Bevir, *supra* note 97 at 11.
[107] Lyn Richards & Janice M. Morse, *Read Me First for a User's Guide to Qualitative Methods,* 3rd ed (California: Sage Publications, 2013) at 206.

different actors. In addition, there are almost certainly voices and perspectives (e.g. of individual patients and providers) not captured in public facing documents. I was also limited to English language materials, and thus Quebec should be viewed as underrepresented in this study.

To address these limitations proactively, I used the same systematic search strategies for each case study, documented in detailed research memos. I also used a form of snowball sampling in which I followed leads to additional relevant sources found in data collected in my initial searches (e.g. in Hansard records and media articles) or in my literature review. These strategies helped augment my initial data collection, and as a result I am confident that my data presents a reasonably full picture of the relevant regulatory and governance landscape for each case study, at least until the completion of this research. Each of the case studies is still evolving in different ways, so this research captures a particular period.[108]

One important limitation of qualitative research of this nature is the potential for researcher bias, including confirmation bias, and subjectivity in the analysis and interpretation of results. Recognizing these limitations, I was guided by Guba and Lincoln's leading work in qualitative research which uses the term "trustworthiness" to describe research that produces legitimate knowledge. The four criteria for trustworthiness include authenticity, portability, precision, and impartiality.[109] Throughout my analysis, I made every effort to ensure authenticity (sometimes referred to as credibility) by critically reflecting on my descriptions to ensure they reflected the content of the materials. The portability (alternatively referred to as transferability) of this work is reflected in the degree to which lessons from these case studies can be extended to other areas that share similar features. I used systematic data collection with detailed research memos and thick description in each case study to support the precision (or dependability) of this research, meaning the results reported are as consistent with the data as possible, and make sense with the approach taken in the project. Finally, in furtherance of impartiality (or confirmability), I continually reflected on and challenged my own interpretations of the data by revisiting my initial coding and subsequent analysis throughout the research and writing process, recognizing that as the researcher, I bring my own subjectivity and individual perspective to the work.[110]

8.7 Future research considerations

Throughout my data collection and analysis, I identified several questions and avenues of research which were beyond the scope of this project but worth noting because of their potential significance to the broader field of study. In this section, I will briefly address the value that informant interviews would bring to future work on this topic, the interesting questions left outstanding regarding the possibilities that research ethics review processes may offer for future regulation and governance of access to unproven medical interventions in Canada, what the current health system focus on patient and family-centered care might mean for future policy development in this area, and finally, the importance of exploring what the events surrounding the COVID-19 pandemic may mean for the future of health and science communication and trust in science.

[108] My primary data collection period was September – November 2020.
[109] Yvonne Lincoln & Egon Guba, *Naturalistic inquiry* (California: Sage Publications, 1985).
[110] See also Loleen Berdahl & Jason Roy, *Explorations; Conducing Empirical Research in Canadian Political Science,* 4th ed (Ontario: Oxford University Press, 2021) at 232-246.

This research relied on multiple sources and types of documentary data, which added considerable richness to the case studies. However, conducting informant interviews to build on this research would be a fruitful avenue of future work. Interviewing representatives from key regulatory and governance actors involved in these or similar cases would facilitate a more in-depth exploration of the motivations and decision-making processes that underpin decisions regarding access to unproven medical interventions. In a related vein, work on strengthening the medical professional self-regulatory model would benefit from developing insights regarding whether and to what extent regulatory capture has (or has had) an influence on the approaches taken in response to provision of unproven medical interventions by medical professionals.[111] My analysis of chelation therapy in particular raised pressing questions about the influence of consumer pressure and potential regulatory capture by providers on the nature and quality of oversight provided by medical professional self-regulatory bodies for unproven medical interventions that fall within the CAM umbrella. There is important research to be done on this issue, particularly given that public and provider interest in CAM remains strong.[112]

My analysis in this project followed the data, and research ethics oversight processes did not feature as a particularly influential or notable aspect of regulation and governance of access to the unproven medical interventions studied here. There may be several potential explanations for that observation, including that research ethics review processes are generally confidential and thus related activities may not have been captured in my searches of publicly available information. Nonetheless, future research that deliberately explores the role of research ethics review in regulation and governance of access to unproven medical interventions would be valuable. This question connects to the issues discussed earlier regarding how evidence is constructed and interpreted, and to decisions about how the concepts of medical or clinical innovation and research are understood and operationalized. For the purpose of defining the subjects of study in this work, I distinguished unproven medical interventions provided in a treatment capacity from interventions provided in research ethics-approved contexts. However, as discussed in Chapter 1, distinctions between unproven interventions, clinical innovation, and experimental interventions provided in a research context are far from straightforward. In future, oversight processes that extend from or build upon research ethics review processes could have an impactful role to play in regulation and governance that facilitate responsible medical innovation and controlled access to unproven medical interventions, with appropriate oversight of safety and efficacy, mechanisms for peer review, and ethical protections for participants.

Another worthwhile avenue for future exploration relates to the broader context in which questions of access to unproven medical interventions are situated when regulatory and governance actors make decisions about their priorities, instrument selection, and processes. At present, patient or patient and family-centred care priorities are emphasized in healthcare systems across the country.[113] These approaches share similar foundations to patient-oriented

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[111] For an overview of theoretical and empirical work on regulatory capture, see Ernesto Dal Bó, "Regulatory Capture: A Review" (2006) 22:2 Oxford Rev Economic Policy 203.

[112] It has been argued that academics have an important role to play in identifying regulatory capture, and in devising responses to mitigate its potentially harm impacts. See e.g. Jason Maclean, "Regulatory Capture and the Role of Academics in Public Policymaking: Lessons from Canada's Environmental Regulatory Review Process" (2019) 52:2 UBC L Rev 479 at 481.

[113] See e.g. Health Canada, "Patient partnership, public empowerment", in *Unleashing Innovation: Excellent Healthcare for Canada* (Ottawa: Government of Canada, 2015) 47, online (pdf):

research orientations, which have similarly taken root in Canadian health research arenas.[114] These philosophies or orientations to practice involve a strong emphasis on individual medical self-determination, on patient-identified priorities, and on the active engagement of patients and families as partners in healthcare and health research. These approaches do not require or demand that patients receive unfettered access to any medical intervention, proven or otherwise, that they might wish to receive. However, their prevalence in Canadian healthcare and health policy arenas does perhaps signal a growing expectation that patients' interests in a particular unproven medical intervention, along with their risk preferences and priorities, will be part of decisions regarding access. At the very least, exploring the implications of these patient-oriented agendas is likely a worthwhile topic for future health-related research in regulation and governance.

Finally, the development of this project and most of the case study activity preceded the COVID-19 pandemic. With the limited exceptions in the case study on unproven stem cell interventions,[115] the pandemic did not feature in my data. However, forward-looking insights regarding how we manage access to unproven medical interventions in future must consider the influence of this pandemic on science and health communication practices, public perceptions of science, and public trust in "expertise" including medical, scientific, and regulatory authorities. These considerations are closely connected to questions of compliance and to the ultimate effectiveness of regulation and governance.[116] At the time of writing, this global pandemic is still evolving and it is too soon to evaluate its impact in these areas. However, early signals suggest its impact has been, and will likely continue to be, significant.[117] Accordingly, there will be important work to be done to understand what the contested politics and very public evolution of scientific knowledge related to COVID-19 will mean for the context of regulation and governance of access to future unproven medical interventions.

8.8 Conclusion

Interdisciplinary social science scholarship will have an important role to play in the continued evolution of regulation and governance theory and practice, including with respect to

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<healthycanadians.gc.ca/publications/health-system-systeme-sante/report-healthcare-innovation-rapport-soins/alt/report-healthcare-innovation-rapport-soins-eng.pdf>.

[114] See Canadian Institutes of Health Research, "Strategy for Patient-Oriented Research; Putting Patients First" (2014) online: *Government of Canada* <cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf>.

[115] See Leigh Turner, "Preying on Public Fears and Anxieties in a Pandemic: Businesses Selling Unproven and Unlicensed 'Stem Cell Treatments' for COVID-19" (2020) 26:6 Cell Stem Cell 806.

[116] Some scholars have previously pointed to waning public trust in science and medicine. See e.g. Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002) at 11. It may be that the COVID-19 pandemic is exacerbating those issues, at least among some groups and individuals, which may have a lasting effect well beyond that particular crisis.

[117] COVID-19-related research and understanding about these issues is expanding rapidly at the time of writing. By way of examples only, see Scott Robinson et al, "The Relevance and Operations of Political Trust in the COVID-19 Pandemic" (2021) 81:6 Public Administration Rev 1110. Robinson et al. found substantial variation in trust for different actors (e.g. WHO, CDC, state health departments, etc.) that were involved in COVID-19 planning and response. Higher levels of trust were associated with stronger compliance and support for policy measures. See also Anwar Sheluchin, Regan Johnston & Clifton van der Linden, "Public Responses to Policy Reversals: The Case of Mask Usage in Canada during COVID-19" (2020) 46:S2 University Toronto Press S1119. Sheluchin et al. point to a public opinion survey that suggests Canadians' trust in public health officials remained consistent through changing policies on mask use during the early phases of the COVID-19 pandemic.

unproven medical interventions. As one scholar has argued, "[o]nly by further developing and applying shared conceptual frameworks taking into account the real complexity of governance regimes we can build the knowledge base needed to advance our understanding to a state that we can give meaningful policy advice".[118] With the current pace of biomedical research, technological advancement, and spread of information, this work is much needed in order to benefit from the opportunities that medical advancements may offer for improving human health, among other potential advantages (e.g. health system cost savings), while mitigating potential risks to both individuals and the public interest. However, the realities of limited resources demand that we not "reinvent the regulatory wheel" every time a new technology or medical intervention emerges onto the public scene.[119] Ideally, we can work towards systems of oversight that provide stability and consistency, while being responsive to specific issues that new interventions may raise.[120]

The research presented here contributes to this broader agenda by advancing understanding about how access to three different examples of unproven medical interventions in Canada has been approached in the past, using the frameworks of regulation and governance. It is reasonable to expect that we will continue to experience growing demands for access to unproven medical interventions in Canada. It also seems likely that in this modern era of biomedicine, social media, and online information, the treatment options available to patients both in the global marketplace and domestically will continue to expand. Accordingly, it is an opportune time to focus on developing and strengthening regulatory and governance approaches to managing new unproven medical interventions. Being ready to respond in a timely, principled, and consistent manner to new types of unproven medical interventions would further the interests of both fairness and efficiency. Ideally, this research can serve as a resource to guide future strategies of regulation and governance that are theoretically grounded, legally sound, and able to account for the diverse interests engaged in these complex health law and policy issues.

[118] Claudia Pahl-Wostl, "A conceptual framework for analysing adaptive capacity and multi-level learning processes in resource governance regimes" (2009) 19 Global Environmental Change 354 at 363.
[119] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: Oxford University Press, 2008) at 290.
[120] See e.g. Mandel, *supra* note 102 at 92. Mandel argues that this is an opportune time for governance systems to evolve alongside emerging technologies and proposes an approach that emphasizes a proactive and flexible form of governance. Key aspects of his proposed approach include data gathering, filling regulatory gaps, industry stewardship, agency expertise and co-ordination, governance adaptability, and stakeholder involvement.

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APPENDIX: Original Conceptual Framework

REGULATION

Feature	Description	Elements and Considerations
Actor(s)	State (provincial or federal government) or body acting under state authority	○ *Jurisdiction, sphere of authority or influence* ○ *Nature of expertise or specialist knowledge* ○ *Degree of democratic legitimacy and public accountability* ○ *Degree of coordination between actors*
Clarity of purpose	The extent to which the purpose or intention behind regulatory activity can be discerned, either explicitly (e.g., via mandates, purpose statements) or implicitly	○ *Priorities and imperatives* ○ *Constraints and challenges* ○ *Opportunities and strengths*
Process & Legitimacy	Considerations relating to both the decision-making process and implementation	○ *Engagement:* the degree to which different stakeholders participate or have voice in the regulatory process (including decision-making and implementation) ○ *Jurisdiction:* accounts for division of powers considerations and scope of authority ○ *Respect for autonomy*[1]: includes consideration for how regulation impacts or accounts for individuals' ability to exercise medical self-

[1] The concepts of autonomy and the public interest are addressed in Chapter 4, Sections 4.1.1 and 4.1.2, *above*, respectively.

		determination, and the basis upon which any limitations are made ○ *Public interest considerations:* the extent and nature of both explicit and implicit public interest considerations in the regulatory agenda
Instruments used	The tools or strategies used to exert influence (i.e. to steer conduct), such as information, incentives, coercive measures (including law); degree of instrument mixes, and empirical foundations for the approaches taken	○ *Target of intervention*: including both subject and timing ○ *Appropriateness*: includes considerations of fit ○ *Complementary mix*: includes consideration of the extent to which different instruments (e.g. information, incentives, command and control strategies, etc.) are used and how they relate to one another
Responsiveness	The degree of adaptability and nimbleness reflected in the regulatory approach	○ *timing of regulatory activity or intervention* ○ *flexibility*: adjustments or shifts of approach in relation to new developments
Compliance & Enforcement	Consideration of styles or modes of enforcement and evidence (if any) regarding compliance	○ *Proactive vs reactive* ○ *Style*: includes use of persuasion, incentives, sanctions (consideration given to severity)

GOVERNANCE

Feature	Description	Elements and Considerations
Actor(s)	Entities (state and non-state) with some form of influence; influence defined in relation to questions of access	○ *Jurisdiction, sphere of authority or influence* ○ *Degree of coordination between actors and initiatives* ○ *Accountability*: includes considerations of how and to whom or what actors are held accountable for their actions
Instruments used (or modes of governance)	The tools or strategies used to exert influence (i.e. to steer conduct), such as information, incentives, coercive measures (including law); degree of instrument mixes and empirical foundations for the approaches taken	○ *Coherence*: with goals or purposes (explicit and implicit) ○ *Complementarity:* with the activities of other actors in the field (external) and with other activities of the same actor (internal) ○ *Clarity of purpose*: with respect to particular activities or initiatives
Adaptive Capacity	Ability and willingness to adjust strategies in response to lessons learned or new developments	○ *Evidence of learning* ○ *Flexibility* ○ *Resilience*