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Patient Safety Law: Regulatory Change in Britain and Canada

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To my parents

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Abstract

Did governments in different countries regulate common concerns about patient safety differently? If so how and why did they do this? This thesis undertakes a historical comparison of the regulation of patient safety in Britain and Canada between 1980 and 2005. These jurisdictions began the period with very similar regulatory frameworks, but by 2005 there were distinct differences in each jurisdiction's regulatory response to patient safety. Britain was very actively regulating all aspects of service provision within its health system in the name of patient safety, whereas Canada's regulatory direction showed adherence to the 1980s model with only scattered incremental developments. This thesis assesses the broader sociopolitical context and the structure of the health systems in each jurisdiction and concludes there are differences in the logics of these systems that established a foundation for future regulatory divergence. It is argued that between 1980 and 2005 there were two factors that influenced regulatory directionality in each jurisdiction: changing political norms associated with the development of neoliberalism and the New Public Management; and events or scandals associated with the provision of health services. The differing levels of penetration of both the changing political norms into governance cultures and of scandals into the public and political consciousness are critical to explaining regulatory differences between jurisdictions. The thesis concludes that what and how governments chose to regulate is a function of the perceived need for action and the dominant social and political norms within that society. Context is everything in the formulation of regulatory approaches to address pressing social problems.

List of Abbreviations Used

BSE   Bovine spongiform encephalopathy ("mad-cow disease")

CEO   Chief Executive Officer

CGR   Clinical Governance Reviews

CHA   *Canada Health Act*

CHRE   Council for Healthcare Regulatory Excellence

CMO   Chief Medical Officer

CPS   Crown Prosecution Service

CPSI   Canadian Patient Safety Institute

CPSM   College of Physicians and Surgeons of Manitoba

CPSO   College of Physicians and Surgeons of Ontario

CRC   Canadian Red Cross

DHAs   District Health Authorities

EKHA   East Kent Health Authority

FHSA   Family Health Service Authority

FPC   Family Practitioner Committee

FTP   Fitness to Practise

GDP   Gross Domestic Product

GP   General Practitioner

GMC   General Medical Council

HAI   Hospital-Acquired Infection

HPAA   *Health Professions Act* (Alb.)

HPAB   Health Professions Advisory Body

HPBC	*Health Professions Act* (BC)
HPC	Health Professions Council (British Columbia)
HPLR	Health Professions Legislation Review (Ontario)
HPRAC	Health Professions Regulatory Advisory Council (Ontario)
HR Act	*Human Rights Act 1998* (U.K.)
HSC	Hospital for Sick Children
HSD Act	*Hospital Insurance and Diagnostic Services Act 1957* (C.)
LMC	Local Medical Committees
MC Act	*Medical Care Act 1966* (C.)
MRSA	Methicillin-resistant *Staphylococcus aureus*
MSC	Medical Services Committee
NCAA	National Clinical Assessment Authority
NDP	New Democratic Party
NGO	Non-governmental organisation
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NI Act	*National Insurance Act 1911* (UK)
NICE	National Institute for Clinical Excellence
NPM	New Public Management
NSF	National Service Frameworks
Ont.	Ontario
OPQ	Office of the Professions of Québec (Office des professions du Québec)
PC	Privy Council
PCC	Professional Conduct Committee

PCO	Primary Care Organisation
PIC	Professional Inspection Committee (Québec)
PPC	Preliminary Proceedings Committee
RHAs	Regional Health Authorities
RHPA	*Regulated Health Professions Act* (Ontario)
RLCH	Royal Liverpool Children's Hospital
SARF	Social Amplification of Risk Framework
SCC	Supreme Court of Canada
SPM	Serious Professional Misconduct
TSAPP	Taskforce on Sexual Abuse of Patients by Physicians
UK	United Kingdom
US	The United States of America
WHSC	Winnipeg Health Sciences Centre
YRHA	Yorkshire Regional Health Authority

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> "Writing a book is an adventure; to begin with it is a toy and an amusement, then it becomes a mistress, and then it becomes a master, and then it becomes a tyrant, and the last phase is that just as you are about to be reconciled to your servitude, you kill the monster and fling him to the public." (Sir Winston Churchill)

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The Problem

Internationally, between 1980 and 2005, many health systems saw episodes of failure with disastrous consequences for patients. Children died unnecessarily after undergoing pediatric heart surgery in Bristol, Britain, and Winnipeg, Canada. The blood systems in many countries were poorly managed, resulting in significant numbers of people contracting HIV/AIDS or hepatitis C. Health professionals in Britain and the United States have committed mass murders of patients. Patients have lost their lives as a result of failures in drug monitoring and approval systems (notably in the United States and Canada). Medical research has gone dreadfully wrong, including gene-transfer research in the United States and France and cancer research in New Zealand.

While remarkable in their size and scope, and in the publicity they garnered, these incidents are not isolated. Recent empirical studies from Canada, Australia, Denmark, New Zealand, the United States, and the United Kingdom reveal that between four and seventeen per cent of hospitalized patients experience an adverse event[1] during hospitalization.[2] Thus, on a daily basis there are many less public failures within health systems – a wrong diagnosis, a misread test, an incorrectly dispensed medication, or poorly performed surgery – most of

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[1] An 'adverse event' is an occurrence in the healthcare setting where something happens to injure or harm a patient. The term 'adverse event' has received a multiplicity of definitions. See J. Davies, P. Hebert, C. Hoffman & the Royal College of Physicians and Surgeons of Canada, *Canadian Patient Safety Dictionary* (Ottawa: College of Physicians and Surgeons of Canada, 2003) at 39-40 online at: RCPSC <http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf>.

[2] In Canada, it is estimated that 7.5 per cent of hospitalized patients experience an adverse event, of which 37 per cent are preventable. In real terms, it is estimated that 9,250 to 23,750 Canadians die each year as a result of unsafe care and treatment and many thousands more are physically injured. See G. Baker, *et al.* "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170:11 C.M.A.J. 1678 [Baker, "*Adverse Events*"]. Similar results have been found in other countries that have studied the incidence of adverse events. See T.A. Brennan *et al.* "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 N. Engl. J. Med. 370 [Brennan, "Adverse Events"]; R. Wilson *et al.,* "Quality in Australian Health Care Study (1996) 164:12 Med. J. Aust. 754 [Wilson, "Quality"]; C. Vincent, G. Neale, & M. Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322:7285 BMJ 517, erratum in: (2001) 322:7299 BMJ 1395 [Vincent, "Adverse Events"]; T. Schioler *et al.,* Danish Adverse Event Study "[Incidence of Adverse Events in Hospitals. A Retrospective Study of Medical Records]" (2001) 163:39 Ugeskr Laeger 5370 [Schioler]; P. Davis, *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115:1167 N.Z. Med. J. U271 [Davis]. Evaluation of the rates of adverse events in other health-related sectors such as long-term care, residential care, home care and primary care is currently underway.

which have at least the potential to cause physical, emotional, psychological and/or financial distress.

Adverse events in health services have been, until recently, a silent epidemic. Silent, because many patients never knew that some of the range of negative outcomes they experienced when receiving health services might be due to an adverse event, rather than the recognized risks of treatment or the progression of their disease or condition. This epidemic is no longer silent, at least in a policy sense. Internationally, patient safety has become a significant public policy issue.[3] This does not appear to be because there has been a significant upsurge in adverse events in health systems – adverse events have always occurred in health systems and have always been subject to some degree of regulation.[4] It is rather that there have been significant changes in awareness of and concern about safety and risk.[5] Specifically, in the patient-safety context, there is an increasing understanding of the risks and consequences of receiving unsafe health services. This increased awareness of risk, and therefore safety, is a tangible manifestation of what Beck and others call the 'risk society'.[6] A policy response to risk is often an inclination to regulate; hence, the focus of this thesis is to analyse developments in the frameworks for the regulation of patient safety in Britain and Canada.

The movement of patient safety from back to centre stage between 1980 and 2005 offers an opportune moment to critically analyse developments in this area by comparing the regulatory responses of two jurisdictions, Britain and Canada, jurisdictions confronted by the same policy problem. How did these governments regulate the provision of health services to protect users of such services before 1980 and did these regulatory frameworks shift during the period 1980-2005? If these regulatory frameworks did indeed shift, were there significant divergences between the jurisdictions and, if so, what could these divergences be attributed to?

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[3] The term 'patient safety' as discussed later refers to the prevention of iatrogenic injury (injuries caused by the provision of health services as opposed to the underlying disease process).

[4] D. Moss, *When All Else Fails: Government as the Ultimate Risk Manager* (Cambridge, M.A.: Harvard University Press, 2002) at 13 [Moss].

[5] See, for example, D. Lupton, *Risk* (London and New York: Routledge, 1999) [Lupton]; V. Covello & J. Mumpower, "Risk Analysis and Risk Management: An Historical Perspective" (1985) 5:2 Risk Anal. 103 [Covello]; M. Douglas, *Risk and Blame: Essays in Cultural Theory* (London: Routledge, 1992) [Douglas]; U. Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992) [Beck, "*Risk Society*"].

Britain and Canada provide an especially apt comparison for taking up such questions. Before 1980, each jurisdiction had had similar regulatory frameworks to address patient safety. Subsequently, the regulatory frameworks grew further divergent. Given that medical knowledge and health management practices do not respect national boundaries, the divergences suggest that other factors have played an important role in shaping regulatory responses. What are these factors? To identify these factors I ask a series of further questions. Does health system design constrain a government's regulatory response to a policy problem within that sphere? Do constitutional, political and social norms influence governance? How influential are changes in political norms on the regulation of patient safety? What role do scandals play as drivers of regulatory change?

The answers to these questions provide important insights into the processes of regulation. They also illuminate the factors that may incline one jurisdiction to adopt a different regulatory response to a common problem than that adopted in another jurisdiction. Such insights may allow regulators seeking to adopt regulatory solutions from other jurisdictions to determine whether such solutions will be likely to be successful in different contexts. The fact that two jurisdictions with such common regulatory pasts have so dramatically diverged is not only a provocative puzzle for comparative public policy research, more importantly, it is potentially life and death matter for patients.

Defining Some Key Terms

Before I proceed any further, I must define some key terms and concepts. 'Patient safety' has been defined in multiple ways, but for the purposes of this thesis I define it as systems to prevent iatrogenic events.[7] Iatrogenic events are injuries caused by the provision of health services as opposed to those caused by an underlying disease process. Health services include personal and public health services, so such services as preventative strategies, treatment, and personal care provided by health-providers (individual and organizational,

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[6] Beck, *ibid.*; A. Giddens, "Risk Society: The Context of British Politics" in J. Franklin, ed., *The Politics of Risk Society* (Cambridge: Polity Press, 1998) 23 [Giddens, "Risk Society"].

[7] M. Mello, C. Kelly & T. Brennan, "Fostering Rational Regulation of Patient Safety" (2005) 30:3 J. Health Pol. 375 [Mello, "Fostering Regulation"].

licensed or non-licensed) or in acute hospitals, community clinics, mental health facilities, and long-term or community-care facilities fit within the scope of this definition. I also talk of health professionals and health-providers. I use the term health professionals to refer to members of health professions and health-providers to refer to institutional or organizational providers of health services, such as hospitals.

The 'governance of patient safety' encompasses a panoply of regulatory processes that directly or indirectly intend to manage, prevent or limit iatrogenic events. However, for the purposes of this thesis, a more limited definition is employed, and the 'governance of patient safety' means the regulation of health-providers (individuals and institutions/organizations), health procedures, and the treatment environment that directly or indirectly intend to manage, prevent or limit iatrogenic events. The regulation of drugs and devices is outside the scope of this thesis.

Regulation is a process of imposing social order through the creation of rules. However, there is some contention about the interpretation of this definition. Traditionalists, as MacDonald notes, ground their concept of regulation in the theory of legal positivism – regulation is therefore a product of the political state and its agents.[8] Traditionalists regard regulation as a top-down projection of state authority. Because of constitutional arrangements, the state and its agents have a monopoly over the creation of law and legal processes.[9] Only the state and its agents regulate, and the paradigmatic form or expression of regulation is legislation; therefore, traditionalists equate regulation with law. According to this view, there is a clear distinction between what is, and what is not, law and therefore what is and what is not regulation.

A broader, modernist view of regulation, again according to MacDonald, suggests that non-state normative orders are part of the regulatory system.[10] This perspective suggests that regulation is an interdependent endeavour involving a variety of actors within and outside

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[8] See discussion in R. MacDonald, "The Swiss Army Knife of Governance" in P. Eliadas, M. Hill & M. Howlett, eds., *Designing Government: From Instruments to Governance* (Montreal & Kingston: McGill-Queens University Press, 2005) [MacDonald].

[9] R. Rhodes, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability* (Buckingham: Open University Press, 1997) [Rhodes].

[10] MacDonald, *supra* note 8.

the political state all seeking to create a form of social order. So, adopting a modernist view, law, or regulation, includes tacit and implicit processes of social ordering such as custom, practice, and culture.[11] It can also be understood to include bottom-up forms of regulation that also create rules and social ordering, such as tort law, a mechanism that relies on individual patients to initiate claims.[12] I acknowledge the truth of the latter – that custom, practice, and culture developed by actors at all levels in the health system (including government) and bottom-up regulatory mechanisms play a significant role in shaping and establishing social order in the health system. The state's regulatory role fits within a broader regulatory context as part of a network of policy and other actors who, through one mechanism or another, regulate the health system. Non-state actors make important contributions to the regulatory process. However, the focus of this thesis is on the *state's* role in regulating patient safety in the health system.

I talk in this chapter and throughout the thesis of the concept of a health system. In functionalist terms, all societies and cultures depend upon individual members to perform specific social roles to enable societies to function to fulfil the social needs of their members.[13] Illness, trauma, and death impede, at the very least, an individual's ability to perform social roles[14] and are a recognized social risk. The devastating effects that illness, injury, and death have on societies and economies is well known.[15] All societies and cultures develop responses to these risks, including the development of specialized occupational

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[11] MacDonald, *supra* note 8.

[12] See discussion in Mello, "Fostering Regulation", *supra* note 7.

[13] M. Field, "The Concept of the 'Health System' at the Macrosociological Level" (1973) 7 Soc. Sci & Med. 763 at 764-765 [Field].

[14] This is so whether that social role is perceived in functional or economic terms or holistically, as part of social and societal development. Critical disability theory offers a persuasive critique of purely economic analyses of societal functioning; see, for example, D. Pothier & R. Devlin, *Critical Disability Theory: Essays in Philosophy, Politics, Policy and Law,* (Vancouver & Toronto: UBC Press, 2006).

[15] An extensive enumeration of illustrations is neither possible, nor is it necessary for the purposes of this thesis, but illustrative is the impact that the 'Black Death' had on societies in Europe, Asia, and the Middle East in the 14th century. The Black Death caused the deaths of up to one third to one half of Europe's population, and some economic historians have concluded that the plague contributed to a recession, as well as other social and economic changes such as increased social mobility. See F. Braudel, *Civilization and Capitalism, 15th-18th Century, Vol. I: The Structure of Everyday Life,* (Berkeley: University of California Press, 1992) [Braudel]; less dramatically, perhaps, but just as pervasive is that countries whose citizens experience poor health do less well economically. Or, as Abel-Smith put it, "countries had poor health because they were poor and to some extent they were poor because they had poor health." B. Abel-Smith & A. Leiserson, *Poverty, Development and Health Policy,* (Geneva: World Health Organization, 1978) [Abel-Smith, "*Poverty*"].

roles, structures, and facilities.[16] These responses evolve according to social norms intrinsic and extrinsic to the system. Systems usually reflect developments in socialization and move from the simple to the increasingly complex. So any system is merely the aggregate of the degree of commitment and resources (human, economic, cultural, and political) a society devotes to a particular concern, whilst concurrently also making commitments and devoting resources to other concerns.[17] It is therefore important to acknowledge that the development of a health system, or a legal system for that matter, is merely one subsystem within a larger system of governance. The development of a specialized subsystem is part of the broad social evolutionary forces at play in a society at any given time. We also often infuse the concepts of systems with more modern understandings of how societies are organized, centring on a strong nation state. Certainly the early history of each jurisdiction indicates that central authorities, the Crown, and its agents, exercised control imperfectly, leaving much scope for actions by other policy actors. As the power of the state increased, so did the degree of its involvement in systems as regulator.

The Literature

Patient safety has been an increasingly significant academic concern since the mid 1990s. There are a multitude of publications discussing patient safety in a clinical context and characterizing it as a responsibility of health-providers – individual and organizational.[18] There are publications examining the governance of patient safety at a macro level as a function of government and as a system in and of itself. There have, of course, been examinations of more specific issues or elements of the governance of patient safety. Health professional regulation is one such issue and has been subject to a great deal of academic scrutiny from a regulatory perspective, as well as from sociological, anthropological, political, and historical perspectives.[19] The regulation of healthcare is another,[20] as are the legal

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[16] Field, *supra* note 13.

[17] *Ibid.*

[18] While it is clearly impossible to list all books and articles that have been written to date, the U.S. Agency for Healthcare Research and Quality provides a list of references, including those the Agency considers 'classics', the most influential, frequently cited articles, books, and resources. Online: AHRQ <http://www.psnet.ahrq.gov/>. See recently, J. Healy & P. Dugdale, eds., *Patient Safety First,* (Sydney: Allen & Unwin, 2009).

[19] See for examples of assessments from a largely regulatory perspective: E. Kuhlmann & M. Saks, eds., *Rethinking Professional Governance: International Directions in Healthcare* (Cambridge: The Policy Press, 2008) [Kuhlmann]; M. Davies, *Medical Self-Regulation: Crisis and Change* (Aldershot: Ashgate, 2007) [Davies, "*Self-*

systems that address medical error (criminal law, discipline, and the tort of negligence).[21] There have been a few jurisdiction-specific analyses of how governments use or could use law to govern patient safety through the use of regulation. The most significant include the seminal text *To Err is Human* by the Institute of Medicine in the United States,[22] and works from New Zealand[23] and Australia,[24] as well as a body of work from scholars in the United States,[25] the United Kingdom,[26] and Canada.[27]

What is missing from this literature is an examination of the evolution of the governance of patient safety in a comparative context. Identification of factors specific to governance, health governance, and the governance of patient safety that results in governments taking

Regulation"]; J. Allsop, & M. Saks, *Regulating the Health Professions* (London: Sage Publications 2003) [Allsop, "*Regulating*"]; R. Blair, & S. Rubin, eds., *Regulating the Professions: A Public-Policy Symposium,* (Lexington, Mass.: Lexington Books 1980) [Blair, "*Regulating*"]; G. Freddi & J. Björkman, eds., *Controlling Medical Professionals: The Comparative Politics of Health Governance* (London: Sage, 1989) [Freddi & Björkman]; D. Gladstone, ed., *Regulating Doctors* (London: Institute for the Study of Civil Society, 2000) [Gladstone]; J. Glynn & D. Gomez, *Fitness to Practise: Health Care Regulatory Law, Principle and Process* (London: Thomson/Sweet and Maxwell, 2005)[Glynn]; T. Jost, ed., *Regulation of the Healthcare Professions* (Ann Arbor, Mich.: Health Administration Press, 1997) [Jost, "*Regulation*"]; M. Stacey, *Regulating British Medicine: The General Medical Council* (Chichester: Wiley, 1992) [Stacey, "*Regulating*"].

[20] J. Healy, *The Governance of Healthcare: Reluctant Regulators* (forthcoming, Ashgate, 2010) [Healy, "Regulators"]; K. Walshe, *Regulating Healthcare: A Prescription for Improvement?* (Buckingham: Open University Press, 2003)[Walshe, "*Regulating Healthcare*"]; T. Brennan, "The Role of Regulation in Quality Improvement" (1998) 76:4 Milbank Q. 709 [Brennan, "Role"]; T. Jost, "The Necessary and Proper Role of Regulation to Assure the Quality of Health Care" (1988) 25:5 Houston L. Rev. 525 [Jost "Necessary"].

[21] See, for example, A. Merry & A. McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001)[Merry]; R. Bovbjerg, R. Miller & D. Shapiro, "Paths to Reducing Medical Injury: Professional Liability and Discipline vs. Patient Safety and the Need for a Third Way" (2001) 29:3-4 J.L. Med. & Ethics 369 [Bobvjerg]; J. Holbrook, "The Criminalisation of Fatal Medical Mistakes: A Social Intolerance of Medical Mistakes has Caused them to be Criminalised" (2003) 327:7424 B.M.J. 1118 [Holbrook]; C. Murdoch & J. Brockman, "Who's On First? Disciplinary Proceedings by Self-Regulating Professions and Other Agencies for 'Criminal' Behaviour" (2001) 64:1 Sask. L. Rev. 23 [Murdoch].

[22] U.S., Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 2000) [IOM "To Err"].

[23] P. Roberts, *Snakes and Ladders: The Pursuit of a Safety Culture in New Zealand Hospitals* (Wellington: Victoria University Press, 2003).

[24] J. Braithwaite, J. Healy & K. Dwan, *The Governance of Health Safety and Quality: A Discussion Paper* (Canberra: Commonwealth of Australia, 2005) [Braithwaite, "*Governance*"].

[25] Mello, "Fostering Regulation", *supra* note 7; P. Aspden *et al*, *Patient Safety: Achieving a New Standard of Care* (Washington D.C.: National Academy Press, 2004); L. Palmer, "Patient Safety, Risk Reduction and the Law" (1999) 36 Hous. L. Rev. 1609 [Palmer]; IOM "To Err", *supra* note 22.

[26] J. Bridgeman, "Learning from Bristol: Healthcare in the 21st Century" (2002) 65:2 Mod. L. Rev. 241; C. Newdick, "N.H.S. Governance after *Bristol*: Holding on, or Letting Go?" (2002) 10:2 Med. L. Rev. 111 [Newdick, "N.H.S."].

[27] E. Bonney & G. Baker, "Current Strategies to Improve Patient Safety in Canada: An Overview of Federal and Provincial Initiatives" (2004) 7:2 Healthc. Q. 36; G. Baker & P. Norton, *Patient Safety and Healthcare Error in the Canadian Healthcare System: A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere* [Baker & Norton]*,* online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2002-patient-securit-rev-exam/index_e.html>

divergent approaches to regulation can be more fully identified and analysed by using a comparative method (as discussed in more detail in the approach section of this chapter). As promising as the comparative framework is, very few researchers have used such an approach. Baker et al and Downie et al conducted comparative synthesis research into patient-safety-focused regulatory initiatives.[28] Baker's work examined regulatory processes occurring at governmental and non-governmental levels, whereas Downie's research focused on legal frameworks, including some discussions of the regulation of drugs and devices. This research showed that internationally regulatory actors were adopting different approaches to patient safety. Nonetheless, the studies were more descriptive than analytical and did not engage in any great depth with questions relating to why regulatory responses differed. Only Healy's forthcoming work undertakes a cross-national survey of a number of international jurisdictions and their regulation of patient safety, examining this issue through the lens of responsive regulation.[29]

Contributions of the Thesis

Applying a governance lens to the regulation of patient safety promises to extend our knowledge and understanding of patient safety and of health governance. It situates the discussion of the regulation of patient-safety issues within a literature that reassesses the methods and mechanisms with which societies deal with public problems. Employing this approach provides a valuable global context to the analysis of regulatory evolution. This thesis proposes to fill gaps in the literature by undertaking a detailed comparison between Canada and Britain and the divergences in their approaches to regulating patient safety between 1980 and 2005. Such a comparison is important because the different approaches in each jurisdiction to the specific issue of why and how to regulate patient safety illuminate differences in political, legal and health-related cultures, as well as societal values that lead to the enactment of regulation.

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[28] Baker & Norton, *supra* note 27; J. Gardner *et al*, for the Advisory Committee on Health Services Working Group on Quality of Health Care Services, *Governments and Patient Safety in Australia, the United Kingdom and the United States A Review of Policies, Institutional and Funding Frameworks, and Current Initiatives,* online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2002-gov-patient-securit/index_e.html>; J. Downie *et al*, *Patient Safety Law: From Silos to Systems* [Downie], online: Health Canada <http://www.patientsafetylaw.ca>.
[29] Healy, "Regulators" *supra* note 20.

Approach of the Thesis

The research questions informing this thesis are addressed using a multi-method orientation that draws on legal, historical, sociological, and political literature. This thesis is best understood as engaging with the sociology of law methodological school. Sociology of law bridges the gaps between law and sociology, social policy, economics, political science, anthropology and other disciplines within the humanities and social sciences. Those who use the sociology-of-law approach draw extensively on insights from the social sciences and humanities, and these disciplines influence the perspectives and methodologies of scholars of sociology of law. Scholars who use the sociology-of-law approach also take account of juristic ideas and practice.[30]

One of the tasks of sociology of law is to explore the social forces which bring about changes in the law. Stuart Henry captures this he states that sociology of law is "… not simply the study of law and society but the study of the interrelationship of law with society."[31] Sociology of law demonstrates that law is born of sociopolitical contexts existing in different historical eras and different societal structures, or forms of organization that give rise to different laws and legal systems.[32] It seeks to discover if and how law affects human behaviour. Conversely, it also examines how social change affects law, whether of a cultural, political, or economic nature. Accordingly, all those who undertake research into sociology of law use multidisciplinary methodologies. It is important to note from the outset, however, that this is not a purely sociological thesis, rather I approach the analysis as a legal scholar who is interested in the design of public institutions and legal processes and in questioning when, why, and how governments choose to use regulatory tools in relation to patient safety in the health system. In exploring the research questions set out above I use analytical approaches from a number of disciplines and draw upon critical analysis that has emerged from these different perspectives.

Examinations of the legal frameworks that surround health systems are well suited to sociology of law. At first glance, healthcare is about healing the sick, but, as Fierlbeck notes:

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[30] R. Cotterrill, ed., *Sociological Perspectives on Law: Volume II,* (Aldershot, U.K.: Ashgate, 2001) [Cotterrill].
[31] S. Henry, "Preface" in D. Milovanovic, ed., *A Primer in the Sociology of Law* 2nd ed. (Albany, N.Y.: Harrow and Heston, 1994) at viii [Henry].

[I]t is also a source of cultural identity, economic industry, a way of comprehending the nature of human beings and of being human, a political arena for vested interest politics, personal identification, communal identification, economics, sciences, and ideological beliefs.[33]

These factors are not static; ideological beliefs and identification, for example, evolve, develop, and change over time. So in addition to the concept of 'health' being complex and interdependent, it is also inherently fluid. Any social activity of any complexity requires the imposition of social order and therefore rules of conduct. A sociological approach to examining the role of law in the regulation of the provision of health services would therefore suggest that the many complexities and the fluidity inherent in the concept of 'health' – and therefore the provision of health services – influence the scope and shape of law. In turn, in formulating our conceptions of health systems, health services, health-providers, and concepts related to 'health', we are influenced by the structures we use to impose social order and the prevailing social and cultural constructs of our time. Rousseau stated that "Society has to be studied in the individual, and the individual in society; those who wish to separate politics from morals will never understand either."[34] We can separate patient safety from its broader setting in complex political and societal structures for some analytic purposes. However, if we truly want to understand why governments have responded differently to patient safety, we need to consider patient safety as part of a whole, as part of broader sociopolitical and socioeconomic processes in each country. We also need to consider patient safety in the context of the historical development of institutions of governance within the health system and more broadly. Thus this research also adopts a historical framework reflecting my view that regulation is an essentially temporal process.

This project employs a comparative methodology by conducting a micro-comparison of the evolving regulatory frameworks around patient safety in two jurisdictions: Britain and

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[32] *Ibid.*

[33] K. Fierlbeck, "Canadian Healthcare Reform and the Politics of Decentralisation" in C. Altenstetter & J.W. Bjorkman, eds., *Health Policy Reform: National Variations and Globalization* (New York: St Martin's Press, 1997).

[34] J.J. Rousseau, quoted in R. Titmuss, *The Gift Relationship: From Human Blood to Social Policy* (New York: Pantheon Books, 1971) at 13 [Titmuss].

Canada. Such an examination is important, as comparing how and why regulation has evolved in different countries may offer insights about our systems of governance, in particular which features are characteristic of a jurisdiction's approach to regulation. It may therefore help us understand how regulatory innovations from other countries may or may not be readily adaptable to the social context within which regulation is occurring.

Why Britain and Canada

A logical question then is: why Britain and Canada? Canada and Britain are often subject to comparison, as there are sufficient similarities between them in terms of culture and legal and political structures to make such a comparison meaningful.[35] For the same reasons, macro-level decision-makers in one country often study the innovations of another. Canada and Britain share 'Westminster'-type parliamentary systems and similar parliamentary conventions. However, a significant constitutional difference is that Canada has a federal system, whereas Britain is a devolved unitary state.[36] Accordingly, in Canada, the Constitution divides responsibility to provide and regulate health services between the federal and provincial/territorial governments with the primary responsibility for regulating the safety of institutions and professions accorded to the provinces/territories. In Britain, the responsibility for providing and regulating health services is a national or regional responsibility, in that the central government has devolved powers in relation to health to the Scottish, Welsh, and Northern Ireland Parliaments. The British Parliament retains the responsibility for providing and regulating health services in England, and for regulating some aspects of health in which there is a national interest, e.g. the continuing regulation of health professionals.

In both countries, in common with many other countries in the West, there was a significant reappraisal of the manner in which governments governed in the period from the late 1970s to the 1990s.[37] Influenced by the neoliberal economic models emerging primarily from the

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[35] See in the health field, for example, C. Tuohy, *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada* (New York: Oxford University Press, 1999) [Tuohy "Logics"].

[36] It is also a federacy in that the Channel Islands and the Isle of Mann are Crown dependencies. A further complication is Britain's membership in the European Union.

[37] See, for example, D. Longley, *Health Care Constitutions* (London: Cavendish, 1996) [Longley]; M. Moran, *Governing the Health Care State – A Comparative Study of the UK, the United States and Germany* (Manchester:

Chicago School,[38] governments were convinced, again to varying degrees, that there needed to be a reappraisal of the appropriateness and efficiency of government provision of services that the free market could more appropriately and efficiently provide. In addition, governments were re-examining the way in which bureaucracies functioned, favouring increased fiscal accountability mechanisms, flexible, responsive and professional management cadres, deliverable outputs, ideally linked to desirable policy outcomes, and so on. Public sector reform proceeded more quickly and more completely in Britain (and New Zealand) than it did in Canada (and Australia and the United States).[39] This resulted in more complete and thorough transformations in the manner in which the British public sector operates than it did in the public sector in Canada. In short, the culture of the governmental policy process in Britain and Canada comes from similar roots, yet as a result of reforms is different – perhaps substantially different – in the two countries.

The provision of health services by the state to some, or preferably all, citizens has long been considered a pillar of the welfare state, along with other social policies that redistribute social risks, such as social services. Both Canada – and increasingly Britain – fit within what Esping-Anderson categorizes as the 'liberal' model of the welfare state.[40] Esping-Anderson suggests that liberal welfare states, certainly in regard to the delivery of social services, limit assistance to targeted groups who are in the 'bad' risk strata through means-tested assistance, modest universal transfers, or modest social insurance plans. Canada and Britain fit within the 'liberal' cluster, as do Australia, New Zealand, and the United States. Within this 'liberal' cluster there is considerable variance within types, especially in regard to the provision of health services. Both Canada and Britain aspire to the universal provision of health services but do not achieve it. Both use different mechanisms to provide and fund such services,

Manchester University Press, 1999) [Moran, "*Governing*"]; and M. Moran, & T. Prosser, eds., *Privatization and Regulatory Change in Europe* (Buckingham and Bristol, PA: Open University Press, 1994) [Moran & Prosser].
[38] Moran & Prosser, *ibid.*
[39] See, for example, Longley, *supra* note 37; World Bank, Administrative and Civil Service Reform "OECD Countries" online: World Bank
 <http://www1.worldbank.org/publicsector/civilservice/oecdcountries.htm>; D. Porter & D. Craig, "The Third Way and the Third World: Poverty Reduction and Social Inclusion in the Rise of 'Inclusive' Liberalism" (2004) 11:2 Rev. Int'l Pol. Econ. 387; M. Barzelay, *The New Public Management: Improving Research and Policy Dialogue* (Berkeley, University of California Press, 2001) [Barzelay]; P. Aucoin, *The New Public Management: Canada in Comparative Perspective* (Montreal: Institute for Research on Public Policy, 1995) [Aucoin].
[40] The others are: social democratic (Nordic countries) and conservative (continental Europe). See G. Esping-Andersen, *Social Foundations of Post-Industrial Economics* (Oxford: Oxford University Press, 1999) [Esping-Andersen]. This typology is not without its critics, who argue that there are more than three models.

with Britain embracing a 'national' health system funded through taxes, and a social insurance program in Canada, also funded through taxes.[41] Similarly, the health system in Britain reflects a form of state hierarchy, in that the centre controls functions, at least nominally, whereas the systems for delivering health services across Canada reflect values related to professional collegiality.[42] Within Canada the legal framework surrounding the provision of health services is designed in such a way to create disincentives for doctors to accept private funding.[43] This in effect creates a one-tier health system for certain defined core health services; outside this core area of service provision, government permits private provision and thus a two-tiered system. In contrast, Britain has a two-tiered system of public and private provision of all health-related services. In both countries, there is a trend towards some form of devolution in the administration by government of the health system. In Canada, this has involved provincial/territorial governments devolving powers to regions or districts (regionalization) in most provinces/territories. Britain initially devolved powers to the regions, but since the 1990s has been in a period of post-regionalization where services have been gradually further devolved from regions to individual National Health Service (NHS) Trusts, i.e. hospitals or other health-providers, such as ambulance services.

A comparison of Britain and Canada, in respect of patient safety, shows startling similarities in incidence, incidents, and issues. However, a comparison also shows that in some respects Britain and Canada demonstrate striking dissimilarities in terms of choices in respect of regulatory interventions. Britain and Canada have both relatively recently undertaken studies into the incidence of adverse events in hospitals in each country. In 1999, British data indicated an 11.7 per cent incidence rate for adverse events, with 48 per cent of these events deemed preventable.[44] Canadian data from 2004 indicated a 7.5 per cent incidence rate for adverse events, with 37 per cent of these events deemed preventable.[45] Both jurisdictions have had some form of inquiry, public or coronial, into the deaths of children undergoing paediatric cardiac surgery; both have had issues related to the safety and security of the blood system; and both have had wide publicity accorded to the rates of nosocomial infections in

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[41] Moran, "*Governing*" *supra* note 37 at 17.

[42] Tuohy, "Logics" *supra* note 35 at 27.

[43] C. Flood & T. Archibald, "The Illegality of Private Health Care in Canada" (2001) 164:4 CMAJ 825.

[44] M. Woloshynowych, G. Neale & C. Vincent, "Adverse Events in Hospitalised Patients: A Pilot Study and Preliminary Findings" (2000) 1:2 Clinical Governance Bulletin 2 [Woloshynowych].

[45] Baker, "*Adverse Events*", *supra* note 2.

hospitals. The differences between these countries do not relate to incidence, incidents, or issues but rather are in relation to their responses to these issues. Canada and Britain are eminently comparable, especially in regard to the issue of regulating patient safety.

Methods

The research methods employed in this thesis are nonempirical, involving critical review and analysis of existing literature. More importantly, I draw heavily from primary sources – so-called 'grey' literature – and also various legal instruments, including legislation, regulations, and policies and guidelines.   These resources will be analyzed and evaluated using the conceptual framework set out below.

The Conceptual Framework

This research presents a way of understanding the processes of regulatory change in health systems in response to a particular problem – that of the safety of patients receiving health services – and how these responses differ between countries. I draw upon studies that have identified local specificities as important mediating factors in determining specific policy outcomes.[46] These contexts establish the parameters within which regulators make choices about what to regulate, how to regulate, and to what ends. As such, this project draws upon theories from political science that seek to explain policy evolution, notably the literature on "path dependency",[47] "punctuated equilibrium",[48] and Tuohy's "accidental logics".[49] Broadly, these frameworks suggest policy decisions accumulate over time and accretion can create limits for future policy-makers[50] – or, in other words, once a country or region starts down one path, it is difficult to reverse course.[51] Change will still occur, but it will likely be bounded change unless something occurs to puncture the equilibrium or to create a window

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[46] For example, Tuohy, "Logics" *supra* note 35.

[47] A. Kay, "A Critique of the Use of Path Dependency in Policy Studies" (2005) 83:3 Pub. Admin. 553 [Kay]; P. Pierson, "Increasing Returns, Path Dependence and the Study of Politics" (2000) 94:2 Am. Pol. Sci. Rev. 251 [Pierson].

[48] F. Baumgartner & B. Jones, *Agendas and Instability in American Politics* (Chicago: University of Chicago Press, 1993) [Baumgartner].

[49] Tuohy, "Logics" *supra* note 35.

[50] Kay, *supra* note 47.

[51] Pierson, *supra* note 47.

of opportunity, a policy 'accident' that is conducive to change.[52] Thus time, or the temporal progression of the process of policy development, becomes a key focus for analysis rather than a merely incidental factor.

One of the central critiques, of path dependency in particular, is that the concept does not in and of itself provide a necessary or sufficient condition to understand or explain the processes leading to policy change. Path dependency stresses the 'how' of policy-making – an empirical question – rather than the 'why', which requires theorizing.[53] As Eagleton notes:

> For much of the time, our intellectual and other activities bowl along fairly serenely, and in this situation no great expenditure of theoretical energy is usually necessary. But there may come a point where these taken-for-granted activities begin to falter, log-jam, come unstuck, run into trouble, and it is at these points that theory proves necessary. Theory on a dramatic scale happens when it is both possible and necessary for it to do so – when the traditional rationales which have silently underpinned our daily practices stand in danger of being discredited, and need either to be revised or discarded. This may come about for reasons internal to those practices, or because of certain external pressures, or more typically because of a combination of both. Theory is just a practice forced into a new form of self-reflectiveness on account of certain grievous problems it has encountered.[54]

Theory, in its various guises, drives analysis around the 'why' questions. Ideas, and especially expert knowledge, as well as political ideologies, drive policy analysis. From this perspective, it is helpful to draw upon governance theory and insights from social theory to seek to explain why, in the context of patient safety, regulatory paths in Britain and Canada changed markedly or remained consistent with a pre-existing regulatory path.

Beginning with social theory: social theorists increasingly describe many societies (particularly in the West) as being at some form of impasse, where new social structures and norms are

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[52] *Ibid.*
[53] Kay, *supra* note 47.

superseding the old, previously dominant structures of power and authority. This transition is occurring, not from the top-down, but almost stealthily, and certainly – at least to a degree – unwittingly.[55] This slow, often-hidden impetus for change has profound implications for governance, for law and for how law is used to address public problems.[56] While cultural theorists operate at a macro or "world-historical"[57] level of analysis, there are also many researchers who seek to ascertain whether and to what extent cultural theories are borne out by lived experience, adding an empirical layering to a theoretical discussion. From social theory I suggest, in the context of regulating safety in the health system, that certain factors derived from social theory are of central concern to regulators. These include: 1) the degree of risk associated with the provision of health services; 2) the levels of distrust or mistrust associated with the current institutional and structural regulatory arrangements; 3) whether accountability measures are (in)effective; and 4) the desired level of control by the state. I maintain that these factors contribute to the decision-making process about what, when, why and how to regulate in respect of patient safety and, I would suggest, in matters touching upon public safety more generally.

Social theorists suggest broad cultural shifts associated with the concepts of risk, trust, accountability and control are emerging. It is widely agreed that the concept of risk has, to quote Lupton, "become an increasingly pervasive concept of human existence in western societies"[58] which acts to organize, monitor and regulate the conduct of societal actors. Giddens and Beck suggest that we increasingly live in a 'risk society' where we have an overwhelming preoccupation with regulating risks to the public.[59] Ericsson and Haggerty conclude that "a risk society is a regulatory society."[60] Some scholars suggest that we –

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[54] T. Eagleton, *The Significance of Theory and Other Essays,* (Cambridge, Mass.: Blackwell, 1990) at 26 [Eagleton].

[55] U. Beck, "The Reinvention of Politics: Towards a Theory of Reflective Modernization" in U. Beck, A. Giddens & S. Lash, eds., *Reflexive Modernization: Politics, Tradition and Aesthetics in the Modern Social Order* (Cambridge: Polity Press, 1994) 1 [Beck, "Reinvention"].

[56] See, for example, L. Salamon, "The New Governance and the Tools of Public Action: An Introduction" in L. Salamon, ed., *The Tools of Government: A Guide to the New Governance* (New York: Oxford University Press, 2002) 1 [Salamon "Introduction"].

[57] C. Hood, H. Rothstein & R. Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford: Oxford University Press, 2001) [Hood, "*Risk*"].

[58] Lupton, *supra* note 5 at 25.

[59] See, for example, U. Beck, A. Giddens & S. Lash, eds., *Reflexive Modernization: Politics, Tradition and Aesthetics in the Modern Social Order* (Cambridge: Polity Press, 1994) [Beck, "*Modernization*"].

[60] R. Ericson, & K. Haggerty, *Policing the Risk Society* (Toronto and Oxford: University of Toronto Press & Oxford University Press 1997) [Ericson].

certainly we in the Western world – live in a "post-trust society"[61] at least insofar as societies are increasingly expressing distrust, or suspicion, of traditional and established institutions of social order, such as governments, professions, religious institutions and other social edifices that were traditionally trusted to regulate risks. If the public or key policy-actors begin to distrust, or at least to feel ambivalent, about key institutions, policy-actors may change the policy and legal frameworks surrounding those key institutions in an attempt to restore or bolster trust. Rowe and Calnan note that "changes in trust relations reflect changes to the distribution of power, modes of governance and accountability within the health service."[62] Changes in frameworks of control can causally impact upon perceptions of trust or distrust or, again from Rowe and Calnan, "changes in trust are driven by the dialectical relationship between trust, power, governance and accountability, so that each affects the other in a continuing iterative process."[63]

These broad theories of social change are interesting and compelling but do not particularly assist with the analysis of why there has been change in respect of a particular issue or regulatory concern. For that I must have recourse to the more applied levels of social theory. In particular, theorists and empiricists alike consider that the interrelationships between trust/distrust and risk/risk perception are key determinants of the acceptability of policy or, for the purposes of this thesis, regulation, although there is some contention about the causality of the relationships between risk and trust. Some empiricists claim that trust is the determining factor in the perception of risks and the acceptability of policies, i.e. they posit a causal explanation:[64] trust influences risk perception which influences perceptions as to the acceptability of policies. Others argue that the acceptability of a policy could be a determinant of trust, so that trust and risk could be indicators of a more general attitude or perception about a policy, i.e. they posit an associationist model of trust:[65] trust influences and is influenced by perceptions of policy acceptability which in turn influences and is influenced by risk. There is empirical evidence to support both interpretations of the

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[61] See, for example, R.E. Lofstedt, *Risk Management in Post-Trust Societies,* (Basingstoke, U.K.: Palgrave MacMillan, 2005) [Lofstedt].

[62] R. Rowe & M. Calnan, "Trust Relations in Health Care: Developing a Theoretical Framework for the 'New' NHS" (2006) 20:5 J. Health Org. Manage. 376 at 379 [Rowe].

[63] *Ibid.* at 379.

[64] For a general overview, see discussion in W. Poortinga & N. Pidgeon, "Trust in Risk Regulation: Cause or Consequence of the Acceptability of GM Food?" (2005) 25:1 Risk Analysis 199 [Poortinga].

relationship between risk and trust, although the evidence to date more strongly supports the associationist model.[66]

Setting aside empiricism for the present, in this thesis I argue on a normative level that both the causal and the associationist models apply, at least in relation to the regulation of patient safety, but that these models must expand to include the interrelated concepts of accountability and control. Perceptions that mechanisms both exist and are adequate to ensure that individuals and organizations are accountable for their actions are an important determinant, I suggest, as to whether current controls on specific activities or practices are sufficient and, accordingly, whether changes in the levels and mechanisms of control are required. Trust is a determining factor of the perception and acceptability of risk, which is in turn a determining factor as to the degree of accountability required of policy-actors, which in turn determines policy or regulatory acceptability, which in turn impacts upon perceptions of how much control is required, which impacts upon trust, and so on.

I further contend that the concepts of risk, trust, accountability, and control are key factors driving safety regulation and regulation in the health system more generally. It has long been recognized that there are risks of harm associated with the provision of health services.[67] Accordingly, individuals and groups have historically employed a number of regulatory strategies to manage such risks – most saliently, for the purposes of this thesis at least – the development and use of the common law and direct regulation through legislation (discussed in more detail in Chapter 2).[68] Consumers of health services in the 20th and 21st centuries are more aware of the probability of the standard risks of adverse outcomes associated with the competent provision of health services.

Trust is, and has always been, a cornerstone of the relationships between the public and health systems, organizations, institutions, and professions within the health system and

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[65] *Ibid.*

[66] *Ibid.*

[67] In respect of historical occurrences, see for example G. Ayliffe & M. English, *Hospital Infection: From Miasmas to MRSA* (Cambridge: Cambridge University Press, 2003) [Ayliffe]; and for modern confirmation Baker, "Adverse Events", *supra* note 2; Brennan, "Adverse Events" *supra* note 2; Wilson, "Quality", *supra* note 2; Vincent, "Adverse Events", *supra* note 2; Schioler, *supra* note 2; Davis, *supra* note 2.

[68] Also one sees the employment of insurance and voluntary self-regulation, Covello, *supra* note 5.

individuals and health-providers, institutional and individual.[69] At the macro-systems level, health services are a public good, substantially funded and/or provided, managed and regulated by the state, or by policy-actors to whom that state has delegated authority. When the state delegates authority to other actors, it generally does so as it – and the public more generally – trusts a policy actor to act in the public interest towards the public good. In the health system, policy actors that provide health services, or that are representatives of those who do, i.e. health professions, have moral, ethical, and legal obligations to do no harm to those who use those services. These obligations form the basis of the public trust in those institutions, as health-providers or as self-regulatory policy actors (macro-level trust relationships). Additionally, trust, as an ethical and a legal construct, is central to the relationship between individual health professionals and individual patients.[70] Micro-level trust relationships may influence macro-level trust and vice versa, although these relationships are complex.[71] Trust has become a significant issue with some, such as Mechanic, arguing that, for a number of reasons, public trust in health institutions and in healthcare-providers is in decline, a claim to some extent backed by empirical data.[72]

The concept of accountability has also assumed a prominent place in discussions about the health system. Emanuel and Emanuel suggest that at times a single "key word" comes to dominate discussions about a topic and serves to both organize related ideas on the topic and as a shorthand expression for an entire view to the extent that the topic seems incomplete without that term.[73] They suggest, in the United States context at least, that in health policy "accountability" has become a key word.[74] Others agree that accountability is a core element in health policy and, to an extent, drives many of the health reforms seen internationally in

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[69] M. Calnan & R. Rowe, "Researching Trust Relations in Health Care: Conceptual and Methodological Challenges – An Introduction" (2006) 20:5 J. Health Org. Manage. 349 [Calnan].

[70] See, for example, V. Sharpe, "Introduction: Accountability and Justice in Patient Safety Reform" in V. Sharpe, ed., *Accountability: Patient Safety and Policy Reform* (Washington D.C.: Georgetown University Press, 2004) [Sharpe, "Introduction"]; C. McLeod, "Understanding Trust" in F. Baylis *et al.*, eds., *Health Care Ethics in Canada* 2nd ed. (Toronto: Harcourt Brace and W.B. Saunders, 2004) at 186.

[71] See, for example, B. Misztal, *Trust in Modern Societies: The Search for the Bases of Social Order* (Cambridge: Polity Press, 1996) [Misztal]; Calnan, *supra* note 69 at 353-354.

[72] See D. Mechanic, "In My Chosen Doctor I Trust" (2004) 329 BMJ 1413 [Mechanic].

[73] See, for example, E. Emanuel & L. Emanuel, "What is Accountability in Health Care?" (1996) 124 Ann. Int. Med. 229 [Emanuel].

[74] *Ibid.*

the last twenty years.[75] The concept of accountability for action or inaction within the patient–health professional relationship has always been important, especially in the context of adverse events, although latterly also in terms of the quality of practice in general.[76] However, this is not the sole locus of accountability for professionals. As Stacey describes in respect of doctors:

> There are so many ways in which a doctor may be held to account for her/his actions; for clinical actions to individual patients and, in medical audit, to colleagues; at law, in terms of obligations to patient or employer; to the profession for his/her behaviour; to employers for the money spent and the priorities adopted in treatments. Furthermore, as a collectivity the profession is held to account to the public at large for the quality of medical care in general and particular.[77]

The discourse of control also has a prominent place in the health context as direct regulation, as well as other regulatory tools, has increasingly been used to support the development of a state-sponsored health system and through that to control actors, individual and institutional, and activity within that system.

The sense that government uses regulation to control activity in a sector is linked with the other analytical framework employed in this analysis – governance. 'Governance' has many definitions and is a term that is remarkable for its fluidity and its generality.[78] I prefer the definition of governance as being "the sum of the many ways individuals and institutions,

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[75] See, for example, D. Brinkerhoff, "Accountability and Health Systems: Towards Conceptual Clarity and Policy Relevance" (2004) 19(6) Health Pol'y & Plan. 371 [Brinkerhoff]; A. Simanowitz, "Accountability" in C. Vincent, M. Ennis & R. Audley, eds., *Medical Accidents* (Oxford, Oxford University Press, 1993) 209 [Simanowitz]; J. Oakley & S. Clarke, "Introduction: Accountability, Informed Consent and Clinician Performance Information" in S. Clarke & J. Oakley, eds., *Informed Consent and Clinician Accountability: The Ethics of Report Cards on Surgeon Performance,* (Cambridge: Cambridge University Press, 2007) 1 [Oakley]; M. Rodwin, "Patient Accountability and Quality of Care: Lessons from Medical Consumerism, and the Patients' Rights, Women's Health and Disability Rights Movements" (1994) 20:1-2 Am. J. L. Med. 147 [Rodwin].

[76] See, for example, Simanowitz, *supra* note 75; Oakley, *supra* note 75; Rodwin, *supra* note 75.

[77] M. Stacey, *Medical Accountability,* (Background paper prepared for a meeting organised by the King's Fund Institute and the Centre for Medical Law and Ethics: King's College, London, 1989) cited in Simanowitz, *supra* note 75 at 211.

[78] See discussion in P. Eliadas, M. Hill & M. Howlett, eds., *Designing Government: From Instruments to Governance* (Montreal & Kingston: McGill-Queens University Press, 2005) [Eliadas]; also L. Salamon, ed., *The Tools of Government* (New York: Oxford University Press, 2002) [Salamon, "*Tools*"]; and Rhodes, *supra* note 9.

public and private, manage their common affairs."[79]   Central to the concept of the 'new' governance is the recognition that government is not the sole actor in the policy sphere. Governance focuses on interactions between multiple state and non-state actors. The 'new' governance suggests that this approach is different from the previous model that focused mainly on state interactions. There has always been state and non-state involvement in regulation, if you use regulation in the broadest sense of the word. So what is new is possibly the extent of and recognition of non-state penetration into the regulatory realm and the use by governments of more inclusive regulatory mechanisms.[80]   A complex array of public and private actors, at the individual, local, regional, national, and international levels are, or can be, active in the policy sphere and help define a set of policy objectives. These policy objectives are then pursued through the use of a dense mosaic of regulatory tools, which may place public agencies in complex, interdependent relationships with a host of third-party actors, as the newer regulatory tools often involve shared discretion over the use of public authority and public funds.[81]   However, old regulatory forms – command and control regulation – are often still used to govern these interrelationships. Tool choice tells us something about the nature and perhaps quality of the relationships between stakeholders in these sectors.

It is important to acknowledge that although this research places government and government agencies at the centre of the research paradigm – perhaps reinforcing the image of the centralized, monolithic, bureaucratic state – this is not the complete picture. Although top-down activity by legislatures and government administrative agencies shapes the behaviour of health-providers, other forces are also influential. These forces include, to a greater or lesser degree, depending on the context, private and quasi-private bottom-up approaches such as tort law. However, even what is seen as top-down activity can be attuned to what Salamon calls the central reality of public problem-solving, namely its collaborative nature.[82]   Public problem-solving relies on third-party actors, in addition to

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[79] K. Webb, "Sustainable Governance in the 21st Century: Moving Beyond Instrument Choice" in Eliadas, *supra* note 78.

[80] Some suggest that 'New Governance' is a political construct used to rationalize the privatization and commercialization of public services.

[81] Salamon, "Introduction" *supra* note 56

[82] *Ibid.*

government, to address public problems and pursue public purposes.[83] A classic example is the traditional regulatory treatment of patient safety by governments characterized by Mello et al as "an unparalleled faith in the ability of medical professionals to regulate themselves."[84] This is in itself an expression of commitment to collaborating with a third-party actor by delegating discretion considered in other settings a state responsibility. So the governance approach also takes account of how the use of particular regulatory instruments encapsulates the nature of the relationships with other policy actors.

One of the significant differences between the 'new' governance and more traditional public administration is that the unit of analysis shifts from the traditional program or agency analysis to analyzing the tools of public action that are employed.[85] Rather than seeing policy programs as unique, it examines commonalities and difference on the basis of the regulatory tools used or embodied. The types of tools used may have changed but, despite this, common features are identifiable, regardless of the field or jurisdiction where they are used. The process of choosing a particular regulatory tool to address a specific issue once identified is a complex and not well understood process. As Rhodes notes, there are clearly limits and constraints on central intervention, whether through the use of legal regulatory instruments or not.[86] Limits may, for example, be a result of the many interdependencies within policy domains[87] and accordingly the degree of deference given to some policy actors in health systems, such as physicians, may influence instrument choice.[88] Proponents of the 'new' governance suggest that the views, actions, and responsiveness of the other actors within the polity, including the public, non-state actors, politicians and the bureaucracy, influence the process of tool selection. Some further note that the decision to use a particular regulatory tool is in itself a political act as it defines the set of actors as part of the cast of players who are involved in implementation and the roles they will play.[89] Since actors will all have perspectives, standards of practice, skills, and incentives and these will all

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[83] *Ibid.*
[84] Mello, "Fostering Regulation", *supra* note 7.
[85] Salamon, "Introduction" *supra* note 56 at 9.
[86] Rhodes, *supra* note 9.
[87] *Ibid.*
[88] See, for example, Tuohy, "Logics" *supra* note 35.
[89] Salamon, "*Tools*", *supra* note 78.

differ, determining the choice of tool may influence the outcome, as it gives some actors an advantage in shaping the new policy.

Cultural norms and ideological predispositions also shape choices and in turn affect public attitudes towards the state.[90]   So, to use Salamon's example, a pro-market bias may affect tool choice in the United States, whereas governments in Canada and Western Europe are more wary of the market but may be more receptive to command- and control-type regulation.[91]   Ultimately, however, one needs to look beyond tool choice to determine whether the regulatory change involves what Hall terms a first- or second-order change (changes in instruments and their use) or a third-order change to the regulatory (or, in Hall's work, policy) paradigm.[92]   A shift in a regulatory paradigm is indicative of a change that moves away from or transforms the traditional regulatory path.

Limitations

The strength of comparative research is the window it opens to enable the evaluation of other ways of regulating common problems. It is an important, but complex, methodology to employ because of the requirement that the broader context of political and legal systems and social and cultural norms form part of the analysis. Because of the complexity of the methodology, any comparative work is vulnerable to critiques. Some may suggest that, because of different constitutional frameworks, comparisons between Britain and Canada are untenable. Obviously, the large literature using these countries as comparators belies this point. Some may suggest that more than two jurisdictions are necessary for meaningful comparative work. However, a multiplicity of comparators can upset the delicate balance between breadth and depth of analysis and hence I worked with two jurisdictions. As a final comment, comparative work is both challenging and difficult, and one is often left with as many questions as answers, even after sustained scrutiny of the issues in question. This is how it should be. Diversity and difference are important and render even the best of comparisons imperfect.

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[90] Salamon, "Introduction" *supra* note 56 at 11.
[91] *Ibid.* at 11.

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Others might critique the variables that have been used in this thesis to shape the comparative analysis. These were chosen as a result of some deliberation. It was clear from the extensive literature focusing on health systems policy and regulation in the British context that the NPM and event-driven change were two key variables predicating change, both of which appeared understudied in the Canadian context. An analysis of the health systems in each jurisdiction and the governance systems as they applied to health more generally are central to a comparative and sociology-of-law approach to analysis. If we truly want to understand why governments have responded differently to patient safety, we need to consider patient safety as part of broader sociopolitical and socioeconomic processes in each jurisdiction. All contributions intended to fill a gap within the comparative scholarship of patient-safety regulation should be welcome.

Lastly, it may be said that my methods of critical review and analysis of existing literature (including grey literature), of legislation, and other legal instruments is limited, and the thesis could have benefited from empirical study. This is a valid point. However, the evaluation of literature and legal instruments is both an accepted and important method of enabling critical analysis. It allows for an examination of a broader context. Empirical research methods, on the other hand, may result in more limited projects constrained in part by the logistics of research and the focus and interests of any research participants. Further, I simply point out that any doctoral research project is bounded both by resources (time and monetary) and the competencies of the researcher in question. I freely admit that my competencies in empirical research are limited. The employment of empirical research techniques could shape the design of any future work in this area.

The Argument

I suggest that the regulatory framework that governed patient safety in each jurisdiction was very similar at the beginning of the 1980s (discussed in Chapter 2). This is of course partly attributable to Canada beginning as a colonial possession of Britain, with the resultant importation (at least in English Canada) of the legal frameworks that governed patient safety in Britain at that time. Whatever the genesis of these regulatory frameworks, the

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[92] P.A. Hall, "Policy Paradigms, Social Learning, and the State" (1993) 25:3 Comp. Pol. 275 [Hall].

commonalities are striking. Both were characterized by a dependence upon self-regulation by health professionals and by health-providers. The preference for self-regulation was in itself historically contingent. The provision of health services had traditionally been a matter for the private and charitable sectors and for health professionals acting as entrepreneurs. Under this model, government's interest was limited to ensuring that those providing health services were qualified to do so by meeting basic standards (often established by the health profession) and to ensure that those harmed by the provision of health services had some means of seeking redress. Although attitudes about the role of government in healthcare changed as a consequence of two world wars and a severe economic depression, the regulatory framework around patient safety essentially remained the same – how clinical services were provided was a matter for professionals who had the requisite expertise, knowledge and experience and who should not be second-guessed by government or the courts. It was a risk-management strategy predicated on trust in professionalism and expertise, with an expectation that professionals would be accountable to their fellow professionals, to individual patients, and so to the public. It was a strategy where control was formally delegated by government to other actors.

While the regulatory frameworks around patient safety were markedly similar, at least until the 1980s, I suggest that the first steps leading to divergence in each jurisdiction's regulatory path became apparent when those regulatory frameworks were placed within each jurisdiction's broader governance context. This context includes the structures and institutions within each health system but also how the health system fits into the broader social, economic and political frameworks that shape the governance of public problems across the ambit of state responsibility.[93] I argue that the structures and institutions of the health system are influential factors in setting jurisdictions along different regulatory paths (discussed in Chapter 3). In Britain, the post-World War II government nationalized the existing hospital sector (comprised of private/charitable organizations that provided health services, as well as public services run by local authorities) to create the NHS. In future, the government would fund, plan, manage and operate hospital services. In face of opposition from the medical profession, the government 'encouraged' medical professionals based in

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[93] By 'institutions', I mean organizations and their instruments of social control. By 'structures', I mean the balance of power between actors within the system. See Tuohy, "Logics" *supra* note 35.

hospitals (consultants) to participate by, as Aneurin Bevan, the then Minister of Health, reputedly put it, "stuff[ing] their mouths with gold".[94] Hospital consultants would be paid a salary (including a system of bonuses or distinction awards), but would be able to maintain their lucrative private practices, and they would also play an important and central role in the management structures of the NHS.[95] General practitioners were mollified by keeping their autonomy – they would not become salaried employees of the new order but were to be paid on a capitation basis as independent contractors and their contracts administered by local committees upon which their representatives would sit. Thus a national health system was created where the Ministry of Health funded health services through regional boards that reported to the Minister of Health.

In Canada, it will be seen that events took a different turn. The constitutional division of powers resulted in the provinces/territories being responsible for health policy, but their limited fiscal capacities meant that they were dependent upon the federal government's so-called 'spending power' to fund a major portion of any universal free public health system. This ultimately resulted in the federal government entering into an agreement with the provinces to co-fund provincially based insurance schemes to ensure access to medically necessary health services. Health systems remained firmly rooted in the provinces under provincial administration, only somewhat constrained by the parameters of the agreement with the federal government. While provincial governments would regulate and administer the health system in each province, services would be delivered by non-governmental actors acting as agents of government. It was not until the 1980s that a greater degree of centralisation in administrative practices through processes of regionalization was seen. In addition to the constraints imposed by constitutional arrangements, culture and ideology, as well as pragmatism, may have been important factors in determining the shape of these arrangements. The provincial and federal governments were looking to the creation of the NHS in Britain for inspiration, but were also attuned to the debates in the United States where socialism was, and still is in many quarters, a dirty word, and this attitude shifted across the border.[96] This meant that Canadian governments tended to be somewhat

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[94] Cited in *Oxford Dictionary of National Biography,* online: *Oxford Dictionary of National Biography*
<http://www.oup.com/oxforddnb/info/freeodnb/magazine/health/> [Oxford].
[95] Tuohy, "Logics" *supra* note 35.
[96] See, for example, Tuohy, "Logics" *supra* note 35.

ideologically hybrid – not socialist and not libertarian – concerned, as Kenny described it, "with peace, order and good government"[97] and thus with mediating between socialism and libertarianism. This is perhaps illustrated by a certain pragmatism displayed when organizing provincial health systems when Medicare was introduced. Policy-makers at provincial and federal levels recognized that the system of private provision (for-profit or not-for-profit) of health services worked reasonably well and that the nationalized system in Britain of public delivery had attracted some criticism.[98] A middle way was to create state-supported health insurance funds to ensure universal access to a bundle of 'core' health services.

Thus, the pattern in Canada was to establish health insurance programs that would enable all Canadians to receive free hospital and primary medical-care services. The federal government would partly fund such programs, but its influence in how these programs would be operated and managed would be limited by the terms of its agreement with the provinces/territories. Provincial/territorial governments were in turn responsible for funding, planning and managing health policy. This included determining what services should be provided and ensuring some integration between health services providers to meet the needs of the populations they served. Delivery of hospital-based services was delegated by governments to a variety of for-profit, not-for-profit, or local organizations (there are very few state-owned and -controlled hospitals[99]) and to individual medical professionals.

As in Britain, Canadian governments recognized that the acquiescence of the medical professions was critical to the success of the new health insurance programs. Unlike in Britain, medical professionals were not really divided between hospital-based and non-hospital-based interests, and salaried positions were rare.[100] The continuation of fee-for-service agreements between provinces/territories and medical professionals meant medical professionals remained agents at best, but were not embedded in the same way as in Britain in any local or regional management structure.

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[97] N. Kenny, "The Continental Divide: A Modest Comparison of American and Canadian Values in Healthcare" (2004) 1:2 Org. Ethics 65 at 69 [Kenny].
[98] See, for example, Tuohy, "Logics"*supra* note 35.
[99] Exceptions include, for example, psychiatric facilities.
[100] Tuohy, "Logics" *supra* note 35.

The first critical point of departure between the two jurisdictions in terms of the regulatory path established by the health system was that the British government's responsibilities vis-à-vis the health system were broad, encompassing direct responsibility for funding, planning, management, ownership, and delivery. Thus the extent of their responsibilities within the health system was greater than that of Canadian governments. Although the British government chose the expedient approach of enabling medical power and autonomy to self-regulate professional practice and created a hierarchical system that gave much organizational authority to consultants to self-regulate the practices of the hospitals within which they worked, the public system was still owned, operated and managed by the state. Ultimately, in this system, consultants were state employees. Primary care providers were contracted to the state and embedded within state mechanisms. Thus the nature of the relationship between the state and medical professionals had a very different basis in Britain from what it did in Canada where the operational edifices of the medical profession were not integrated with governmental management structures to any extent. This difference did not manifest in any real differences in the levels of accommodation accorded to medical professionals within each system, at least initially. It did, however, establish conditions within which the state in Britain could, if it chose to do so, exercise greater control through the use of organizational mechanisms over those who provided health services – organizations and individuals. In Canada, the delivery side of the health system was not as firmly integrated into the management side and thus in practice there was less government control and, therefore, in some senses, a less hierarchical structure.

In terms of the broader governance context (discussed in Chapter 4), federalism is, at least to some extent, thought to be a predictor of stability in regulatory frameworks and in approaches to regulation. In contrast, a unitary political system is perceived in many respects to be more responsive to public concerns and therefore more likely to create regulatory patches or fixes to mitigate problems with the original regulatory framework. Constitutions and politics play a role in influencing the level and extent of regulatory change within those systems. It is not just constitutional structures that are important; rather the general social, political, economic and cultural context within which that constitutional structure functions may be even more important as a predictor of change.

I argue that the marked divergence seen from the 1980s in each jurisdiction's regulatory frameworks are attributable to what Tuohy terms "windows of opportunity"[101] that open at certain times and not others because of factors in the broader political system – *and*, I assert, unlike Tuohy, in the health system as well. In the case of patient-safety regulation, I suggest that the "windows" in question in Britain were the commitment of successive British governments to the tenets of the New Public Management (NPM), imposing private sector controls over public sector operations (discussed in Chapter 5), and a series of significant patient-safety scandals that emerged into the public domain, particularly in the late 1990s (discussed in Chapter 6).

The enthusiastic uptake of the NPM theories into the regulatory frameworks by successive governments in Britain saw a transformation in regulatory practices with a focus on clear prospective and retrospective accountabilities and control from the centre exercised by a variety of monitoring bodies.[102] Ideologically, the NPM encapsulated a profound distrust of policy and regulatory actors, suspecting that these bodies were likely to be subject to capture by vested interests.[103] This distrust tipped over into self-regulatory bodies, which were perceived likely to be captured by the self-interest of the professions and hence to act in ways that were not in the government or the public interest. Successive British governments influenced by the NPM entered into a period of intense regulatory activity where risk management and trust deficits combined to produce regulation that was focused on increasing control through the establishment of accountability frameworks. The health sector was decidedly not immune from this regulatory trend.

In the British context, I contend that the number, scope and scale of the scandals in question illustrated the risks, not just of receiving health services, but of self-regulation where self-regulatory actors failed to take appropriate steps to create conditions for prospective or retrospective accountability. This created a trust deficit where traditional institutions of governance were not longer trusted in light of their past failures. The response was to

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[101] *Ibid.*

[102] See, for example, C. Pollitt, "Justification by Works or Faith? Evaluating the New Public Management" (1995) 1:2 Evaluation 133 [Pollitt "Justification"]; Aucoin, *supra* note 39; P. Dunleavy & C. Hood, "From Old Public Administration to New Public Management" (1994) 14:3 Public Money & Management 152 [Dunleavy].

[103] See, for example, Pollitt, "Justification" *ibid.*; Dunleavy, *ibid.*; Aucoin, *supra* note 39.

increase accountability and other control mechanisms and move to meta-regulatory frameworks which provided oversight of key systemic actors, at the same time increasing associational pressure on self-regulatory actors to perform or face losing their authority.

I suggest that similar windows did not open in Canada, so we did not see marked changes to regulatory forms and practices but rather a process of regulatory evolution occurring within the bounds of pre-established norms. The commitment of Canadian governments to the tenets of New Public Management could be characterized as lukewarm at best, and therefore did not fundamentally change the regulatory and governance climate nationally or in the provinces or territories.[104] As I subsequently argue in following chapters, the accountability and control requirements that were a feature of regulatory frameworks in Britain were not imported into the Canadian regulatory landscape to anywhere near the same extent. Canada's systems retained trust in key institutional actors for longer, and the manner in which they began to lose trust in those actors can be attributed more to concerns about access to health services.

Further, there were few patient-safety-related scandals erupting in Canada during this period; and those that did, I argue, were limited in their regulatory impact by geographical or subsystemic[105] factors. There was no generalised loss of trust in existing regulatory actors, with, of course, the notable exception of the Canadian Red Cross.[106] Some regulatory evolution did occur – regulatory structures are not usually static. This evolution was not necessarily led by, although it was generally supported by, government. I argue that the evolutions in regulatory practices and policies occurred as a response to evolution in professional and legal thinking about safety. Professional evolution saw health professionals, health professions and health organizations becoming more concerned about patient safety and the risks associated with the provision of health services. Changes in the manner in which key individuals and organizations viewed patient safety in turn influenced regulatory and policy evolutions to give health professions and organizations the tools to better respond to safety concerns. The approach of government was to work with and support responsible

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[104] Aucoin, *ibid.*

[105] They related to a subsystem within the broader health system and were handled in such a manner to deny or minimize any broader systemic implications.

[106] See discussion in Chapter 6.

professional practices, rather than to impose change from the top. Changes in common law reflecting a desire to enable patient self-determination and level the relationships between health professionals and providers and patients occurred at an earlier stage than in Britain. In summary, I argue that such evolutions in regulatory practices in Canada were very much framed within the existent and accepted regulatory framework.

The Chapters to Come

The following chapters show how I developed this argument. Chapter 2 reviews the pre-1980 regulatory frameworks in each jurisdiction designed to address patient safety, and asserts that both jurisdictions entered the 1980s with broadly similar regulatory frameworks. Chapter 3 focuses on the structure of each jurisdiction's respective health system(s) and each health system's institutions of governance, and examines their features. Chapter 4 examines the differing regulatory contexts in each jurisdiction, in particular the influence of the constituent constitutional structures on processes of regulatory change. Chapter 5 analyzes the nature of post-1980 changes to political norms in each jurisdiction and the implications of these factors for health governance. Chapter 6 analyzes the connections between patient-safety-focused 'scandals' and regulatory change. Chapter 7 re-examines the regulatory frameworks as at 2005 and traces the divergences between the jurisdictions. The final chapter draws together the threads of the argument presented in this thesis. Informed by the exploration of the British and Canadian experiences it offers insights into health governance more generally.

Chapter 2
Off With His Hands: The Development of a Regulatory Consensus Around the Regulation of Patient Safety

Introduction

The first surviving written reference to the legal regulation of health risks dates from 1795–1750 BCE. The Babylonian *Code of Hammurabi* stated: "If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off."[107] The Babylonians were not alone in recommending extreme sanctions against health-providers who erred; Alexander the Great, for example, recommended crucifixion.[108]

The need to regulate the provision of health services is also evident in common law and legislative histories of Britain and Canada, with records that law was employed in the health context dating from shortly after the Norman Conquest.[109] The legal instruments used to regulate risks associated with the provision of health services shifted and changed across the centuries, shaped by historical contexts. With the rise of the nation state, we saw the emergence of much more systematized forms of regulation aimed at dealing with the issues facing societies by increasingly more complex social problems. In Canada and Britain, the state acknowledges responsibilities for regulating the safe provision of health services. The scope of the state's regulatory responsibilities continues to develop, in concert with evolutions in our understandings of the appropriate role of the state and of the nature of health and health services. In Britain and Canada, health regulation has long recognized that public problem-solving in complex areas of practice requires collaboration between many actors.[110] These actors included legislators, employing the state's monopoly over law; health

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[107] L. King, trans., *The Code of Hammurabi*, online: Avalon Project
<http://www.yale.edu/lawweb/avalon/medieval/hamframe.htm>.
[108] J. Duffin, *History of Medicine: A Scandalously Short Introduction* (Toronto: University of Toronto Press, 1999) [Duffin].
[109] See, for example, C. Wood, "Historical Perspectives on Law, Medical Malpractice and the Concept of Negligence" (1993) 11:4 Emerg. Med. Clin. Nth. Am. 819 [Wood]; *Mort's Case* (1374) Y.B. Hill. 48 Edw. III, pl. 11, fol. 6 (1374) [Mort's Case] and A. McCoid, "The Care Required of Medical Practitioners" [McCoid] in T Roady & W. Andersen, eds., *Professional Negligence* (Nashville, Tenn.: Vanderbilt University Press, 1960) 13 [Roady].
[110] The 'new governance' literature has only relatively recently acknowledged that governance and regulation are the province of multiple actors, not just the state.   Salamon, "*Tools*", *supra* note 78; Braithwaite, "*Governance*",

professions and providers, developing codes and standards of professional practice through informal self-regulation; and patients who were engaged with the regulatory process through litigation. As this suggests, regulation in this context has emerged as much from bottom-up processes as it has from top-down ones. It has also developed incrementally.

By the middle of the 20th century, there was a general convergence among most common-law jurisdictions, including Canada and Britain, about the best way and the most appropriate legal tools through which to regulate patient safety in the health system. This chapter describes that convergence. Subsequent chapters assess the context-specific factors in each jurisdiction that led to regulatory divergence by 2005. Characteristic of the regulatory convergence in this area was what Mello et al described as, "an unparalleled faith in the ability of medical professionals [and other health-providers] to regulate themselves."[111] The degree of trust afforded to professional groups, especially the medical profession, was evidenced by the state's willingness to devolve to professional bodies various forms of quasi-legislative authority. It was, however, bounded trust. Externally controlled retrospective accountability mechanisms were also in place.

What is particularly striking in respect of Canada and Britain is that, despite the somewhat flexible dimensions of health regulation, they were closely aligned in their approaches to it at the beginning of the 1980s. In this chapter, I seek to understand the conditions upon which this regulatory convergence was formed. As illustrated in this chapter, there are a number of points of convergence between Canada and Britain, in particular their common legal heritage, their reliance on professional expertise, and knowledge and similar understandings about the appropriate scope of government in social and economic life. However – and crucially for my analysis in subsequent chapters – I also show significant points of divergence in the emergence of their respective regulative frameworks. It is here, in this historical context, that we find the beginnings of fractures in the regulatory convergence that, while seemingly minor before the 1980s, become significant afterwards.

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supra note 24. See also F. McDonald, "Working to Death: The Regulation of Working Hours in Health Care" (2008) 30:1 Law & Pol'y 108 [McDonald "Working to Death"].
[111] Mello, "Fostering Regulation", *supra* note 5 at 375.

This chapter provides an introduction to the events and influences that led to the pre-1980s convergence about how to address patient-safety issues and illustrates the nature of that convergence. Although the consensus was sustained into the latter part of the 20ᵗʰ century, importantly the chapter also foreshadows some divergences that may explain in part why regulatory responses to patient safety in each country in the 1980s and 1990s were so very different in degree and scope – themes that are developed more extensively in later chapters. It also illustrates a central argument of this thesis that changes in governance approaches to patient safety emerge from societal shifts in respect of the state's perception of its governance role, in particular the extent of its responsibilities in relation to health and healthcare. Evolutions in governance are accompanied by social evolutions, and the state is not immune to these developments. In this chapter, I examine the development of the frameworks used to regulate patient safety in each jurisdiction.[112] First, I provide a brief historical overview of regulation in this area. I then analyze the regulatory tools traditionally employed in this area. These include: voluntary self-regulation; the criminal law; tort and contract law; government-sanctioned self-regulation; and direct regulation by the state. These many tools create a framework which responds to and addresses the risks associated with the provision of health services.

Historical Overview

The regulatory framework for the regulation of patient safety developed incrementally over a period of many hundreds of years and was influenced by the shape and structures of the health systems in each country. McDonald notes:

> The health systems that grew and evolved during this period [pre-World War I] in response to the risks associated with illness, disability, trauma and death were relatively simple. The needs of individuals, the entrepreneurship of individual health

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[112] France also had a significant role in colonizing Canada. Although I may touch upon health system-related issues from Québec, the emergence of a patient-safety regulatory framework in Québec is not directly the subject of this thesis. For pragmatic reasons relating to time, space, language and the nature of the legal system (civil law in Québec as opposed to common law elsewhere in Canada), the focus is upon developments in common-law jurisdictions. Developments in Québec are left for others to explore. It is, however, important to note that the role of Québec in Canadian federalism is absolutely essential to understanding how federalism has evolved and operates in Canada, and Québec's role has consequences for how the federal government exercises its powers.

providers, and the charity of organized religions and devout men and women influenced its continuing existence and its shape and purpose. Health systems, such as they were, were only indirectly a concern of the state.[113]

The relationships between patients and health-providers during the pre-World War I period were largely direct and personal, whether it was a commercial or non-commercial interaction, not mediated through a web of complex health services and a multiplicity of providers. For the most part, it was a relationship characterized by some passivity on the part of the patient, who generally accepted whatever the health-provider recommended.[114] This pattern remained largely unchanged until the early to mid-20th century. It was not until the early to mid-1900s that health systems as we understand them today developed. There was increased demand for health services because of significant advances in the processes for diagnosis and treatment, including the increasing development and use of highly complex technologies. Patients became less a passive recipient of treatment and more engaged and involved in decision-making about treatment decisions. These factors, and others, resulted in more complex interactions between the patient, often a multiplicity of health-providers, many of whom provided a specialist service, and health systems.

Initially, the state played a limited role in ensuring the health of its citizens. The state was focused primarily on domestic and international security and matters touching upon trade and commerce. Thus, the early state involvement in patient safety from a legal sense was fairly limited – the regulation of the business of providing health services through the availability of civil proceedings and professional regulation, and ensuring good order through the use of the criminal law. It was not until the late 18th and the 19th century when this perception changed. The state increasingly assumed a role in the regulation of public-health-related issues once science linked problems with the physical environment (e.g. rampant, uncontrolled industrialization, pollution, and increasing urbanization) to poor health outcomes and understood how infections and infectious diseases spread.[115] There was

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[113] F. McDonald, "The Criminalisation of Medical Mistakes in Canada: A Review" (2008) 18 Health L.J. 1 at 5 [McDonald, "Criminalisation"].

[114] T. Szasz & M. Hollender, "A Contribution to the Philosophy of Medicine: The Basic Models of the Doctor-Patient Relationship" (1956) 97:5 Arch. Int. Med. 585.

[115] See, for example L. Gostin, *Public Health Law: Power, Duty, Restraint*, 2nd ed. (Berkeley: University of California Press & Milbank Memorial Fund, 2008) [Gostin].

generally no question that the state should assume responsibility for ensuring its population's access to health services until the First World War and the Great Depression illustrated its necessity.

The emergent legal framework around patient safety reflects, to some extent, these systemic trends, but it also reflects developments in what legal tools were available, necessary and effective. The regulatory tools (civil/criminal law) initially used to regulate patient safety recognize the limited role of the state in this sphere. The tools enabled reparations to be made to those harmed, deterrents created, and justice to be seen to be done, but largely left the question of prospective regulation to those in the best position to make and enforce standards of practice – health-providers (individual and organizational). The health professions, especially medicine, were supported by a grant of state power. These regulatory frameworks were also structured in such a way as to regulate the transaction or interaction between a patient and a health-provider – a simple, one-dimensional relationship. Important, too, was the increasingly central role of the state in governance. Britain moved from an absolute to constitutional monarchy and Canada from a group of semi-autonomous colonies, to a quasi-independent federated dominion to an independent country. Government's central role rendered logical the use of tools of direct regulation, such as legislation regulating health facilities. Direct regulation developed further as a regulatory tool in this area once government formally assumed responsibility for funding and/or delivery of health services (discussed in Chapter 3). Despite the increased tendency to use direct regulation, such regulation was still underpinned by the perception that health professionals and health-providers had a greater knowledge, expertise and experience and could be trusted to act in the public interest.

Criminal Law

There are a number of models assigning hierarchies in regulation, including a model of ascending hierarchies of coercion.[116] In this hierarchy, the criminal law sits at the apex of the regulatory triangle as the ultimate form of regulatory coercion. The criminal law is central to

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[116] N. Gunningham & P. Grabosky, *Smart Regulation: Designing Environmental Policy* (Oxford: Clarendon and Oxford University Press 1998) [Gunningham]; Braithwaite, "*Governance*", supra note 24.

the internal security of states, and effective criminal justice systems are essential to good governance.[117] Fleming notes that criminal law (and tort law) stem from "a common desire for vengeance and deterrence …"[118] The criminal law is the penultimate symbol of societal condemnation of an act or practice, as it generally comprises offences that are *mala in se* ('evil in itself') and which therefore incorporates moral denunciation of the act and punishment of the offender. Criminal law has a constitutive function, too, as criminal prosecutions contribute to the development of standards of practice and conduct for individuals and, in this context, for professions.

The criminal law has a long history as a regulatory tool in respect of patient safety. The Babylonian *Code of Hammurabi* discussed in the introduction is evidence of that. But the common law, too, has a long history of using criminal law in this context, albeit relatively rarely. The criminal law regulated patient safety when alleged negligence in a health professional's practice resulted in the death or grievous injury of a patient.[119] Criminal law was, and is, also used in a patient-safety context where a health professional deliberately and intentionally intends to harm a patient. Examples of this include patients who are deliberately murdered (e.g. by serial killers or in the context of so-called 'mercy killing'); sexually abused; and physically and/or psychologically abused (e.g. beatings, torture, etc.).[120]

For many hundreds of years, the common law had a general law of wrongs that provided vengeance, deterrence, and compensation.[121] Early law did not distinguish intentional murder from accidental killing; if the actions of the individual caused the death of the person, that was sufficient. It also did not distinguish between criminal acts and tortious ones. It

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[117] J Baker, *An Introduction to English Legal History,* (London: Butterworths, 1971) [Baker, "*Legal History*"].

[118] J. Fleming, *An Introduction to the Law of Torts,* (Oxford: Clarendon Press, 1985) at 1 [Fleming, "*Law of Torts*"].

[119] See, for example, McDonald, "Criminalisation", *supra* note 113; R Ferner & S. McDowell, "Doctors Charged with Manslaughter in the Course of Medical Practice, 1795-2005: A Literature Review" (2006) 99:6 J. R. Soc. Med. 309 [Ferner]; P. Skegg, "Criminal Prosecutions of Negligent Health Professionals: The New Zealand Experience" (1998) 6 Med L. Rev. 220 [Skegg]; A. McCall Smith, "Criminal or Merely Human?: The Prosecution of Negligent Doctors" (1995) 12 J. Contemp. Health L. & Pol'y 131 [McCall Smith "Criminal"]; A. McCall Smith, "Criminal Negligence and the Incompetent Doctor" (1993) 1 Med. L. Rev. 336 [McCall Smith, "Negligence"].

[120] The other health-related foci of the criminal law have a less proximate connection to patient safety. For many years, the law criminalized the provision of abortions primarily for moral reasons. Criminal law is used in respect of health professionals (especially doctors) who traffic prescription drugs in the course of their professional practice. Criminal charges may be laid against doctors, and other health professionals, who allegedly have committed fraud in respect of their claiming practices.

[121] Baker, "*Legal History*", *supra* note 117 at 1.

was not until the 1500s that 'murder' came to denote malicious or premeditated killing and 'manslaughter' was used to denote killing without malice but in circumstances amounting to a felony.[122]

Case reporting from the early period in common-law history is sparse; hence, identification of cases where health-providers faced what we would consider criminal proceedings is not easy, but records show an example dating back to the 14th century.[123] It was such an established part of the criminal law that by 1660, Christopher Merrett (a fellow and historian of the College of Physicians) could write: "If one who is no physician or surgeon (or who is not allowed to use or practice such faculty) will take a cure upon him, and his patient dieth under his hand, this has been holden to be a felony."[124] The criminal law permitted criminal proceedings against health professionals, and such charges were indeed laid, albeit rarely.

British courts increasingly recognized that criminal convictions were not appropriate in every instance where a patient died after treatment or care by a health-provider. By the mid-19th century, the courts acknowledged that health-providers were "not immune to human error".[125] Judges directed juries to convict the accused of criminal charges *only* if the provider owed a duty of care to the injured party and had acted with a gross want of skill and care.[126] In other words, the courts concluded that the criminal law should only be used for the most serious of circumstances in which a patient died, where the conduct in question amounted to a gross departure from expected professional standards. In an 1862 case, the judge said:

> Every medical man was of course liable to make a mistake, and he would not be criminally responsible for the consequences if it should appear that he had exercised reasonable skill and caution, and it was only in the case where a medical man, as he had

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[122] Baker, "*Legal History*", *supra* note 117.

[123] O. Quick, "Prosecuting 'Gross' Medical Negligence: Manslaughter, Discretion and the Crown Prosecution Service" (2006) 33:3 J. Law & Soc 421 [Quick, "Prosecuting"].

[124] Quoted in H. Cook, *The Regulation of Medical Practice in London under the Stuarts 1604-1704* (PhD. Thesis, University of Michigan, 1981) [unpublished] at 185 [Cook].

[125] Ferner, *supra* note 119 at 313.

[126] Central Criminal Court, April 10, *The Times* 11 April 1862: 10.

before stated, was guilty of gross negligence, or evinced a gross want of knowledge of his profession, that he could be held criminally responsible.[127]

The courts adopted a pragmatic approach in criminal cases involving doctors and other health-providers, recognising the public interest in doctors and other health-providers continuing to provide health services. The courts also implicitly recognized the risks associated with the provision of health services. Implicitly, the courts acknowledged – to quote Kenny and Giacomini slightly out of context – that "moral quandaries arise not in the question of *whether* to harm or benefit but *how* to harm *and* benefit: whom, how much, how certainly, in what ways, and so forth".[128] Hence, the courts concluded that the ultimate sanction of the state – the use of the criminal law – should be used judiciously in the public interest. They came to recognize that the inherent risks associated with the provision of health services were generally outweighed by the benefits, and that there was a public interest in generally limiting the extent to which law imposed disincentives on the provision of health services.

In 1925, the English Court of Appeal clarified the standard for gross negligence in the *Bateman* case stating that, to be convicted, the defendant's negligence must be "so gross that it showed such a disregard for the life and safety of others as to amount to a crime against the state and conduct deserving punishment."[129] The court took pains to clarify that it must be more than a mere mistake that renders a health-provider liable for conviction for a criminal offence such as manslaughter. Until the passing of the *Criminal Code of Canada*[130] (the *Code*), the common law applied in Canada, and health professionals could face charges of manslaughter for gross negligence in their practice. The *Code* was subsequently amended to create a specific offence of criminal negligence causing death or criminal negligence causing grievous bodily harm, the former replacing negligent manslaughter. Despite this change to the name of the offence, the standard to be applied in each jurisdiction was and is gross negligence.[131]

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[127] *Ibid.*
[128] N. Kenny & M. Giacomini, "Wanted: A New Ethics Field for Health Policy Analysis" (2005) 13:4 Health Care Analysis 247 at 254 (original emphasis) [Kenny & Giacomini].
[129] *R. v. Bateman* (1925) 19 Cr App R. 8.
[130] *Criminal Code,* R.S.C. 1985, c. C-46 [*Criminal Code*].
[131] McDonald, "Criminalisation", *supra* note 113.

While in Canada and Britain the criminal law could be used to sanction the conduct of erring health professionals, it is also evident that it was seldom used. Recent research indicates that authorities in Britain charged approximately 43 doctors with manslaughter due to alleged errors between 1795 and 1980 (a 185-year period) and at least eleven pled guilty or were convicted.[132] Many of the cases occurred in the 19th century and were connected to obstetrics; childbirth was increasingly medicalized at this time and involved the use of new technologies, such as forceps.[133] Only one charge was laid between 1935 and 1980.[134] In Canada, there is no record of a doctor facing criminal charges before 1935 (although this does not mean to say that such charges were not laid), and it seems only six doctors faced charges of manslaughter, criminal negligence causing death, or criminal negligence causing grievous bodily harm, from 1935 to 1980.[135] While there were three convictions during this period, none were sustained on appeal.[136]

In both Canada and Britain, the criminal law has had limited use in this context. Although used rarely, it was available in the regulatory arsenal in 1980 – the ultimate sanction for professionals who erred and thus the ultimate accountability tool. The criminal law was firmly ensconced as forming one – perhaps, given usage patterns, relatively minor – element of the regulatory framework to address patient-safety issues.

Civil Proceedings

Arguably less coercive than the criminal law is what Viscusi terms "regulation by litigation."[137] Although Viscusi tends to use this term in the context of deliberate attempts by the state to use the threat of civil proceedings to change corporate behaviour, the label is, I argue, also applicable when individuals bring civil proceedings against health professionals and providers.[138] While civil proceedings are designed to provide successful claimants with

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[132] Ferner, *supra* note 119.
[133] *Ibid.*
[134] *Ibid.*
[135] McDonald, "Criminalisation", *supra* note 113.
[136] *Ibid.*
[137] W. Viscusi, "Overview" in W. Viscusi, ed., *Regulation Through Litigation* (Washington: AEI-Brookings Joint Center for Regulatory Studies, 2002) [Viscusi].
[138] McDonald, "Working to Death" *supra* note 110.

compensation for harm and provide a form of accountability and hence justice of sorts, increasingly, at least in theory, it is also suggested that civil proceedings have a prospective or regulatory function.[139] Civil proceedings are said to create incentives, economic and otherwise, for those committing 'wrongs' (and hopefully their colleagues) to create risk-management systems to prevent future harms.[140] Certainly, current research suggests that many claimants bring legal proceedings, at least in part, to invoke the prospective element of successful litigation – they seek systems change to ensure what happened to them happens to no-one else.[141] However, in actuality, claims about litigation's prospective effect are strongly contested, with some researchers suggesting that there is little evidence to support such claims.[142]

Civil proceedings brought by individual claimants are a bottom-up form of regulation. Although the state enables this regulatory mechanism, if nothing else by the operation of the legal system, it is impotent unless aggrieved persons bring proceedings. Use of civil proceedings for patient-safety-related purposes has a long history. As discussed in the previous section, civil and criminal law proceedings were intertwined until around the 1700s,[143] but the difference became that civil proceedings provided redress to individuals and criminal law was concerned with public order and punishment.

Initially, claimants could bring an action, such as trespass, seeking a private remedy for wrongs.[144] Trespass against the person addressed nearly every wrongful act, whether criminal or tortious in nature, that impacted upon the person forcibly and directly. Trespass on the case included harms resulting from carelessness or arising indirectly, including performing carelessly a task undertaken with consent.[145] It involved a lack of force because of the prior consensual relationship or because the act caused indirect harm to the plaintiff.

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[139] M. Madden, "Tort Law Through Time and Culture" in M. Madden, ed., *Exploring Tort Law* (Cambridge: Cambridge University Press, 2005) [Madden].

[140] See discussion in McDonald, "Working to Death" *supra* note 110.

[141] *Ibid.*.

[142] See, for example, M. Mello & T. Brennan, "Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform" (2002) 80 U.Tex. L. Rev. 1595 [Mello & Brennan]. See also Mello, "Fostering Regulation" *supra* note 5.

[143] The distinction between criminal law and civil remedies became important when responsibility for punitive processes passed from communities to local or national entities and so financial penalties were forfeited to authorities rather than being of benefit to the family. Baker, "*Legal History*", *supra* note 117.

[144] *Ibid.*

In all of the early cases involving 'negligent' acts, there was a pre-existing relationship between the parties.[146] The person who caused the harm was responsible, not for doing the act but for doing it carelessly. The degree of fault only became relevant as part of a defence of accident, and even then the defendant would have to establish the extent to which the accident was preventable.[147] The common law imposed duties upon those who were in a 'common calling', including physicians, surgeons, and apothecaries, but also common carriers and inn-keepers – based, some think, on the concept of deceit.[148] The nature of these callings meant that there had to be a degree of pre-existing relationship between the parties in order that services are provided. Doctors (or the closest equivalent) were considered to be a common calling, as they claimed to serve the public, in this case by providing a specialized and skilled service. If, in the course of one's interaction with a doctor, there was no skill (manual dexterity, knowledge, and training), or a lack of care, then there was a breach of the representation that the person was skilled at their trade.[149] However, because the person caused the damage by performing negligently a service which they were paid to perform with care, they could also be sued for breach of contract.[150]

The first recorded mention of the liability of a health-provider for an action on the case i.e. a civil action, dates from 1290 and involved a doctor.[151] In 1374, J. Mort, a surgeon, undertook to heal his patient's hand, but instead, it was alleged, acted with a lack of care and skill so as to maim it.[152] The court dismissed the case on a technicality but noted that if the surgeon had done as well as he was able and had employed all diligence in ministering to the patient, then "it is not right that he should be held culpable."[153] Another case, also from 1374, laid the ground for claims in contract. The courts examined the quality of the services performed pursuant to the surgeon's duties under the contract and decided that if there was due diligence, there should be no liability.[154] In 1436, Newton stated: "So if a doctor takes upon himself to cure me of my disease and he gives me medicine, but does not cure me, I

[145] *Ibid.*
[146] *Ibid.*
[147] *Ibid.*
[148] N. Arterburn, "The Origin and First Text of Public Callings" (1927) 75 U. Pa. L. Rev. 411 [Arterburn].
[149] *Ibid.*, and see Roady, *supra* note 109.
[150] Baker, "*Legal History*", *supra* note 117.
[151] Wood, *supra* note 109 at 823.
[152] *Mort's Case, supra* note 109, and McCoid, *supra* note 109 at 14.
[153] *Mort's Case, ibid.* and McCoid, *ibid.*

shall have an action on my case."[155]   Later cases also focused on remedying injuries caused by ignorance and lack of skill by a person purporting to be qualified.[156]   However, there were not many of these cases (at least as far as can be told from the records) until later in this period.   Those cases that were brought, not surprisingly, focused on injuries rather than illness or disease, as effective treatments for illness were some centuries away whereas surgery, although primitive by modern standards, could be efficacious.   Winfield suggests that there were few cases because it was not until later that the professions attained social dignity by measures taken to eliminate "quacks and swindlers" and therefore it became worth suing them.[157]   It may have also been that simply being able to access health services was important, and death and illness was more common so people were less likely to sue.   It was also difficult to bring proceedings to a court (due to the confusing writ system).[158]

There is some disagreement about when the general law of negligence began to emerge.   The classic account is that of Winfield, who dates negligence from 1825 onwards.[159] But others consider that the segregation of the law of torts from other areas of law began to occur from around 1720.[160]   Some associate the creation of negligence with theorists' categorizing law and divining rules for each area of law, some with universal application.[161]   Still others suggest that the establishment of negligence was associated with the dominance of certain philosophical perspectives, most notably liberal individualism.   They note that negligence rests on an individual's choice to pursue a particular course of action and that individual's responsibility for the consequences of wrongful choices.[162]   Irrespective of why it developed, there is general acceptance that the advent of a tort of negligence had a strong association with the industrial revolution.[163]   The late 18th century and 19th century saw the proliferation

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[154] *Stratton v. Swanlone* (1374), Y.B. Hill. 48 Edw. III, fol. 6 [*Stratton*].

[155] *Trespass* (1436) YB 14 H vi, f. 18, pl.58 [*Trespass*].

[156] See, for example, *Slater v. Baker* (1767), 2 Wils. 359, 95 E.R. 860 (K.B.) [*Slater*].

[157] P. Winfield, "The History of Negligence in Torts" (1926) 42 L.Q. Rev. 184 at 187 [Winfield "History"].

[158] Baker, "*Legal History*", *supra* note 117.

[159] Winfield, "History" *supra* note 157.

[160] P. Winfield, *The Province of the Law of Tort* (Cambridge: Cambridge University Press, 1931) [Winfield, "*Tort*"]; also see discussion in J. Conaghan & W. Mansell, *The Wrongs of Tort,* (London & Boulder, Col.: Pluto Press, 1993) at 70 [Conaghan].

[161] See discussion in Conaghan, *ibid.*

[162] *Ibid.*

[163] See, for example, Winfield, "*Tort*", *supra* note 160; Conaghan, *supra* note 160.

of causes of action and special duties of care, but a general duty of care was not formulated until the beginning of the 20th century.

In 1615, Sir Edward Coke discussed the negligent provision of health services, noting "the law gives the party sufficient remedy to recover … for default of performance, or for negligence in the performance."[164] By the late 1700s, legal scholars explicitly recognized a special category of law that related to health-providers. In 1768, Blackstone linked the concept of professional malpractice to physicians and included under the title *mala praxis* (malpractice) "injuries … by the neglect or unskilful management of physician, surgeon or apothecary … because it breaks the trust which the party had placed in his physician and tends to the patients destruction."[165]

Although a cause of action against individual health-providers had been identified as early as 1298 in English law, it was not until the 1700s and 1800s that a broader category of negligence emerged, which also had application to the manufacturers of medications and medical devices, and institutions that provided health services. Again, it is noticeable that the evolution in the law reflected and addressed the greater complexities of an industrializing society.

With regard to hospitals and institutional liability, it was by no means clear until well into the 20th century the extent of a facility's liability in tort for negligent acts.[166] In the mid-1800s in Britain, hospitals were exempt from tort liability because the courts initially believed that charitable operations deserved immunity, a position never adopted by Canadian courts.[167] There were a number of reasons postulated for this immunity, all essentially coming back to the fact that in a society where voluntary societies provided the majority of social services for the poor, some protections on their activities were required to ensure continued provision of

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[164] 80 E.R. 1164 (1625) quoted in Wood, *supra* note 109.

[165] W. Blackstone, *Commentaries on the Laws of Britain,* vol. 3 (Oxford: Clarendon Press, 1768) at 122 [Blackstone].

[166] See, for example, E. Picard & G. Robertson, *Legal Liability of Doctors and Hospitals in Canada* 3rd ed. (Scarsborough, Ont.: Carswell 1996) [Picard & Robertson].

[167] See discussion in J. Fleming, "Developments in the English Law of Medical Liability" [Fleming, "Developments"] in Roady, *supra* note 109 at 97 in respect of the English position, and in *Christian Brothers of Ireland in Canada (Re)* [2000] O.J. No. 117 (QL) [*Christian Brothers*].

services (provision which incurred no costs to the state).[168] However, by 1866, the House of Lords had abandoned this idea as being unsatisfactory and determined that liability should as a matter of consistency rest with a charity for harms caused by its negligence or the negligence of its employees, either directly or vicariously.[169] What remained uncertain in both countries was the extent of a facility's responsibility for negligence in respect of professional, as distinct from administrative, duties. In both countries, a facility had a general duty to ensure that professional employees were qualified and competent, but otherwise had no responsibility for negligent acts.[170] This changed in Canada from the 1930s when hospitals became liable for actions of employees, even if they were professionals and acting in a professional capacity.[171] The process of change also commenced in Britain in 1942.[172]

Governments paid scant attention to medicines, despite governments, health professions, and the general public regularly expressing concerns about the quality and effectiveness of such products. The common law provided some limited redress throughout the 19th century; however, its ability to deter future conduct remained limited. If an apothecary or pharmacist prepared the medication as a person in a common calling, there was a specific duty of care and thus redress through the tort of negligence. Patent medications were always popular with the public, and an increasingly corporatized society saw an increase in manufacture of so-called 'medicines' in the 1800s. This increase, and corporatization and industrialization more generally, raised questions as to whether manufacturers of products, including medications, owed a direct duty of care to users of those products. A person who purchased a medication and suffered harm could sue the seller in contract, alleging a breach of the general contractual terms that the goods were warranted for safe use. In turn, the seller could sue the manufacturer for a contractual breach.[173] The purchaser could not directly sue the manufacturer. Additionally, if a person purchased a medication for the use of another person who sustained harm, there could be no redress as in tort law there was no general

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[168] See discussion in *Christian Brothers, ibid.*
[169] Fleming, "Developments" *supra* note 167 in Roady, *supra* note 109 at 97.
[170] Picard & Robertson, *supra* note 166 and Fleming, "Developments" *supra* note 167 in Roady, *supra* note 109 at 97.
[171] See discussion in Picard & Robertson, *supra* note 166.
[172] Fleming, "Developments" *supra* note 167 in Roady, *supra* note 109 at 97.

duty of care and that person was not the party to the contract.[174] The common law's stance on product-related issues reflected the political values of the time; some argue that prior to the 20th century, the common law protected the interests of manufacturers, who were considered vital to the growing economy, by not imposing liability for products.[175] By the late 19th century, however, the manufacturing sector was developed and producing significant amounts of consumer goods, encouraging society to demand more-effective consumer protection, a demand met by the courts.[176] In 1932, the House of Lords in *Donoghue v. Stevenson* clarified the law by creating a general duty of care.[177] Lord Atkin affirmed the proposition that:

> A manufacturer of products, … with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.[178]

In Britain and in Canada, the doctrines of direct and vicarious liability in respect of the negligence of facilities providing health services continued to expand. Lord Denning attributed the British expansion to the development of the NHS.[179] It also aligned closely with developments in employment law and the continued evolution in the conduct of commercial affairs both of which came to recognize the necessity of flexibility in employment-type relationships.[180]

Once the general duty of care in negligence was established, proceedings in negligence increased markedly, including in relation to patient-safety issues. In the decades following World War II, there was a gradual increase in the numbers of such proceedings in both

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[173] See, for example, A. Linden, L. Klar & B. Feldthusen, *Canadian Tort Law: Cases, Notes & Materials* 12th ed. (Toronto: Butterworths, 2004) [Linden].

[174] See, for example, R. Martin, "Categories of Negligence and Duties of Care: Caparo in the House of Lords" (1990) 53:6 Mod. L. Rev. 824 [Martin].

[175] Conaghan, *supra* note 160.

[176] *Ibid.*

[177] *Donoghue v. Stevenson* [1932] A.C. 562 (H.L.) [*Donoghue*].

[178] *Ibid.* at 580.

[179] Fleming, "Developments" *supra* note 167 in Roady, *supra* note 109 at 97.

[180] *Ibid.*

countries.[181] In Britain, the Royal Commission on Civil Liability and Personal Injury estimated that by 1978 there were an estimated 500 claims against the NHS annually.[182] There were broadly comparable rates of increase in such proceedings between Britain and Canada,[183] such that by the 1980s there was talk internationally of a malpractice 'crisis'. Generally, the 'crisis' did not seem to be framed as a patient-safety issue, rather as a financial issue for doctors and insurance companies concerned about cost increases. The focus of attention was how civil proceedings, insurance, and related matters should be organized to enable economic efficiency and the continued provision of health services.[184]

A schism developed between the jurisdictions in terms of the approaches to standards of care, clearly having little effect on the relative rates of claims for negligence in each jurisdiction. In Britain, the Bolam test indicated that the standard of care is established by determining whether a body of similarly skilled health-providers is practising consistently with the conduct in question.[185] Deferring to the medical profession in particular, the courts in Britain did not (at least until very recently) consider whether the risks associated with that practice were reasonable, as the courts considered that they lacked expertise in determining whether one therapeutic approach was better than another.[186] There was also a presumption that doctors acted in the best interests of their patients and in accordance with the spirit of a profession that emphasized excellence.[187] No lesser authority than Lord Woolf suggested that in comparison with other common-law countries, like Canada and Australia, the legal system in Britain during this period was excessively deferential to the interests of the medical profession.[188] The court's deference to professional judgements, particularly that of doctors, continued when the court considered what information was required to be provided to a

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[181] V. Harpwood, *Medicine, Malpractice and Misapprehensions,* (Abington: Routledge Cavendish, 2007) [Harpwood] and D. Dewees, M. Trebilcock, & P. Coyte, "The Medical Malpractice Crisis: A Comparative Empirical Perspective" (1991) 54:1 Law & Contemp. Probs. 217 [Dewees].

[182] Harpwood, *ibid.*

[183] Dewees, *supra* note 181.

[184] See, for example, Harpwood, *supra* note 181; Dewees, *supra* note 181.

[185] *Bolam v. Friern Hospital Management Committee* (1957) 1 WLR 583 (H.L.) [*Bolam*].

[186] H. Woolf, "Are the Courts Excessively Deferential to the Medical Profession?" (2001) 9:1 Med. L. Rev. 1 [Woolf].

[187] *Ibid.*

[188] *Ibid.*

patient to enable consent. Lord Woolf described the court's approach as "patients are entitled to know only what their doctor thinks they should."[189]

The courts in Canada were not similarly deferential. In the early 1950s, Canadian courts recognized that there were occasions when an accepted standard of practice could be negligent. This would occur when those practices were fraught with risks – risks that could readily be determined and judged unreasonable by lay people.[190] Justice Coyne stated that if the Bolam approach was followed in Canada, health professionals, "could legislate themselves out of liability for negligence to the public by adopting or continuing what was an obviously negligent practice."[191] In 1980, Canada also departed from the common-law norm when the Supreme Court of Canada recognized the doctrine of informed consent.[192] The Canadian Supreme Court applied a modified objective test to determine what information should be provided to patients.[193] While the differences in approaches are conceptually interesting and important from a patient-rights perspective, in regulatory terms it appears that the different approaches made no real difference, as claim rates for negligence remained comparable between jurisdictions (as set out above).[194]

The risk-management strategy inherent in the tort of negligence evolved in the 20th century beyond harms associated with how health services were provided to include the information that was provided to the patient so that the patient could assess risk and agree or disagree with the proposed action – the doctrine of informed consent. Although the emergence of informed consent was linked with moral imperatives associated with autonomy and self-determination,[195] informed consent can also be seen as a risk-management strategy for patients and for health professionals and providers.[196] As Lantos bluntly puts it:

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[189] *Ibid.*

[190] *Anderson v. Chesney* (1949) 4 D.L.R. 71 (Man. C.A.) affirmed in (1950) 4 D.L.R. 223 (S.C.C.) [*Anderson*].

[191] *Ibid.*

[192] *Reibl v. Hughes* (1980) 114 D.L.R. (3d) 1 [*Reibl*].

[193] The plaintiff must establish that if the health professional had disclosed information, a reasonable patient in the position of the plaintiff would have declined the procedure.

[194] In relation to informed consent, see also G. Robertson, "Informed Consent Ten Years Later: The Impact of *Reibl v. Hughes*" (1991) 70:3 Can. Bar. Rev. 423 [Robertson].

[195] See, for example, R. Faden & T. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1981) [Faden].

[196] See, for example, J. Lantos, "Informed Consent: The Whole Truth for Patients?" (1993) 72:9 Cancer 2811.

because the legal doctrine of informed consent was first codified in the context of malpractice suits, there is a defensive-medicine approach to much of the discussion of informed consent in the clinical context … we tell patients the risks of treatments in order to prevent them from suing us … Informed consent forms become waivers of liability … Obtaining informed consent can be seen as a pre-emptive legal strike in an essentially hostile relationship between doctor and patient.[197]

In both jurisdictions, civil litigation, especially negligence claims, were – and are – a central component of the regulatory framework around patient safety.

Voluntary Self-Regulation

Using an ascending hierarchy of coercion model of regulation,[198] the bottom layer of the hierarchy is voluntary self-regulation, which relies on individuals, organizations or associations to voluntarily self-regulate with no active state involvement (direct or indirect).[199] Until the 19th and 20th centuries, it was a primary mode of regulating patient safety. The basis of self-regulation is the perception that individuals or organizations may be best placed to regulate performance and conduct because they have the knowledge and expertise to do so. It may equally be the case that the state, for some reason or another, does not see the social imperative to regulate or is simply unable to. Certainly, prior to the 19th and 20th centuries in both jurisdictions there were more pressing concerns for governments than the regulation of patient safety.

Relying on individuals and organizations to voluntarily self-regulate is highly tenable when the regulators are assumed, to quote Kagan and Scholz, to be "responsible political actors",[200] or Braithwaite "virtuous" actors.[201] Given that providers of hospital services, until about the 19th century, were overwhelmingly religious and/or charitable in nature, it would have seemed at the time a reasonable assumption that these providers were indeed both responsible and virtuous enough to self-regulate risks to patients (as much as it was possible

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[197] *Ibid.* at 2813.
[198] Gunningham, *supra* note 116; Braithwaite, "*Governance*", *supra* note 24.
[199] J. Black, "Constitutionalising Self-Regulation" (1996) 59:1 Mod. L. Rev. 24.
[200] McDonald, "Working to Death" *supra* note 110.

to do so given the knowledge and practices at that time). The emergence of private-for-profit hospital services in the 19th century seemed, in Britain in particular, to bring with it a number of scandals, a lessening of the reliance on voluntary self-regulation, and a greater employment by the state of command and control regulation to create minimum standards.[202]

Until the 15th to 16th centuries, individual providers of health services were less homogenous – some were from religious backgrounds, some had begun to make claims to expertise based on science, some drew upon traditional knowledge, and others were no doubt charlatans. Those from religious backgrounds could generally be assumed by the state to be 'virtuous' (although undoubtedly there was the odd bad apple) and also to be subject to some oversight by the religious hierarchy to which they belonged. In respect of the others, for the most part that their vocation was to heal, or at least to care for the sick, could have been enough at that time for authorities to assume beneficent intent.

For some occupational groups, notably medicine, claims to virtue were bolstered by external developments.[203] The 12th century saw the resurgence of the classical practice of medicine with the reopening of the universities and the availability of Greek, Roman and Muslim works on healing. Despite this, there remained few (successful) treatments, with the primary expectations of a health professional being to diagnose and predict the outcome of an illness and to provide some alleviation of suffering.[204] But the resurgence of classical medicine led to stratification of health-providers on the basis of their learning. Those unable to make claims to learning and science were increasingly marginalized as the centuries passed. In 12th century Europe, some formal standards for training and apprenticeship in the practice of medicine were developed.[205] Such standards were slower to develop in Britain, partly because it took longer for the new knowledge to travel across the Channel from Europe, and partly because Britain lacked mechanisms through which the formation of professional associations could be supported (see the discussion of chartering below). Both standards

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[201] *Ibid.*
[202] See subsequent discussion in the direct regulation section of this chapter.
[203] In a reflection of the times, these were almost exclusively male dominated.
[204] Duffin, *supra* note 108.
[205] K. Park, "Medicine and Society in Medieval Europe 500-1500" in A. Wear, ed., *Medicine in Society: Historical Essays* (Cambridge: Cambridge University Press, 1992) 59 at 70 [Park]; Duffin, *ibid.*

and professional associations did, eventually, develop. For many professions, voluntary self-regulation continued to be the norm, although the privilege of government-sanctioned self-regulation was eagerly sought by many groups.

In North America, accreditation was a key part of voluntary self-regulation of hospitals. Accreditation was initially driven by the health professions, led by the American College of Surgeons, which, in 1917, developed a hospital standardization program. In 1951 the Joint Commission on Accreditation of Hospitals was created by a number of actors, including the Canadian Medical Association, to provide voluntary independent accreditation of hospitals. In 1953 a Canadian organization, the Canadian Commission on Hospital Accreditation, performing the same functions as the Joint Commission was formed by the Canadian Hospital Association, the Canadian Medical Association, the Royal College of Physicians and Surgeons and l'Association des médecins de langue française du Canada.[206] Hospitals could voluntarily choose to seek accreditation to provide an indication to the public that the facilities and services provided complied with established standards. Accreditation grew in Canada from 1960 when there were less than 350 accredited facilities to 850 by 1980.[207] Conversely, accreditation did not play a role in respect of regulating British hospitals until the early 1980s.

Government-Sanctioned Self-Regulation

Government-sanctioned self-regulation occurs when government delegates regulatory powers to professions to self-govern. Some have described this conferral of powers as creating almost a "'state within the modern state' with either acquired or invested sovereignty."[208] There were, of course, limits to that sovereignty, as government also constrained the "character and extent" of that power.[209] The relationship between the state and the professions has been characterized as a form of social contract. In 1975, the British Committee of Inquiry into the Regulation of the Medical Profession described it as:

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[206] L. Bohigas *et al.,* "Accreditation Programs for Hospitals: Funding and Operation" (1996) 8:6 Int'l J. Quality & Safety in Health Care 583.

[207] Accreditation Canada, "History" [Accreditation], online: Accreditation Canada <http://www.accreditation.ca/about-us/history>.

[208] G. Larkin, "Medical Dominance in Britain: Image and Historical Reality" (1988) 66: Suppl 2 Milbank Q. 117 at 118.

A contract between the public and the profession, by which the public go to the profession for medical treatment because the profession has made sure it will provide satisfactory treatment. Such a contract has the characteristic of all freely made contracts – mutual advantage.[210]

As Stacey noted, there is a form of public accountability inherent in this characterization of the relationship – a collective accountability of the profession for ensuring professionals practise appropriately.[211]

From the 13th century, the state recognized the economic necessity of creating mechanisms to establish public or private corporations and to define their privileges and purpose.[212] In Britain, the granting of a Royal Charter was the only way, until the industrial revolution, to incorporate a company. Chartering enabled government to regulate and hence to control, to some degree, the internal functions and operations of the chartered corporation. The Crown, as advised by the Royal Council (Privy Council), had to approve all changes to the corporation's charter, and thus to its purpose and functions.[213] A charter was not an operational necessity, but conveyed "pre-eminence, stability and permanence".[214] Being chartered was recognition by the state or another government actor, e.g. the City of London, that the association of individuals seeking chartered status had a recognized and accepted position in society – that to some extent their operations had the trust of government – affording it some legitimacy. That legitimacy was only bolstered if the organization had internal rules. Henry VIII granted Royal Charters to a number of hospitals, starting in 1547 with Bethlem and St Bartholomew's.[215] Charters were the primary tool used by the Crown to

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[209] *Ibid.* at 120.

[210] U.K., Committee of Inquiry into the Regulation of the Medical Profession, *Report of the Committee of Inquiry into the Regulation of the Medical Profession,* (Cmnd 6018) (London: HMSO, 1975) 3 [Committee of Inquiry, "*Regulation*"].

[211] M. Stacey, "The General Medical Council and Professional Accountability" (1989) 4:1 Public Policy and Administration 12 [Stacey, "Medical Council"].

[212] U.K., Privy Council Office, "Royal Charter" online: Privy Council Office <http://www.privy-council.org.uk/output/page26.asp> [U.K. Privy Council Office].

[213] *Ibid.*

[214] *Ibid.*

[215] *Ibid.*

regulate the purpose, and to some extent the practice, of hospitals, until 1572 when direct regulation was used to create corporations.[216]

In Britain, medical practice was first indirectly sanctioned by government through the conferral of guild status to associations of doctors by the City of London. Guild masters were accountable, at least in theory, to both city officials and to their members.[217] Medical guilds actively instituted measures to improve medical practice and to provide safeguards against risk, at least within London. The guilds did this by controlling entrance, setting fair fees, regulating medical activities, and punishing malpractices.[218] For example, the 1423 rules for the short-lived Guild of Physicians and Surgeons state that physicians and surgeons cannot accept cases that are "desperate or deadly" or where they may result in "death or maiming" without prior consultation with specially appointed peers.[219] So for members of that guild, high-risk cases were subject to a mandatory second opinion. This process offered protection for the patient against unskilled care, and for the professional and the profession protection against allegations that a cure should have been possible. Cosman notes that the available evidence suggests that this process lowered the number of malpractice suits and was "a successful modality for the control of malpractice."[220] However, these rules did not survive for many years, probably because members feared losing patients and looking inferior before their peers, and uncertainty as to when to seek such a consultation.[221] However, it was the first semblance of self-regulation of the health professions in Britain that was quasi-sanctioned by the state. Medical guilds or professional associations continued to rise and fall for the next several hundred years, until the first instance of what we today understand to be government-sanctioned self-regulation.

From the 15th century, the recognition, status, and authority of physicians, apothecaries and surgeons began to grow as a result of receiving formal recognizance by the Crown. Henry VIII's reign saw the first use of legislation to regulate the practice of medicine. In 1511, *An*

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[216] *Hospitals for the Poor Act 1572* (U.K.), 14 Eliz. I. c. 14.
[217] M. Cosman, "Medical Malpractice and Peer Review in Medieval Britain" (1975) 80:3 Pt. 1 Trans Sect Otolaryngol. Am. Acad. Ophthalmol. Otolaryngol. 293 [Cosman].
[218] *Ibid.*
[219] *Ibid.*
[220] *Ibid.*
[221] *Ibid.*.

Act for the Appointing of Physicians and Surgeons came into force.[222] It recognized that "Phyfick" and surgery "to the perfect Knowledge whereof be requifite both great Learning and ripe Experience."[223] It sought to protect the "king's liege people" from ignorant persons with no training (described as Artificers, Smiths, Weavers and Women!) who take it upon themselves to provide health services (using noxious medicines, sorcery and witchcraft).[224] These unqualified providers "to the high Difpleafure of God, great Infamy to the Faculty …" caused "… grievous Hurt, Damage, and Deftruction of many of the King's liege People, moft efpecially them that cannot difcern the uncunning from the cunning."[225] To protect the public, the Act said that a person could not style himself (and it was always a 'him' at this time) a physician or surgeon within or outside London without the approval of the local bishop. Bishops were empowered, with the assistance of an expert or a panel of experts, to examine candidates in any way that they saw fit before granting approval to practise. The intention was to protect the public from unqualified persons by providing a mechanism that granted standing to 'qualified' individuals. The conferral of standing provided the public with the necessary information to make an informed choice to attend the government-sanctioned health professional or to seek succour from other health-providers, labelled by the state as 'cunning' and therefore untrustworthy.

Seven years later, in 1518, Henry VIII supplemented the Act by awarding a Royal Charter to the College of Physicians in London.[226] The Charter empowered the college to grant licences for physicians and apothecaries to practise. The charter also authorised the college, only within the boundaries of London, to punish unqualified practitioners or those who committed malpractice. The Roll of the College states:

> Henry the Eighth, with a view to the improvement and more orderly exercise of the art
> of physic, and the repression of irregular, unlearned, and incompetent practitioners of

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[222] *An Act for the Appointing of Physicians and Surgeons, 1511* (Eng.) 3 Hen. VIII., c. 11.
[223] *Ibid.*
[224] *Ibid.*
[225] *Ibid.*
[226] U.K., Royal College of Physicians, "Heritage Centre: Royal Connections – Henry VIII, 1491-1547" [U.K. "Heritage Centre"], online: Royal College of Physicians
 <http://rcplondon.ac.uk/heritage/royalconnections/exhib_rc_HenryVIII.htm>.

that faculty, in the tenth year of his reign founded the Royal College of Physicians of London.[227]

However, the charter was ineffective in that it could not compel other actors, such as the City of London, to recognize the powers of the college.[228] To remedy this, in 1523 an Act of Parliament ratified the Royal Charter and expanded the college's powers to include the whole of Britain.[229] Despite this government conferral of regulatory powers, it appeared that the College of Physicians had no real power outside London. Doctors in other cities or rural areas continued to call themselves physicians, choosing by preference, or necessity, to gain a licence from the local bishop.[230] Even within London, bishops continued to provide licences to physicians, despite the Act of 1523.[231] The college gained the reputation of being a closed, exclusive and elite shop, unwilling to approve 'outsiders' until well into the industrial revolution.[232]   Henry VIII also passed another Act in 1540 granting similar rights and privileges within London to the Company of Barbers and Surgeons.[233]

On receipt of a complaint, the college was to commence a disciplinary process where a panel of peers heard and judged the complaint; penalties included losing one's membership, fines, and imprisonment. It appears, however, that there was some disjunction between what the College of Physicians (there is little information about the barber–surgeons) and other groups or individuals thought the college should do with its legal powers.[234] It appears that patients or relatives thought the college should punish practitioners who harmed patients, and the public thought that the college should protect the public from dishonest and harmful practitioners.[235]   The Crown thought the college should provide it with advice on public health and exert authority over its members, and surgeons, apothecaries and unlicensed healers to prevent harm.[236]   The college, however, appears to have thought that its legal

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227 *Ibid.*
228 Cook, *supra* note 124 at 56.
229 *Physicians Act, 1523* (Eng.), 15 Hen. VIII., c. 5.
230 Cook, *supra* note 124.
231 *Ibid.*
232 *Ibid.*
233 *An Act for Barbers and Surgeons, 1540* (Eng.) 32 Hen. VIII., c. 42.
234 Cook, *supra* note 124.
235 *Ibid.*
236 *Ibid.*

powers were best used to suppress rivals, establish a monopoly and a hierarchy of practice.[237] Cook noted that less than one half of the total disciplinary committee hearings between 1635 and 1702 were malpractice cases; the majority were initiated by the college to deal with competitors practising without a licence.[238] Few complainants managed to pursue complaints of malpractice to the point where a verdict was passed.[239] This was in marked contrast to unlicensed practice cases where a verdict was almost always reached and often involved imprisonment.[240]

The colleges lost their regulatory powers during the civil war when, in 1656, a court declared Henry VIII's Act and the charters of the existing colleges null and void; but Cromwell later reinstated the college's powers.[241] In 1704, the House of Lords upheld an appeal from an apothecary prosecuted by the College of Physicians, and the college subsequently stopped disciplining non-college members.[242] The responsibility for regulating most health-providers was once again the sole province of the courts through civil proceedings.

The passing in 1858 of the *Medical Act*[243] heralded a new epoch in the regulation of health-providers in Britain and its colonies. The reforms saw the disparate elements of the medical profession (i.e. physicians and surgeons) united under one regulatory framework. It was a series of reforms, as Loudon notes, initiated by the profession and agreed to by Parliament.[244] The reforms were apparently driven by the profession's desire for social and professional respectability, as well as to provide the justification to increase their incomes.[245] The previous system of regulation, if one can call it such, provided the profession limited powers, and it was argued that patients could have no assurance that the professional they were receiving treatment from was indeed adequately and appropriately trained.[246]

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[237] *Ibid.*
[238] *Ibid.*
[239] *Ibid.*
[240] *Ibid.*
[241] *Ibid.*
[242] U.K., *Journal of the House of Lords*, vol. 17 (1704) 468, 482 and Cook, *supra* note 124 at chap. 7.
[243] *Medical Act, 1858* (U.K), 21 & 22 Vic., c. 90 [*Medical Act, 1858*].
[244] I. Loudon, "Medical Practitioners 1750-1850 and Medical Reform in Britain" [Loudon] in A. Wear, ed., *Medicine in Society: Historical Essays* (Cambridge: Cambridge University Press, 1992) at 219.
[245] *Ibid.*
[246] *Ibid.*

The *Medical Act* established a governing council, the General Medical Council (GMC), a medical register to record addresses and qualifications, and a procedure for determining minimum academic qualifications required for registration. It provided statutory protection of title. It also established a procedure for striking off the register doctors convicted of a felony, misdemeanour, crime or offence that constituted 'infamous conduct', as well as continuing existing powers of discipline. It also prohibited anyone not registered under the *Medical Act* from holding an appointment in any facility or service unless he (or subsequently 'she') was registered.[247] In an era when individuals claimed to be physicians, surgeons, or general practitioners without qualification, or by virtue of an apprenticeship, the legislation sought to ensure some degree of public safety through a process of assuring a minimum and consistent standard for qualification. All those who were on the register were legitimate in the eyes of the profession and the state and hence trustworthy. The legislative scheme also sanctioned a tighter and more exclusive monopoly for the medical profession. Other professions were subsequently regulated, beginning with nurses in 1919, dentists in 1921, opticians in 1958, and allied health professionals in 1960.

This framework remained essentially unchanged until 1973, when a Committee of Inquiry into the Regulation of the Medical Profession was commissioned to review it on the request of the medical profession. The medical profession was in the midst of an acrimonious dispute with its members about fees, but also there were concerns about the registration of international medical graduates and the perceived inadequacies of the existing framework to address the needs of doctors who were impaired. It was clear from the outset that the commission was not to question the fundamental premise of the regulatory structure – self-regulation. When announcing the inquiry, the Secretary of State noted:

> The General Medical Council is a body with a notable record of service to the public and to the profession. It is not contemplated that the profession should be regulated otherwise than by a predominantly professional body, but, as the General Medical Council itself has pointed out, its functions are very much the concern not only of

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[247] *Medical Act, 1858, supra* note 243.

the medical profession but also of the public, as well as of the Universities and other bodies. [248]

In emphasising the "notable record of service", the Secretary of State was in fact reiterating that the government retained its trust in the profession and continued to sanction the profession's self-regulation of its members. It also signalled that the purpose of the review was regulatory modernization, rather than a fundamental reappraisal of the framework itself.

The committee of inquiry noted:

> We are in no doubt that the community will be best served by a professional regulating body. … it is on the self-respect of the medical profession that the public must rely for high standards of medicine … The ultimate safeguard of the public interest is the power of Parliament. The new GMC will be established by Parliament through legislation, and Parliament will be able to intervene if the [social] contract … is not operating in the general public interest.[249]

The new regime, the *Medical Act 1978*, created more flexibility in the processes for handling complaints, allowing those professionals with impaired competence or capacity because of illness to be dealt with through a more-rehabilitative and less-punitive process. It also reformed the governance processes of the GMC. Until these reforms, the governing board of the GMC had been dominated by doctors appointed by various governing agencies (46 members, of which three were lay).[250] Subsequently, the majority of the board members were elected and not appointed, and the presence of lay members on the GMC was state sanctioned rather than at the discretion of the Privy Council, although numbers remained low.

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[248] Quoted in Stacey, "Medical Council", *supra* note 211.
[249] Committee of Inquiry, "*Regulation*" *supra* note 210.
[250] Stacey, "Medical Council", *supra* note 211.

In Canada, the regulation of doctors commenced in the French colony of Québec in 1750, with the passing of an act to regulate medical practice.[251] It stated:

> From information we have received it appears that many unknown individuals coming from Europe and elsewhere have engaged in surgery as much in the cities as in the country districts of this colony, without any permission; that these strangers whose ability is unknown treat the sick with little care and without giving them relief; distribute worthless remedies which give unsatisfactory results, not having all the experience necessary, and leading as a final result to abuses which are prejudicial to the well-being of the subjects of the King. [252]

The Act banned doctors from dressing wounds or treating the sick until they had passed an examination, supervised by the King's physician in Québec. This Act lapsed when the British acquired the colony in 1764.[253] The colonies that were to become Canada also enacted legislation regulating health professionals, starting inevitably with physicians and surgeons. For example, in Québec in 1788, *An Act or ordinance to prevent persons practising physic and surgery within the Province of Quebec, or midwifery in the towns of Quebec and Montreal, without license* was passed.[254] The legislature passed a very similar Act in 1795, when the province of Upper Canada (Ontario) was officially separated from Lower Canada (Québec), to regulate physic and surgery because of the "inconveniences" caused to his Majesty's subjects by "unskillful persons practicing phyfic and furgery".[255] Both Acts set up a licensing system for those who wanted to practise medicine, surgery, or midwifery, which basically required application to designated officials, immediate approval if qualifications were from an approved school, or examination if not. The Acts did not contain any provisions for discipline, only containing cursory qualification standards for initial licensing and penalties for unauthorized practice. The Acts were largely ineffective because there were very few health professsionals of any kind; thus the Act in Upper Canada was repealed in 1806. Another, almost identical, Act was

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[251] The Act is set out in J. Heagerty, *Four Centuries of Medical History in Canada Volume 1,* (Toronto: MacMillan, 1928) at 315 [Heagerty], taken from "L'Acte Médical du Canada" 30 *Bulletin des Recherches Historiques* 108-109.
[252] *Ibid.*
[253] *Ibid.*
[254] Reprinted in W. Canniff, *The Medical Profession in Upper Canada 1783-1850,* Reprint (The Hannah Institute for the History of Medicine, 1980) at 16-18 [Canniff].
[255] *An Act to Regulate the Practice of Phyfic and Surgery* S.U.C. 1795 (35 Geo. III), c. 1.

passed in Upper Canada in 1815, repealed and re-enacted in revised form in 1818.[256] Provisions for discipline for poor practice were to come later in the 19th century. Legislatures across Canada had moved to legislate for the regulation of doctors and other health professionals by the beginning of the 20th century. This regulation was substantially based upon the British model.

In both countries, professional regulation continued to be central to addressing patient-safety issues. The model of government-sanctioned self-regulation put in place in the 1500s was continued, with professional bodies operating under the express authorization of the state, which also defined the extent of their powers and authority. Professional regulation did not change much from the pattern set in the 1858 legislation in Britain and the later legislation in the Canadian provinces. In both countries, the focus continued to be upon standards and accountability. Legislation continued to permit professional bodies to set standards for entry into the profession and for continuing practice, as well as enabling accountability through disciplinary actions against erring health professionals.

At least initially, government or key representative bodies of the profession appointed members of the governing body. It was not until well into the 20th century that physicians elected members and government required at least some representation from lay persons. Both moves, particularly the representation of lay people, were aimed at making the professional bodies more accountable to the public for their actions. Government and the public had concerns that professional regulatory bodies were too much of a closed shop. This meant that they may be predisposed to favour fellow health professionals at the expense of the public interest or the private interests of the aggrieved person.[257] This was one of the first indicators of an emergent lack of trust in the how self-regulators exercised their functions. It also coincided with social movements in the direction of consumerism and participatory democracy.

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[256] Canniff, *supra* note 254.

[257] M. Moran & B. Wood, *States, Regulation and the Medical Profession* (Buckingham: Open University Press, 1993).

Direct Regulation

Although regulatory law may have a lesser normative status than criminal law – regulatory law, for example, is suggested to be a form of *mala prohibita* (wrong because the act is prohibited) – it is an enormously important tool of government and governance. Governments often use direct regulation to regulate risks that the private sector has proven incapable and or unwilling to self-regulate and where there is a strong public interest in government intervention.[258] In the health context, the need for direct regulation initially arose from a series of scandals about abuses within facilities catering for the poor, infirm and/or mentally ill.

The consequences of urbanization and industrialization led to a general recognition that government had a regulatory role to play in an industrial society – namely, to manage risk.[259] The incentives associated with rampant production had rendered free-market actors unable or unwilling to address the risks associated with their operations, which included the risks of unsafe or unhealthy places of work, but also the consequences of poor pay and long hours.[260] Individuals often had no choice but to accept such risks if they wanted to eat, and all the efforts of civil society could not effectively mitigate such risks. The recognition that the state had a legitimate and necessary role as a risk regulator led to a rapid expansion of government's responsibilities beyond traditional concerns of national defence, public justice, and the very basic regulation of social functioning. Thus, government began to pass legislation to regulate risks – risks that manifested at the individual or population level that seriously affected, or that were thought to affect, the current or future health, safety, or wellbeing of citizens.[261]

One issue of continuing concern was alleged abuses within facilities providing care and treatment for the mentally ill. In 1774, the British Government passed legislation to address "great and dangerous Abufes" by requiring all places "for the Reception of Lunaticks" to be licensed.[262] The College of Physicians granted licences for facilities within and close to

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[258] McDonald, "Working to Death" *supra* note 110.

[259] A. Manchester, *Modern Legal History,* (London: Butterworths, 1980) [Manchester].

[260] *Ibid.*

[261] Gostin, *supra* note 115.

[262] *An Act for Regulating Madhoufes, 1774* (Eng.) Geo. III c.49.

London, and Justices of the Peace granted licences outside of London. Licence grantors were required to be available, at the Crown's request, to inspect the premises they licensed and issue inspection reports. Licensing was limited in that it did not per se address issues relating to the treatment provided in those institutions; rather, the licensing process focused on the issues of habeas corpus – hospitals for the mentally ill were not to be used as a convenient means of disposal for unwanted spouses, or unruly parents or children.

In Britain, concerns about the management of hospitals for the mentally ill continued, subsequently focusing on the treatment of patients. In 1807 and 1815, a House of Commons committee investigated the conditions in 'madhouses'. These facilities displayed a wide spectrum of quality, including those that provided good care and those that were dominated by callousness, squalor, coercion, and confinement.[263] A series of Acts was passed from the 1820s onwards requiring medical supervision of asylums, a requirement said by some critics to serve the monopolistic ends of the medical profession rather than as a guarantor that the quality or safety of services would improve.[264] However, these Acts also established Commissioners for Lunacy to monitor the care of patients receiving institutionalized treatment for mental illness (although their effectiveness as a tool to improve conditions for patients was questionable).[265]

However, it was not only conditions in hospitals for the mentally ill that attracted the attention of the public and legislators; concerns soon arose about workhouse infirmaries. In Britain in the 1800s, there were regular scandals about abusive treatment of the poor in workhouses, focusing particularly on the quality (or lack of quality) of health services received in workhouse infirmaries. In a series of articles, the prominent medical journal *The Lancet* castigated workhouses for the quality of health services provided, calling the system "a disgrace to our civilization."[266] The passing of the *Metropolitan Poor Act*, as a consequence of *The Lancet's* articles, saw centralized administration of workhouse infirmaries in London.[267]

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[263] R. Porter, "Madness and its Institutions" in A. Wear, ed., *Medicine in Society: Historical Essays,* (Cambridge: Cambridge University Press, 1992) 277 [Porter].

[264] *Ibid.*

[265] *Ibid.*

[266] Quoted in G. Rivett, "Poor Law Infirmaries" online: NHS history net
<http://www.nhshistory.net/poor_law_infirmaries.htm>.

[267] *Metropolitan Poor Act 1867* (U.K.), 30 & 31 Vic. c.6.

In London, and in other areas, workhouse infirmaries were subject to more rigorous and regular inspections. The law provided for more professionalized administration, better conditions within workhouses, and the building of new hospitals specifically for those with infectious-type diseases. These reforms somewhat improved the safety and quality of services provided to patients within hospital facilities provided within the *Poor Law* structure, at least in London. Conditions continued to be poor in workhouse infirmaries outside of London until well into the 20th century.

Improved regulation of poorhouses within London also did little to improve the safety of patients in voluntary or private hospitals or nursing homes.[268] There were significant abuses associated with the proliferation of nursing homes and private hospitals, including: unqualified persons operating facilities; accommodation that was unsanitary, dirty, noisy, and overcrowded; and some facilities that masqueraded as 'massage hospitals' but which in fact were brothels. The 1900s saw the first demands that private hospitals and nursing homes be licensed and inspected, but, as Abel-Smith notes, there were no similar demands to protect poor patients from similar conditions in some voluntary hospitals.[269] It was not until 1927 that Parliament passed the *Nursing Homes Registration Act*.[270] The Act required that nursing homes be managed by a 'fit' person in 'fit' premises. Nursing homes were also required to employ at least some qualified persons i.e. nurses. Voluntary or private hospitals were not regulated until 1936.[271]

Regulation followed quite similar lines in Canada both pre- and post-confederation. Using what became the province of Ontario as an example, concerns about the conditions of the mentally ill in prisons stimulated efforts to provide treatment facilities for the mentally ill at a provincial level.[272] It was not until 1841 that a temporary facility for the care of the mentally ill was established. There were a number of problems associated with the management of the asylum. Accordingly, in 1853 the first regulation of publicly provided hospitals for the

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[268] B. Abel-Smith, *The Hospital: 1800-1948,* (London: Heinemann 1964) [Abel-Smith].

[269] *Ibid.*

[270] *Nursing Homes Registration Act 1927,* (U.K.) 17 & 18 Geo. V c. 73.

[271] *Voluntary Hospital (Paying Patients) Act, 1936* (U.K.) c. 17.

[272] Upper Canada, Legislative Assembly, "Report of the Petition of the Prisoners in Gaol in York" in *Journal of the Legislative Assembly* (1830) at Appendix 162. For events in the Maritime provinces, see D. Francis, "The

mentally ill occurred with the passing of *The Act for the Better Management of the Provincial Lunatic Asylum.*[273] This was followed by legislation entitled *An Act to Provide for the Inspection of Asylums, Hospitals, Common Gaols, and Reformatories in this Province.*[274] Passed in 1868, it allowed the governor to appoint inspectors and required regular inspections of the conditions in health or penal facilities that received some form of funding from the state (i.e. in the context of healthcare for the care of paupers). Legislated inspection requirements continued, although the legislature eventually created separate requirements and administrative processes for prison inspections and inspections of mental health facilities. Parliament extended regulation to private facilities for the treatment of the mentally ill in 1887 – *The Act Respecting Private Lunatic Asylums*, which required that the proprietor seek a licence, allow regular external visitors (inspections) to monitor conditions, and provide medically supervised and sanctioned treatment to patients.[275]

It was not until 1887 that the regulation of general hospitals commenced through the *Charity Aid Act*, although it is important to note that initial regulation was more concerned with providing institutions with a governance structure and setting rates for poor relief.[276] Later Acts focused more on inspections of public and private facilities, contained provisions for financial sanctions against public hospitals that failed inspection, required licensing for private hospitals and, in the 20th century, nursing homes.[277] Licensing requirements and inspections focused for the most part on sanitary arrangements, the basic environment within which patients received care (i.e. were they abused or neglected), and facility design.

These regulatory initiatives in both Britain and Canada focused on risks identified at that time that impinged upon the safe delivery of health services. These were the risks of hospital-acquired infections within poorly designed, improperly cleaned, crowded, and otherwise unsanitary facilities. Inadequate care of the kind provided by manifestly unqualified or unfit providers, and/or by providers who put profit ahead of the welfare of

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Development of the Lunatic Asylum in the Maritime Provinces" in S. Shortt, ed., *Medicine in Canadian Society: Historical Perspectives* (Montreal: McGill-Queen's University Press, 1981) at 93 [Francis].

[273] *An Act for the Better Management of the Provincial Lunatic Asylum at Toronto,* S.Prov.C. 1853 16 Vict., c. 188.
[274] *An Act to Provide for the Inspection of Asylums, Hospitals, Common Gaols, and Reformatories in this Province,* S.O. 1868 31 Vic. c. 21.
[275] *An Act Respecting Private Lunatic Asylums,* S.O. 1887, c. 246.
[276] *Charity Aid Act,* R.S.O. 1887, c. 248.

their patients, and providers who abused their patients, were other recognized risks. In response, regulation required approval for hospital design and formation, the licensing of individuals and facilities, and regular inspections. Facilities regulation continued to follow the same basic pattern with the focus on infection control, the physical environment within which care was provided, including facility design, and the treatment meted out to patients.[278]

Quality within healthcare facilities became a concern in the 1960s and 1970s. In North America, quality assurance was primarily an academic movement that sprang from emerging evidence about the success of quality management and assurance schemes in manufacturing sectors. Donabedian, a leader of the quality movement, suggested that 'quality' evaluated the science and art of medicine in relation to a single episode of care for a single patient or more broadly to treatments and care provided to patients in institutions.[279] He defined quality at the micro level as "the application of medical science and technology in a manner that maximises its benefits to health without correspondingly increasing its risk."[280] He supplemented this technically focused description with a further requirement that quality includes conformity to "socially defined values and norms that govern the interaction of individuals in general and in particular situations,"[281] and to the ethical aspirations of the profession. Full consideration of quality must also, according to Donabedian, take into account how the individual perceives the care and treatment and how it affects society.[282]

In Canada, there was a general reliance on the professions to address issues relating to the competence of individuals, although credentialling requirements also enabled facilities to address concerns about performance should they arise. Many hospitals voluntarily adopted quality-assurance mechanisms to review, assess, and analyze clinical performance, particularly from the 1970s onwards. In order to get doctors who were concerned about liability to participate and to get broader uptake of quality-assurance mechanisms in hospitals, governments across Canada (with the exception of Ontario) amended existing legislation

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[277] See for example, *Private Sanitaria Act,* R.S.O. 1914, c. 296.

[278] Downie, *supra* note 28.

[279] A. Donabedian, *Explorations in Quality Assessment and Monitoring Vol. 1. The Definition of Quality and Approaches to Its Assessment,* (Ann Arbor, MI: Health Administration Press, 1980) [Donabedian].

[280] *Ibid.* at 5.

[281] *Ibid.* at 5.

[282] *Ibid.* at 5.

relating to evidence to protect information generated as a result of quality-assurance practices being disclosed in court.[283]

Although never as pervasive as in North America, concerns about quality also spread to Britain. The adoption of quality assurance processes within the health system was fostered by several scandals in the late 1960s about the quality of care provided to patients in long-term resident treatment facilities. In the late 1960s, the 'Sans Everything' investigation and the Ely Hospital scandal led to a public inquiry into the quality of the care received by patients in long-stay facilities for the mentally ill or for geriatric populations.[284] These inquiries were instrumental in encouraging the promotion of some new regulatory oversight of quality. There were three key initiatives relating to monitoring, complaints, and peer review. A Hospital Advisory Service was established in 1969 to monitor the quality of care provided for long-stay or chronic users of facilities providing care or treatment for patients experiencing mental illness, intellectual disability, or the elderly.[285] In 1974, government established a Health Services Commissioner to provide a venue for the receipt and independent assessment and investigation of complaints about actions that did not relate to exercises of clinical judgement in relation to care and treatment in NHS facilities.[286] Government relied on the professions to manage poor performance and competence issues for the most part, so although mechanisms for clinical audit and the 'three wise men' system were set up to assess issues with individual performance through peer review processes, they remained largely voluntary.[287]

Perhaps surprisingly, given the levels of government involvement in the provision of health services in each country, direct regulation was used sparingly as a mechanism to address

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[283] Downie, *supra* note 28.

[284] The 'Sans Everything' scandal arose after a publication of a book of the same name where private investigations alleged systemic low standards of care associated with the provision of health services to elderly patients. Government convened a commission of inquiry to investigate allegations that the care and treatment provided to patients with learning disabilities at Ely Hospital in the late 1960s was abusive. See discussion about the effect of these cases for governance in C. Ham & K. Alberti, "The Medical Profession, the Public and the Government" (2002) 324:7341 BMJ 838 [Ham].

[285] See J. Montgomery, *Health Care Law* (Oxford: Oxford University Press, 1997). This was renamed the Health Advisory Service in 1976.

[286] *National Health Services Reorganisation Act 1973* (U.K.), 1973, c. 32 [*Reorganisation Act*].

[287] U.K., The Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* (Norwich: The Stationery Office Limited, 2001) [BRI Inquiry, "Learning from Bristol"].

safety and quality issues. Although both countries used direct regulation to progressively establish licensing requirements for public and private health facilities, these established relatively minimal requirements – a requirement for appropriate staff, appropriate facilities, and provision for inspection. Canada continued to rely greatly on health-providers to self-regulate through accreditation processes and developed mechanisms to support that co-regulatory form of governance. However, the 1970s saw the first indication that Britain might choose to rely more heavily on direct regulation in respect of facility safety and quality, although at this time such mechanisms were still highly limited so as to accord maximum capacity for the exercise of professional autonomy and professional self-regulation. Direct regulation was a part of the regulatory framework, but in both jurisdictions government control of the activities of facilities and professionals was minimal and hence co-regulatory in nature.

Public Inquiries

Public inquiries into matters of public concern have long been an important tool in common-law countries to ensure accountability, particularly of government and government actors, but also of private actors whose actions cause public disquiet.[288] In general, governments most commonly constitute inquiries during periods of crisis, change, growth, or adjustment. While some are convened as a form of social inquiry into a pressing policy problem, others are convened as a response to an issue of grave public concern – scandals and tragedies. Public inquiries addressing matters of public concern ask what happened, why, and what lessons can be learned for the future,[289] and as such they serve both a retrospective and prospective accountability function. Such inquiries may be a trigger for further legal action against those whose conduct was examined during the course of the inquiry and may result in policy recommendations for future regulatory amendments.

There are a variety of ways such inquiries could be constituted. For example, in Britain a Royal Commission of Inquiry can be convened under the *Tribunals of Inquiry (Evidence) Act*

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[288] See generally, A. Manson & D. Mullan, eds., *Commissions of Inquiry: Praise or Reappraise?* (Toronto: Irwin Law, 2003) [Manson].

[289] A.W. Bradley, "Commissions of Inquiry and Governmental Accountability: Recent British Experience" [Bradley] in Manson, *ibid.* at 31.

1921, a public inquiry may be convened under specific statutory powers, for example, pursuant to s. 84 of the *National Health Service Act 1977*, or government may commission a public inquiry without recourse to statutory powers. There are also other forms of public or quasi-public inquiry. For example, in Britain, Parliamentary inquiries have responded to concerns about the safety of the care and treatment of those required to access workhouse infirmaries and of the institutionalized mentally ill.[290] Coroners' inquiries were and are a tool used in both jurisdictions to examine unexpected deaths while in receipt of health services.

Royal commissions of inquiry have a long history in Britain, some suggesting that their institution dates back to the 11th century.[291] It was not until the 19th century that such mechanisms saw extensive use in the health context with British royal commissions inquiring into various public health issues, as well into grave public concerns about the care and treatment of mental health patients.[292] Royal commissions saw use in Canada from confederation in 1867 at both the federal and provincial levels of government. At the federal level, issues related to the provision of health services were examined (see for example the Hall Inquiry discussed in subsequent chapters), but unsurprisingly, given the federal government's limited powers in respect of healthcare, patient-safety-related issues were not, at least prior to the 1980s. At the provincial level, there were Commissions of Inquiry into health related issues, including patient safety, from 1878 to 1945, primarily in relation to allegations of abuse of institutionalised patients.[293] Inquiries related to patient safety tended to only be convened at this time to investigate care and treatment characterised as abusive, rather than safety issues per se.

Post-World War II inquiry processes continued to play a limited responsive and reactive role to address general and specific concerns about patient safety in both countries. Public inquiries, whether royal commissions of inquiry, a public inquiry pursuant to an authorizing statute, a ministerial inquiry, a parliamentary inquiry, or an inquiry commissioned by a hospital board played a small but growing role in inquiring into allegations relating to

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[290] U.K., H.C., *First Report: Minutes of Evidence Taken Before the Select Committee Appointed to Consider Provisions being made for the Better Regulation of Madhouses in Britain* (London: HMSO, 1816).
[291] Manchester, *supra* note 259.
[292] Manchester, *supra* note 259.
[293] L. Maillet, *Provincial Royal Commissions and Commissions of Inquiry 1867-1982,* (Ottawa: National Library of Canada, 1986) [Maillet].

negligent treatment, especially in Britain. The 1946 Act that established the NHS contained provisions for the Secretary of State to commission a committee of inquiry.[294] A local hospital board commissioned the first inquiry relating to patient-safety issues in 1967, and there were two more commissioned by the Secretary of State in the 1970s, again primarily responding to allegations of abuse.[295] In Canada, commissions of inquiry (provincial) were used sparingly in respect of patient-safety issues, again primarily to respond to alleged abuses, rather than unsafe or negligent care or treatment.[296]

In both jurisdictions coronial inquiries and inquests were standard procedures to respond to alleged patient-safety incidents if there was uncertainty about the cause of death.[297] They usually occurred where the family was concerned about the quality of the care the deceased person received or where the coroner identified issues of concern during a routine review. There were numerous recommendations about improving the safe provision of health services forthcoming from these inquiries or from inquests; however, they seldom received much public prominence, or indeed few facilities or professionals knew of them outside of the facility concerned.[298]

Public inquiries played a role in ensuring the accountability of actors and actions within the health sector in both countries. Apart from coronial processes, most public or quasi-public inquiries that addressed so-called scandals in the health system related to allegations that invoked potential criminal consequences – allegations of the abusive care and treatment of patients – thus, public inquiries were only convened in respect of allegations that addressed issues that were fundamental to the functioning of society and the rights of individuals (i.e. into abuses accorded mental health patients or those in residential care. More general concerns about quality and safety were not the subject of such inquiries in this period.

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[294] *National Health Service Act, 1946* (U.K.), 9 & 10 Geo. c. 81 s. 70 [*NHS Act 1946*].
[295] K. Walshe & J. Higgins, "The Use and Impact of Inquiries in the NHS" (2002) 325:7369 B.M.J. 895 [Walshe].
[296] Maillet, *supra* note 293.
[297] Note that some Canadian provinces do not have coroners per se. In these jurisdictions, there are similar processes to review deaths – for example, fatal accident inquiries involving medical examiners. See discussion in Downie, *supra* note 28.
[298] E. Picard & G. Robertson, *The Legal Liability of Doctors and Hospitals in Canada* (Toronto: Thomson Carswell, 2007) [Picard, *Legal Liability*].

That the health-system-related legislation in Britain and in Canadian jurisdictions contained provisions for ministerially convened inquiries was an indication that governments recognized that further accountability mechanisms may be necessary in this context.[299] Other prospective accountability mechanisms such as litigation were often not appropriate or adequate to address systemic abuses and formal commission of inquiries were often costly, and administratively cumbersome – more flexible mechanisms were required. That the employment of these mechanisms was generally limited to inquiring into allegations of abuses by professionals was no limit upon their being used more broadly should the circumstances dictate.

Conclusion

Up until 1980, in both countries, we can discern some key themes in respect of the management of patient safety. First, as a general comment, it is evident that patient safety is not a new issue, but is an issue that societies have always, at least in some measure, engaged with, recognizing the significant impact that unsafe treatment has on patients and on the effective functioning of the societies that they live in.

This examination of the regulatory frameworks employed in Britain and Canada shows a convergence as to how the recognized risks associated with the provision of health services should be governed. The elements of this convergence align with the development of health systems and with perceptions of the appropriate role of government in healthcare, as represented in Figure 1.

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[299] See for example, *NHS Act 1946, suora* note 294...

Figure 1 Evolution in Health Services Regulation Pre-1800 to 1980

Health and Health Services

Direct relationships   Increasingly complex relationships

Transaction/charity   Public provision

Personal responsibility   State Responsibility

Pre-1800 ———————————————————▶ **1980**

Regulatory Framework

Criminal law

Tort and Contract Law

Self-regulation

Government-sanctioned self-regulation

Direct Regulation

Public Inquiries
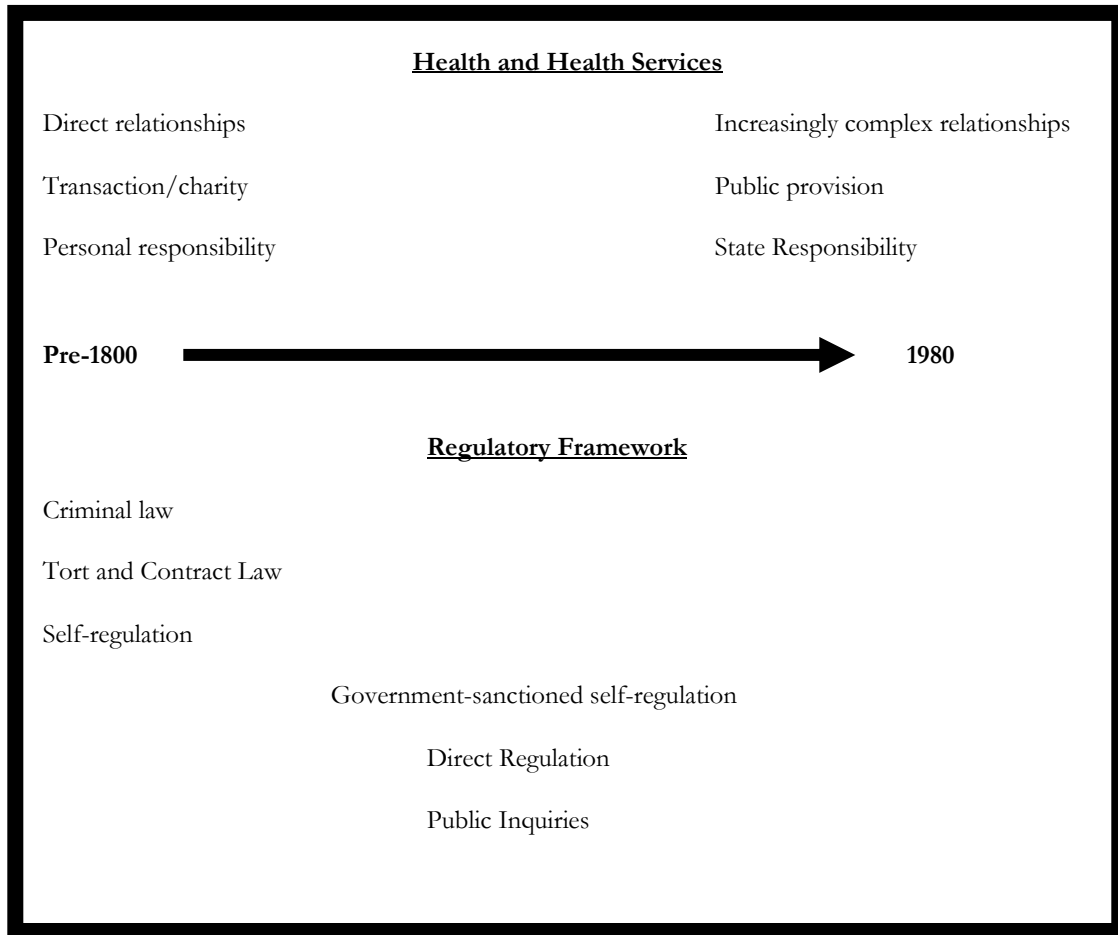
Although health services were first characterized as a private transaction and then as a public necessity, the governance mechanisms that evolved as governments response to patient safety did not markedly change. Thus, there was a convergence in both Britain and Canada as to how much government should intervene to introduce governance measures in relation to patient safety, even if the rationale for this changed. Essentially, the convergence was that a mixed system of governance mechanisms was preferred. Users of health services could seek fiscal redress for harms caused through the use of the bottom-up civil proceedings from individual health-providers, facilities, and manufacturers of health-related products and utilise the prospective function of regulation by litigation. Government supplemented this with basic government-sanctioned self-regulation of many of the professional groups that

provided health services. Professions set standards in respect of qualifications for practice and ensured the accountability of members to the public and to the profession. In return, the public gained some basic consumer information and protection. Top-down regulation of safety and quality issues associated with facilities and products filled in the rest of the regulatory picture, although there was still significant autonomy accorded in practice to facilities with regulatory attention primarily, almost exclusively, focused on input regulation. Government retained the ultimate power to sanction individual health-providers through the use of the criminal law (a tool of very limited use in Canada). Also, government had the capacity to determine how significant an issue of patient safety was in general or in regard to specific cases by using its investigatory powers associated with public inquiries and coronial inquests.

At first, when government regarded health as a private transaction in a free marketplace, government intervention into health was limited to consumer protection (or expansion of state controls depending upon your perspective) rather than risk management. State-sanctioned self-regulation intended to create mechanisms to provide consumers with enough information to make a choice about the qualifications and standing of a practitioner when making market decisions. The industrial revolution saw the characterization of risk change from a matter of the market to a matter of public health, and become less of a private matter and more a central responsibility of the state to mitigate.[300] Government's role as a regulator of risk therefore escalated, but not significantly, in regard to health services, where a hands-off approach leaving issues of risk management to health-providers remained. Government may have adopted this approach because it was busy elsewhere or ensuring access was a greater priority. It may have believed that existing mechanisms were adequate to manage the risk there was real faith in the will and abilities of health professionals and providers to self-regulate safety. As to the last, in granting professions government-sanctioned self-regulatory status, the (perhaps unintended) effect was to improve their social standing and reputation.

An increased professionalism in approach and public presentation also assisted in reassuring the public and government that the profession was committed to public welfare and excellence. The reputation of the health professions was further enhanced through their

association with technological discovery, scientific innovation, and progress, which granted the profession the expertise and knowledge that allowed the public to hope for a better, longer life. All of these factors created a sense that government intervention into healthcare, apart from ensuring access, was not necessary, and indeed that health was such a complex matter that government lacked the expertise to regulate it effectively. In addition, once the social responsibility assumed by the government flowered into the creation of the welfare state, physicians in particular were essential to the success of government plans, so it was a functional necessity to continue to respect their autonomy. Hospitals, too, were accorded considerable autonomy by governments as they were strongly associated with the medical profession and were at the centre of the care and treatment paradigm.

Although regulatory frameworks showed signs of a regulatory convergence, those frameworks were employed in different contexts – contexts discussed in more detail in subsequent chapters. The different contexts, both in terms of the structures of health systems and in governance structures more generally, are important as regulatory frameworks are implemented and thus interpreted in a context-specific manner. Regulatory frameworks shape and are shaped by their context. The following chapter discusses the differences in the structure and function of health systems in Britain and Canada.

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[300] Gostin, *supra* note 115.

Chapter 3
Health Systems: Sites of Convergence, Sites of Divergence

Introduction

As the last chapter demonstrated, in 1980 Britain and Canada had generally convergent regulatory frameworks for healthcare that paid little attention to patient safety. However, within each jurisdiction these similar regulatory frameworks were employed in different contexts, in health systems with different structures and operating logics.[301] This chapter delineates a context – the health system(s) within which the regulatory frameworks analyzed in the previous chapter were employed. Context is important. The structural framework around health systems in each jurisdiction creates conditions within which governments are inclined to select one form of regulatory intervention over another when certain other factors (discussed in Chapters 5 and 6) may impel a review of the accepted regulatory frameworks. The similarities and differences between the health systems suggest conditions for divergences between the jurisdictions – divergences that could influence future regulatory responses and direction.

The period after 1945 was significant for health services provision in both Canada and Britain. Public expectations about access to health services and of the role of the state and health-providers changed.[302] The public increasingly perceived that they were entitled to access health services.[303] Underpinning this shift was the assumption that it is in the public interest that the whole of a nation's population can access what is termed in Canada 'medically necessary' health services. It is, at least to some degree, accepted that the provision of health services improves quality of life and extends life expectancy – benefits with, among other things, obvious economic implications for society as a whole.[304] The perspective that government should enable access to health services also flowed from the commitment of successive governments in Britain and Canada to Keynesian-type economic

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[301] Tuohy, "Logics", *supra* note 35.

[302] See, for example, R. Porter, *Blood and Guts: A Short History of Medicine* (New York and London: W.W. Norton & Co., 2002) [Porter, *Blood*].

[303] See, for example, Commission for the Future of Health Care in Canada, *Building on Values: The Future of Healthcare in Canada,* by R. Romanow (Ottawa: Commission of the Future of Health Care in Canada, 2002) [Romanow, "The Future"].

[304] See generally, R. Evans, M. Barer and T. Marmor, *Why are Some People Healthy and Others Not? The Determinants of Health of Populations* (Walter de Gruyter, New York, 1994)".

theories. However, governments lacked expertise and knowledge about health services. In order to make the new systems work, governments needed to closely engage with those believed to have expertise and knowledge in this area. As discussed in the previous chapter, the medical profession was deemed to have the requisite expertise in determining how, when, and why health services should be available to the public at large.[305] This necessary engagement shaped the development and operation of modern health systems in both Britain and Canada.

Behind the basic assumption that the state should guarantee the population's ability to access at least some forms of health services, there are differences between countries as to how to establish governance frameworks to enable this. There are also differences as to what is the appropriate role of the state and of governments. It is these differences, and in some cases similarities, that are explored in this chapter. Accordingly, I first discuss some key structural and operational norms of the British NHS until 1980, highlighting the influence the structure of the NHS had on future regulatory directions around patient safety.[306] In the second section of this chapter, I undertake a similar examination of the Canadian health systems. In the third section, I examine the convergences and divergences between the two jurisdictions. Throughout, I ask the questions how and why the structural features and operational norms, or, as Tuohy would put it, the "logics"[307] of health systems might affect the future direction of patient-safety regulation. While there are many similarities between the health systems in these countries, there are also some divergences, and these prove significant for future regulation. The central argument in this chapter is that the differences apparent in the health systems in Britain and Canada constitute logics or norms which may have constrained, and may yet constrain, future choices.[308] In short, I suggest, the statist and centralist tendencies

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[305] J. Lewis, "Providers, 'Consumers', the State and the Delivery of Health-care Services in Twentieth Century Britain" in A. Wear, ed., *Medicine in Society: Historical Essays* (Cambridge: Cambridge University Press, 1992) 317 [Lewis].

[306] More comprehensive examinations of the dynamics of each country's health systems can be found in other works. See, for example, Tuohy, "Logics"*supra* note 35; R. Klein, *The New Politics of the National Health Service*, 4th ed. (New Jersey: Prentice Hall, 2001) [Klein, "New Politics"]; S. Giaimo, *Markets and Medicare: The Politics of Healthcare Reform in Britain, Germany and the United States,* (Ann Arbor, MI: University of Michigan Press, 2002) [Giaimo]; W. Lahey, "Medicare and the Law: Contours of an Evolving Relationship" in J. Downie, T. Caulfield & C. Flood, eds., *Canadian Health Law and Policy*, 3rd ed. (Markham Ont.: LexisNexis, 2007) 1 [Lahey]; G. Gray, *Federalism and Health Policy: The Development of Health Systems in Canada and Australia* (Toronto: University of Toronto Press, 1991) [Gray].

[307] Tuohy, "Logics" *supra* note 35.

[308] Kay, *supra* note 47.

in the British system incline it to use forms of regulation that strengthen the role of the state. Conversely, I suggest that the quasi-corporatist and co-regulatory norms embedded in the structures and relationships within Canadian health systems generally incline governments towards the use of regulatory tools that foster partnerships and collaborations.

Britain

Prior to the 20th century, health services in Britain were primarily offered as a matter of charity or entrepreneurial endeavour. Government's role in the health system was reasonably limited. As a provider of services, it focused on providing workhouses and other similar facilities for the very poor, some psychiatric facilities (focusing more on incarceration than treatment), and, increasingly as the 19th century progressed, public health services such as sanitation.[309] Its role as a regulator was discussed in the previous chapter.

By the close of the 19th century, Britain and other nations were moving away from policies and regulation based on individualism towards what Dicey dubbed "collectivism", where the interests of the individual were to some extent sacrificed to confer benefit on the collective whole.[310] In the late 19th and early 20th centuries, the movement towards collectivism began through legislated social programs intended to improve social conditions for the less well off. In the health context, a beginning was made with the passing of the *National Insurance Act 1911* (NI Act).[311] The NI Act was the first step in fundamentally changing the shape of the British health system from a private to a largely public system. The NI Act established an unemployment insurance scheme and a health insurance scheme for a proportion of citizens who were currently employed. The health insurance scheme provided government funding for the provision of health services to the employed poor (the unemployed poor could access health services through the workhouses). The passing of the NI Act had consequences: it increased state involvement in the provision of health services, and established the medical profession as a key stakeholder in the governance of the health system.[312] These were important factors in setting the agenda for future regulation. It cemented the state as a core actor in respect of ensuring the health of its citizenry. Further, the health insurance program

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[309] See for example, Abel-Smith, *supra* note 268.
[310] Manchester, *supra* note 259.
[311] *National Insurance Act 1911,* (U.K.), 1 & 2 Geo. V, Ch. 55.
[312] Lewis, *supra* note 305 and Tuohy, "Logics" *supra* note 35.

created a structure where doctors continued to enjoy autonomy and control over their professional practice and remuneration through the creation of local medical committees dominated by the medical profession.[313] This was an autonomy they were loath to lose, and which the state continued to accommodate in future law reform initiatives.

Although the movement towards collectivism began at the end of the 19th century, certainly in Britain, it was the Great Depression that convinced governments that the laissez-faire approach to the governance of social matters that had been adopted by successive governments was not satisfactory.[314] During this crisis, it became evident that the institutions of civil society (charities and professional associations) did not have the capacity to ensure that the basic social needs of citizens were met.[315] The belief increasingly developed that it was the rightful role of the state to provide social services. Although government involvement in health service delivery was initially constituted through an insurance plan, the stresses imposed upon Britain by the Great Depression and then the Second World War, as well as evolutions in how health services were provided, meant that another fundamental reappraisal of the role of the state in healthcare would occur. The move towards collectivism peaked with the formation of the so-called 'welfare state' in the years following the Second World War.

The demands of the Second World War resulted in government regionalizing hospitals (although local, charitable or private ownership was retained) and providing stable levels of funding in the anticipation of large-scale casualties from German bombing.[316] As a result, the public and the state increasingly perceived hospitals as the centrepiece of the healthcare enterprise – a certainty that was only to increase as the century progressed.[317] The government's wartime action, in combination with the previously introduced health insurance, demonstrated that a broader government role in ensuring access to health services was feasible. The Second World War also established that a portion of the population was

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[313] Giaimo, *supra* note 306.

[314] Manchester, *supra* note 259.

[315] Manchester, *ibid.* and Klein*, "New Politics" supra* note 306.

[316] L. Granshaw, "The Rise of the Modern Hospital in Britain" in A. Wear, ed., *Medicine in Society: Historical Essays,* (Cambridge: Cambridge University Press, 1992) 317 [Granshaw].

not able to access adequate nutrition or sanitation and was generally in poor health. As a result of regionalization, government also recognized that health services were not organized rationally, as different levels and types of services were provided across the country.[318] Hence, the war years saw the development of a broad consensus that Britain needed a comprehensive, universally accessible health service.[319] During the war, the coalition government convened a review of social policy. In 1942, the Inter-Departmental Committee on Social Insurance and Allied Services, chaired by Sir William Beveridge, made a number of recommendations to government to develop a comprehensive social system to be implemented in the post-war years.[320] A key plank in its proposed framework was the development of a free and comprehensive health service at point of need. The plan was highly popular with the public.[321]

Post-war, the Conservative government baulked at the huge cost commitment inherent in the Beveridge plan, but in 1945 the Labour Party won the general election by a landslide. In a first-past-the-post electoral system, that a party was elected by a landslide (albeit without a majority of the general vote) meant that it could claim a mandate. It certainly had the power to bring about reforms, particularly given that the Beveridge Report had been so popular. Thus, the government commenced a program of significant social policy reforms and created the so-called 'welfare state'. In furtherance of the vision set out in the Beveridge Report, government, after much discussion and in the face of some opposition, created the NHS with the passing of the *National Health Service Act 1946* (NHS Act).[322] The NHS commenced operations in 1948. Naturally, as Kingdom notes:

> The NHS is an intensely political institution. Perhaps more than any other part of
> Britain's welfare state it has enshrined the values of collectivism over those of

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[317] See, for example, J. Knowles, "Emergence of the Hospital as a Social Institution" in L. King, ed., *Mainstreams of Medicine: Essays in the Social and Intellectual Context of Medical Practice* (Austin: University of Texas Press, 1971); Granshaw, *ibid.*

[318] Klein*, "New Politics", supra* note 306.

[319] J. Kingdom, "The United Kingdom" in A. Wall, ed., *Health Care Systems in Liberal Democracies,* (London and New York: Routledge, 1996) 127 [Kingdom].

[320] U.K., H.C., "Social Insurance and Allied Services: Report by Sir William Beveridge", Cmd 6404 in *Sessional Papers,* vol. vi (1942) 36.

[321] C. Barnett, *The Audit of War*, (London: Pan, 2001).

[322] See Tuohy, "Logics"*supra* note 35; Lewis, *supra* note 305; Klein*, "New Politics", supra* note 315; J. Finch, *Health Services Law,* (London: Sweet & Maxwell, 1981) [Finch].

individualism … virtually no part of its architecture has been untouched by the interplay of political forces.[323]

The NHS was a comprehensive scheme aimed at providing a free health service for all paid for by government (the provision of private services for those who could afford them continued in parallel to the NHS). The insurance model set up in 1911 was not pursued; rather, the NHS was the first health system to offer care to an entire population based on national *provision* of services.[324] According to Klein, no other advanced post-industrial society has such a centralized healthcare system[325] - not a great surprise considering the wartime dependence on and tolerance of centralized planning in the national interest.[326] Saltman and Otter suggest that Britain is one of a small family of states that is characterized by a distinct paradigm of policy-making: "[t]he dominant policy paradigm during this period of post-war expansion [of health care provision] was a relatively rigid command-and-control planning model."[327] Moran notes that Britain developed a particularly centralized form of command-and-control planning.[328]

Kingdom also posits that:

> If a camel is a horse designed by a committee, the NHS, shaped by several committees and subject to advice from numerous interests, including doctors' associations, trade unions, local authorities, voluntary hospitals, academics and politicians, was scarcely less curious an animal.[329]

The NHS comprised three strands: hospital services, public health, and primary care. The NHS Act nationalized the hospital sector – in "one legislative stroke", government nationalized 1,000 voluntary hospitals, 540 hospitals operated by local government, and a

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[323] Kingdom, *supra* note 319.
[324] Klein*, New Politics, supra* note 306.
[325] *Ibid.*
[326] Giaimo, *supra* note 306.
[327] R. Saltman & C. von Otter, *Planned Markets and Public Competition: Strategic Reform in Northern European Health Systems* (Buckingham: Open University Press, 1992) at 4, cited in Moran, "Governing" *supra* note 37 at 26.
[328] Moran, "Governing" *supra* note 37.
[329] Kingdom, *supra* note 319 at 140.

number of cottage hospitals.[330] Although it was a centralized system, hospitals – which because of the legacy of the war continued to be the centre of the health system in Britain – were organized regionally, reporting to the Minister of Health.[331] The hospital sector was administered, not by local government, but through a centrally created regional system with local management boards for each hospital. These boards reported to regional authorities. These boards were not democratic or bureaucratic in composition, as the medical profession was resistant to democratic or bureaucratic control of the health system. Membership of the boards was by appointment. As Kingdom notes, there was:

> the selective breeding of a new species of constitutional animal, the hospital authority, a non-elected local authority with members appointed by ministerial patronage, and guaranteeing strong representation of the doctors themselves.[332]

Every attempt was made to ensure the autonomy of each region and each hospital, as the government wanted to reconcile its acceptance of the principle of national responsibility for healthcare with the principle of localism – that the system should be responsive to local conditions and needs.[333] The administrative philosophy within the NHS was a product of interactions between levels of governance and a degree of central planning.[334] The principle of localism meant that the centre did not and could not know best, and even when it did, according to Klein, all it could do was ask, educate, inspire and stimulate the regions.[335] There was also tension within the NHS between the centre wanting to ensure accountability and the periphery which perceived that government interfered too much.[336]

Doctors practising within hospitals were employees of the state, albeit extraordinarily privileged employees. Hospital consultants were paid a salary, their contracts were held at the national level, and they did not report to hospital management; rather, they formed self-

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[330] Klein, *"New Politics", supra* note 306 at 1.
[331] Granshaw, *supra* note 316.
[332] Kingdom, *supra* note 319 at 141.
[333] See, for example, Tuohy, "Logics" *supra* note 35; Lewis, *supra* note 305; Klein, *"New Politics", supra* note 306; Finch, *supra* note 322.
[334] Klein, *"New Politics", supra* note 306 at 36.
[335] *Ibid.*
[336] *Ibid.*

governing medical staffs.[337]   Consultants preferred to be employed by the national government rather than at local or regional level, as they believed they would be able to exercise more influence if negotiation occurred nationally.[338]

General practitioners and other primary-care providers (dentists, pharmacists, etc.) became independent contractors to the state. They were paid on a capitated basis, and virtually all of their income derived from the state. Their contracts were administered by local committees (first Executive Councils and later Family Practitioner Committees) comprised of members representing local professional associations, local government, and the Minister of Health. There were direct negotiations between the government and medical groups around remuneration until 1962. After 1962, annual increases in salaries and capitation payments were determined by an independent review body: the Review Body on Doctors' and Dentists' Remuneration.[339]   Public health functions (for example, ambulances, vaccination and immunization, health education, etc.) remained under the control of local government.

Governments of all persuasions were keenly interested in containing costs, and a general attitude of 'do more with less' prevailed. Governments were keen to avoid the appearance of rationing by the state, with the result that doctors undertook rationing at the bedside to remain within the national budget centrally allocated to the regions, and the global budgets allocated to hospitals and units within those facilities.[340]   Perhaps because of the post-war environment from which the NHS sprang, and the impact of the implicit bargain between the state and the medical profession, the national budget for the NHS was not a significant issue for the public through the early operation of the NHS, although rationing became a subject of public discourse from the 1970s. In general, the tripartite NHS system attracted relatively lean funding from central government, especially compared to other health systems like Canada.

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[337] Tuohy, "Logics"*supra* note 35.

[338] J. Hollingsworth, "Structure and Performance of the Medical Care Delivery Systems of the United Kingdom and the United States" [Hollingsworth] in Freddi & Björkman, *supra* note 19.

[339] M. Döhler, "Physicians' Professional Autonomy in the Welfare State: Endangered or Preserved?" [Döhler] in Freddi & Björkman, *supra* note 19 at 178.

[340] See, for example, C. Newdick, *Who Should We Treat? Rights, Rationing and Resources in the NHS,* 2nd ed. (Oxford: Oxford University Press, 2005) [Newdick "*Who*"].

Government recognized that in order for the NHS to function, the cooperation of the medical profession was required, and reached an implicit bargain with the profession. Traditionally, the power of the medical profession has rested upon two pillars: the ability of the profession to determine the health policy agenda, and to define areas out of bounds for non-professionals.[341] Autonomy is portrayed as an indispensable hallmark of professionalism.[342] Autonomy, according to Freddi, includes the following elements: the remuneration of doctors according to a fee-for-service formula determined by the doctor; the right to independent practice – clinical autonomy – where diagnostics and therapeutic decisions are made between the doctor and the patient with no external control; the responsibility to lead and coordinate other health professionals; and addressing professional issues according to a social consensus model with the profession.[343] Tolliday, on the other hand, suggests autonomy includes: the right to independent practice; the right to refuse an individual patient; the responsibility to lead and coordinate other health professions; and the overarching primacy of medical knowledge.[344] However autonomy is determined, there is no question but that the profession wanted to retain as much autonomy as possible. Its retention was a key part of the implicit bargain the medical profession reached with government as part of the negotiations around the formation of the NHS. Autonomy has always been granted to the profession by society, and particularly by the state – a conferral of power which inevitably involves the profession in the political process in Britain and Canada.[345]

In broad terms, part of the implicit bargain between the profession and the state was that the state would not intervene in the profession's exercise of clinical judgement if the medical profession did not challenge the national budget, undertook the rationing of health resources at the bedside, and worked constructively to make the NHS system work.[346] But the bargain also went further than this. Aneurin Bevan, the Secretary of State for Health when the NHS

[341] Klein, "*New Politics*", *supra* note 306.
[342] See, for example, G. Freddi, "Problems of Organizational Rationality in Health Systems: Political Controls and Policy Options" [Freddi, "Rationality"] in Freddi & Björkman, *supra* note 19 at 1; H. Tolliday, "Clinical Autonomy" in E. Jacques, ed., *Health Services: Their Nature and Organisation and Role of Patients, Doctors, Nurses, and the Complementary Professions,* (London: Heinemann, 1978) 32 [Tolliday].
[343] Freddi, "Rationality" *ibid.*
[344] Tolliday, *supra* note 342.
[345] Freddi, "Rationality", *supra* note 342 in Freddi & Björkman, *supra* note 19.

was formed, famously remarked he had to "stuff their [hospital consultants] mouths with gold" to get their cooperation.[347]   The government created a system of distinction awards where consultants could get increased salaries, based solely on the recommendations of their colleagues. Consultants could also retain their private practices, and 'private' beds would be available for their use in public hospitals. However, government was required to do more than wave its fiscal wand to ensure cooperation; a variety of other concessions to the medical profession had to be made, with the result that under the NHS doctors preserved their professional autonomy as well as their influential position at the centre of health service policy development and provision.[348]

Another part of the bargain was that government constituted the NHS to have parallel authority structures: a managerial structure and a clinical structure for the medical profession.[349]   It brought the structures together in "consensus management", which gave effective veto power to the medical profession over decisions made at any and every level.[350] Within this system, the role of the hospital manager has been described as that of a diplomat mediating between different interests with no authority over clinicians.[351]   Managers did not perceive that it was their role to exercise any control over doctors.[352]   This perception was reinforced by the system. For example, a 1979 memorandum from the Department of Health and Human Services stated, "It is the purpose of management to support them [doctors, dentists, nurses and other health professionals] in giving that service."[353]   Conflict was contained and limited through the structural necessity of obtaining consensus between the medical profession and managers, a theme that runs through the history of the NHS.[354] Within the overarching budgets set out by the central state and the regions, doctors had

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[346] R. Klein, *The Politics of the National Health Service,* 2nd ed. (London: Longman, 1989) [Klein, "*Politics,* 2nd ed."]; Giaimo, *supra* note 306.

[347] Cited in *Oxford Dictionary of National Biography,* online: *Oxford Dictionary of National Biography* <http://www.oup.com/oxforddnb/info/freeodnb/magazine/health/>.

[348] Tuohy, "Logics" *supra* note 35; Lewis, *supra* note 305.

[349] Tuohy, *ibid.*

[350] *Ibid.*

[351] *Ibid.* at 163 and Giaimo, *supra* note 306.

[352] Giaimo, *ibid.*; Klein, "*New Politics", supra* note 315; Tuohy, "Logics" *supra* note 35; S. Harrison & R. Schulz, "Clinical Autonomy in the United Kingdom and the United States: Contrasts and Convergence" [Harrison & Schulz] in Freddi & Björkman, *supra* note 19 at 198.

[353] U.K., Department of Health and Social Services, *Patients First* (London: Department of Health and Social Services, 1979) cited in Harrison & Schulz, *ibid* at 203.

[354] Klein*, "New Politics", supra* note 306.

significant autonomy in determining what services were provided, to whom and how, and, in general, medical self-governance proceeded on a collegial basis. The institutionalized medical voice defined issues in terms that ensured that they would represent legitimate expert authority.[355] Thus, the medical profession had great power within the system.[356]

The features identified above persisted, and in some cases were strengthened, through the reforms of 1974. The reforms established 15 regional health authorities (RHAs), 90 area health authorities linked to family practice committees, 200 district management teams, and 200 community health councils. The 1974 reorganization brought the tripartite structure – hospitals, primary care and public health and community services – together under one management framework.[357] The reforms of 1974 promoted a more managerialist ethos and emphasized planning and consensus management. But the reforms may have further contributed to the power of the medical profession. The reforms set the voice of the expert, the medical profession, "into the concrete of the institutional structure even more firmly than Bevan's [Secretary of State responsible for the creation of the NHS] design had done."[358] For example, doctors gained formal representation on regional and district authorities. Since decisions at these levels were thought to require the cooperation of the doctors as experts in the area, it was seen to be a policy imperative to build medical participation formally into the decision-making machinery.[359]

In summary, the key features of the NHS before the 1980s, according to Klein, included a high level of centralization, a geographically dispersed administrative structure (14 regions), a tripartite structure (hospitals, primary health and public health and community care), a corporatist style of policy-making, a lack of clear lines of accountability within its management structure, and a weak system of democratic accountability.[360]

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[355] *Ibid.*

[356] *Ibid.*

[357] Tuohy, "Logics" *supra* note 35.

[358] Klein, "*Politics*, 2nd ed." *supra* note 346.

[359] Giaimo, *supra* note 306.

[360] Kingdom, *supra* note 319.

Canada

Health services in Canada were viewed as a local matter when the federal Constitution was passed in 1867. As discussed in detail in the following chapter, the Constitution gave most health-related powers to the provinces, saving powers in respect of the provision of health services to the armed forces, federal prisoners, aliens (i.e. non-Canadians) and First Nations and Inuit peoples, and powers over quarantine.[361] In Canada, the movement towards a comprehensive publicly funded health system, and indeed a social services system, was attained in a rather different and far more incremental manner than in Britain.

Lahey asserts three roles for governments in Canada in respect of health services: stewardship; regulation; and funding. Governments perform a stewardship role – they establish the general objectives of the system, monitor and evaluate the system's success against its objectives, coordinate and ensure continuity between different parts of the system, and ensure reasonable access.[362] Lahey sums this up by stating:

> In short, it is the general state responsibility of ensuring that there is a functioning health care system in place, capable of delivering to citizens the level of health care that most would agree should be, and that international law says must be, available to all people.[363]

Governments also regulate the quality of health services (discussed in the preceding chapter) and fund the delivery of health services.

Soon after confederation, the four Canadian provincial governments within the confederation began to take on a larger role in regard to healthcare services, for instance in respect of public health and sanitation.[364] Ontario was the first to pass legislation signalling a greater role for the province in regard to healthcare. The *Charity Aid Act* of 1874 stated that all not-for-profit municipal, charitable and religious hospitals were required to accept patients

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[361] This is discussed in more detail in Chapter 4.
[362] Lahey, *supra* note 306.
[363] *Ibid.* at 15.

on the basis of medical need in return for a per diem payment and some regulatory oversight.[365] Much later in the early 1900s the Prairie provinces, particularly Saskatchewan, took the lead in health policy influenced by the cooperative movement which saw the collective development of mutually agreed-upon resources for community benefit.[366] During the First World War, Saskatchewan amended its municipal legislation to facilitate the formation of municipal hospital districts and to allow the appointment of salaried doctors to provide general medical services to the community.[367] The scheme spread on a limited scale to Manitoba and Alberta shortly thereafter.[368]

In the 1920s and 1930s, when Canada was reeling from the devastating effects of the Great Depression, that there were a number of policy inquiries, especially in the Prairie and Western provinces, into the feasibility of establishing a provincial health plan. The Depression generally reinforced the need for communal action and expanded the role of governments in respect of the provision of social services.[369] However, attempts to establish a role for provincial governments to fund health services remained unsuccessful in the face of concerted opposition.[370] For example, the government of British Columbia introduced legislation in 1936 to provide health services for low-income people, an attempt that ultimately failed because of sustained objections from the medical profession.[371] While this undertaking proved unsuccessful, it was significant as it focused public discussion of the issue and garnered public support for a larger role for government in healthcare.[372]

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[364] See generally G. Boychuk, *Patchworks of Purpose: The Development of Provincial Social Assistance Regimes in Canada* (Montreal: McGill-Queens University Press, 1998).

[365] G. Marchildon, *Health Systems in Transition: Canada,* (Toronto: University of Toronto Press, 2006) at 19 [Marchildon].

[366] Gray, *supra* note 306.

[367] Marchildon, *supra* note 365 at 19; Gray, *ibid.*

[368] Gray, *ibid.*

[369] R. Duncan, M. Morris & L. McCarey, "Canada" in J. Johnson & C. Stoskopf, eds., *Comparative Health Systems: Global Perspectives* (Sudbury, Mass.: Jones and Bartlett, 2010) 59 [Duncan].

[370] It was unclear whether the federal government had the constitutional authority to provide these forms of assistance until a series of cases where the Privy Council determined that the federal government had not authority to provide national unemployment schemes, resulting in a constitutional amendment. See, for example, *Canada (Attorney General) v. Ontario (Attorney General); Reference re Employment and Social Insurance Act,* [1936] S.C.J. No. 30, [1936] S.C.R. 427 (S.C.C.) and *Canada (Attorney General) v. Ontario (Attorney General); Reference re Employment and Social Insurance Act* [1937] A.C. 355 (J.C.P.C.) affirming the Supreme Court of Canada [*Canada v. Attorney General*].

[371] Tuohy, "Logics" *supra* note 35.

[372] Gray, *supra* note 306.

During the Second World War, the federal government, following international trends, focused more extensively on the creation of social policy, including health policy. The context was dissimilar from Britain, as the prospect of mass casualties from bombings was slight and hence reorganization of hospital facilities unnecessary. There was also not the same degree of concern as to the general state of the population's health. Any deficiencies in the structure of then-current services and the necessity to rationalize services in the national good was not thrown into such stark relief as it had been in Britain. The post-war atmosphere was different in Canada from that in Britain. Nevertheless, the growing dominance of Keynesian economic thought had an important impact on the health systems in both jurisdictions. After the federal government's powers were constrained by the courts, on one view it could only influence health policy through transferring funding to the provinces with conditions attached.[373] These conditions would be matters of federal provincial negotiation[374] – "[a] national insurance policy, then, would inevitably require a coalition of support within and between levels of government."[375] While there was broad public support for the introduction of some form of national insurance, including some conditional support from professional groups, the provincial governments generally were highly sceptical of federal intentions, believing there had been considerable federal "aggrandisement" during the war years.[376]

The end-of-war federal Liberal government was elected by a bare majority, and hence could not claim a mandate for extensive change.[377] Post-war, it proposed the introduction of compulsory national health insurance system to be partially funded by the federal government. This was rejected by the provinces as constituting too great an incursion upon their jurisdiction and because of disagreements over taxation policy (funding was offered on the condition that the provinces would give up certain taxation powers).[378] The federal government was only weakly committed to funding a health insurance system, and so was

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[373] This view is contested by some. See, for example, A. Petter, "Federalism and the Myth of the Federal Spending Power" (1989) 68 Can. Bar. Rev. 448 [Petter]; S. Choudhry, "Constitutional Change in the 21st Century: A New Debate over the Spending Power" (2008) 34 Queen's L.J. 375 [Choudhry]; S. Choudhry, "Recasting Social Canada: A Reconsideration of Federal Jurisdiction over Social Policy" (2002) 52(3) U.T.L.J. 163 [Choudhry, "Social Policy"].
[374] Tuohy, "Logics" *supra* note 35.
[375] *Ibid.* at 41.
[376] *Ibid.*
[377] *Ibid.*

not prepared to negotiate further with the provinces.[379] Instead, the federal government committed itself to a program of hospital building as a public works measure rather than as part of a welfare program.[380] In the post-war years, medical services continued to be provided on a private fee-for-service basis, and hospitals were operated by voluntary not-for-profit or for-profit organizations. The federal grants program that provided funding for building hospitals was successful in increasing the numbers of hospitals, most of which were operated by municipal authorities and other not-for-profit organizations, and the numbers of private-for-profit hospitals decreased (although there were not all that many to begin with).[381]

The 1944 election of the progressive Douglas government in Saskatchewan saw the first moves to implement large-scale policy and regulatory change to ensure universal access to health services. The government proposed to introduce a comprehensive universal health insurance scheme encompassing the delivery of hospital and doctor services through a regionalized model. This proposal met with intense opposition, particularly from the medical profession. The medical profession objected to regionalization, which would reduce referrals to specialists clustered in the two major cities, and democratization, as elected boards would limit the influence of the medical profession.[382] They also objected to the continuance of the municipal doctors scheme where doctors were paid a salary, preferring a fee-for-service payment model.[383] The government modified its proposals to agree to administration by an independent commission and fee-for-service payment for doctors. Ultimately, government decided pursuing its policy of a comprehensive scheme would be too difficult in the face of the concerted opposition of the medical profession, and left the funding of medical services to a later time, focusing instead on hospital services.

Thus, in 1947, Saskatchewan implemented a universal hospital services plan which provided funding, initially on a per diem basis, and then, after per diems were found to increase utilization, a flat fee based on 90 per cent occupancy rates, for citizens to access hospital

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[378] E. Vayda, "The Canadian Healthcare System" (1986) 7:2 J. Pub. Health Pol'y 205; Gray, *supra* note 306.
[379] Gray, *ibid.*
[380] Lewis, *supra* note 305.
[381] Tuohy, "Logics" *supra* note 35.
[382] Gray, *supra* note 306.
[383] *Ibid.*

services.[384] These included x-rays, laboratory testing, and some medications, provided they were medically necessary.[385] The Saskatchewan model created the pattern for what was to come. It institutionalized what Naylor describes as the "private ownership, public payment" bargain between health-providers and the state.[386] In 1949, British Columbia followed Saskatchewan, as did Alberta, albeit incompletely, one year later.[387] Newfoundland had a similar scheme, although it still had dominion status and was not yet part of Canada.

The late 1950s and 1960s heralded an era of "cooperative federalism" where federal and provincial governments were prepared to work cooperatively together in the national interest.[388] This was significant timing for health policy, as Tuohy notes, because "the British NHS was no longer a bold and promising conception: it was a real-life example" – an example that had attracted much critique, and especially vitriolic criticism from the American Medical Association decrying socialized medicine.[389] The federal government remained reluctant to act on health issues until pressure from the provinces and the public forced it to the negotiating table.[390] After two years of negotiations in 1957, the federal government entered into a cost-sharing agreement with the provinces and territories to fund a health insurance program for the delivery of hospital services. The *Hospital Insurance and Diagnostic Services Act 1957* (HSD Act) set out the conditions that had to be satisfied in order for a province to receive funding.[391] Basically, the provinces were required to meet scope and universal coverage requirements to receive 50 per cent funding from the federal government. By 1961, all provinces had complied with the minimal conditions and were receiving funding. This was an important first step, as agreement established the legitimacy of a federal role in health insurance, even if its constitutionality remains a contested question.[392]

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[384] See, for example, Marchildon, *supra* note 365; Tuohy, "Logics" *supra* note 35; A. Maioni, *Parting at the Crossroads: The Emergence of Health Insurance in the United States and Canada* (New Jersey: Princeton University Press, 1998) [Maioni].

[385] See, for example, Marchildon, *supra* note 365; Tuohy, *supra* note 35; Maioni, *ibid.*

[386] C. Naylor, *Private Practice, Public Payment: Canadian Medicine and the Politics of Health Insurance 1911-1966* (Kingston: McGill-Queen's University Press, 1986) [Naylor]; see also J. Lavis, "Political Elites and Their Influence on Health Care Reform in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada: The Romanow Papers: Volume III,* (Toronto: University of Toronto Press, 2004) 257 at 259 [Lavis].

[387] See, for example, Marchildon, *supra* note 365; Tuohy, "Logics" *supra* note 35; Maioni, *supra* note 384.

[388] Tuohy, *ibid.*

[389] *Ibid.* at 51.

[390] Gray, *supra* note 306.

[391] *Hospital Insurance and Diagnostic Services Act* S.C. 1957 c.8 [HI Act].

[392] Duncan, *supra* note 369, but see Petter, *supra* note 373.

While the introduction of universal insurance schemes for the funding of hospitals services was largely uncontentious, the same could not be said for plans to extend the insurance program to include services provided by doctors. The medical profession continued to oppose any plans for publicly administered medical services, as this would involve negotiations with government over fee levels and methods of payment. The profession strongly advocated the retention of private insurance plans controlled by the medical profession.[393] In 1962, Saskatchewan again took the initiative, extending its health insurance program to include medical services. This extension was controversial. It was bitterly opposed by doctors and triggered a province-wide strike lasting 23 days. The government of Saskatchewan was in a weak position, facing a monopolistic medical association with regulatory, licensing, and political powers, a doctor shortage, and a recruitment and retention problem.[394] It also recognized that it needed the cooperation of the medical profession for the scheme to succeed. Accordingly, an end to the strike was negotiated when government agreed to recognize the autonomy of the medical profession through retention of fee-for-service payments, professional control over payment-setting mechanisms, and the ability of doctors to opt out of the Medicare scheme.[395]

When Saskatchewan designed its medical insurance scheme, it did so, according to Taylor, believing that the success of private insurance plans had "irrevocably institutionalized"[396] fee-for-service payment mechanisms and hence the autonomy of doctors. The model that Naylor describes as "private practice, public payment" was at the heart of the implicit bargain struck between the profession and the government of Saskatchewan: a bargain that was replicated across all Canadian health systems.[397] The Saskatchewan insurance program was popular and administratively straightforward, and set the pattern for provincial and federal reforms.[398] However, in 1963, Alberta adopted a different approach and chose to subsidize

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[393] Gray, *supra* note 306.
[394] *Ibid.*
[395] Marchildon, *supra* note 365; Gray, *supra* note 306.
[396] M. Taylor, *Health Insurance and Canadian Public Policy: The Seven Decisions that Created the Canadian Health Insurance System,* (Montreal: McGill-Queen's University Press, 1979) at 268, cited in Tuohy, "Logics" *supra* note 35.
[397] Naylor, *supra* note 386.
[398] Gray, *supra* note 306.

private insurance premiums for low-income earners as opposed to the adoption of a comprehensive plan.[399]

In 1961, the federal government, prodded by the medical profession, convened a royal commission of inquiry to examine health services in Canada. In a blow to the medical profession, the commission of inquiry rejected voluntary private insurance models, seen in the US and in Australia, in favour of establishing a comprehensive universal health insurance program to include hospital and medical services. Its 1964 report described the Saskatchewan model as:

> … a sound blend of federal financial support and respect for provincial responsibility. In fact, it goes beyond that for in its administration it utilises a number of joint Federal-Provincial committees and working parties. It is a remarkably successful example of what has long been termed 'cooperative federalism.'[400]

The medical profession opposed the commission's recommendations, fearing a loss of autonomy.[401] After a federal–provincial conference in 1965, and in the face of objections by Alberta and Québec, as well as at least one influential cabinet member, the *Medical Care Act 1966* (MC Act) was passed with only two dissenting votes.[402] As Tuohy notes:

> [t]he adoption of medicare was part of a remarkable era in Canadian public policy development, from 1958 to 1971, that also saw the adoption of federal–provincial shared-cost programs for postsecondary education and social assistance, and the establishment of a public pension program involving complex federal–provincial arrangements. These various programs, in effect, constituted a mutually reinforcing momentum of social policy change.[403]

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[399] Tuohy, "Logics" *supra* note 35.

[400] Canada, Royal Commission on Health Services, *Royal Commission on Health Services,* vol. 1 & 2. (Ottawa: Royal Commission on Health Services, 1964) at 413 (Chair: E. Hall), cited in Gray, *supra* note 306.

[401] *Medical Care Act* S.C. 1966 c. 64 [MC Act]; *Canada Health Act* R.S.C. 1984 c. C-6 [CH Act].

[402] Gray, *supra* note 306; Tuohy, "Logics" *supra* note 35.

[403] Tuohy, *ibid* at 55.

The acceptance of medical services insurance remained contentious at the provincial level, with some provinces believing they had been coerced into agreement by the federal government, despite deep-seated objections to its form. Federal cost-sharing was available for both hospital and doctor services for provinces and territories complying with the general principles of universality, portability, public administration, and comprehensiveness, thus defining the shape of Canada's health systems. It was a program of its time, cementing hospitals and doctors at the centre of the health-delivery paradigm. It also preserved significant autonomy for the provinces and for hospitals and doctors in broader systemic management issues. Significantly, what it also did was to create 12, later 13, different health systems within Canada, with little formal integration between them, except that required by the Medicare principles.[404]

Federal legislation established the parameters for provincial/territorial governments; however, the principles are very general, leaving considerable discretionary leeway for provincial/territorial governments.[405] For example, while most provinces used tax-based systems to fund their health insurance schemes, British Columbia, Ontario and Alberta collected insurance premiums. But despite this, Hurley, Lomas, and Bhatia note:

> With the exception perhaps of Quebec, over the past twenty five years the provincial health care systems have shared not only the five principles of Medicare but also similar delivery and management structures. In the coming years they may resemble each other only in sharing the principles of Medicare.[406]

Interestingly, the federal government chose not to place any further conditions on funding transfers – for example, that funding for the health system would be conditional on restructuring the governance of the health system in that province or territory. This lack of action by the federal government points to continued uncertainties about the

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[404] A. Maioni, "Roles and Responsibilities in Health Care Policy" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada: The Romanow Papers: Volume III* (Toronto: University of Toronto Press, 2004) 169 [Maioni, "Roles and Responsibilities"].

[405] K. Banting & S. Corbett, "Health Policy and Federalism: An Introduction" in K. Banting, ed., *Health Policy and Federalism* (Kingston, Ont.: Queen's University Press, 2004) 1 [Banting & Corbett].

[406] J. Hurley, J. Lomas & V. Bhatia, "When Tinkering is Not Enough: Provincial Reforms to Manage Healthcare Resources" (1994) 37:3 Public Admin. 514, quoted in Banting & Corbett, *ibid* at 33.

constitutionality of imposing such conditions.[407] But it also may perhaps point to the political costs associated with the imposition of such terms arising from Québec's separatist aspirations and, increasingly, concerns about the alienation of the western provinces.

What finally emerged in 1972, when all provinces became eligible to receive funding, was a universal social insurance program. Unlike the NHS, the Canadian system does not constitute a national model and nor could it considering the constitutional responsibilities of the provinces and territories. Maioni suggests, "A better description is that of provincially regulated healthcare systems financed by public revenues, and a federal fiscal contribution tied to the maintenance of certain standards across the provinces."[408] Although some uniformity could perhaps be expected to be achieved through the principles set out in the MC Act and the HSD Act, these principles were reasonably general, leaving considerable scope for provincial innovation. Medicare programs were administered by the provinces and territories and jointly funded by the federal and provincial/territorial governments. The program enabled access to "medically necessary" hospital and medical services, provided by non-profit or for-profit actors. It is a publicly funded not-for-profit private delivery system. Uniquely, there was little in the way of formal parallel private delivery system for access to "medically necessary" services,[409] resulting in a reduced role for private insurance plans. As noted by Evans, and unlike Britain, Canada does not have a completely socialized health system(s).[410] Only the health insurance programs could be said to be socialized, because for most doctors and hospital services, they involve exclusive funding by the state (at all levels) to ensure universal access to "medically necessary services".[411]

At the close of the 1970s, the hospital sector was composed of facilities operated by municipal and provincial governments and not-for-profit community or charitable trusts. Generally, the accountability of hospitals was to the communities in which they were based

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[407] Others argue that the federal government both could and should act more aggressively by requiring the provinces and territories to take action to ensure the efficient and effective management of the health system. See, for example, Choudhry, "Social Policy", *supra* note 373.

[408] A. Maioni, "Federalism and Health Care in Canada" in K. Banting, ed., *Health Policy and Federalism* (Kingston, Ont.: Queen's University Press, 2004) 173 at 179 [Maioni, "Federalism"].

[409] Kenny, *supra* note 97.

[410] Cited in F. Stevens, "The Convergence and Divergence of Modern Health Care Systems" in W. Cockerham, ed., *The Blackwell Companion to Medical Sociology* (Malden, MA & Oxford: Blackwell, 2005) at 159 [Stevens].

[411] *Ibid.*

as well as to provincial/territorial governments in respect of financing and regulatory or any contractual requirements.[412] Hospitals were generally financed by global budgets, latterly based on case-mix formulas, negotiated with the state or territorial governments.

Unlike in Britain, in Canada regionalization within provincial and territorial health systems had not yet occurred. This resulted in a more centralized structure, at the heart of which was the Health Department, coupled with local provision of services. The principle of localism was perhaps more finely developed under the Canadian models than under the British regionalist approach due to a greater involvement with the local community.[413] The convergence here is seen in regard to the principle of localism – that local or regional health authorities are better placed to evaluate and provide for the specific needs of that community.

Doctors were not government employees, were usually not the employers of hospitals, but instead had admitting privileges and belonged to the medical staff, which was essentially a self-governing entity within the hospital.[414] Doctors were paid on a fee-for-service basis – the fee structure negotiated between the provincial/territorial medical associations and the government or its delegate. As such, they were not even independent contractors with the government; rather, they were said to have an agency relationship with the state.[415] Remuneration was negotiated with government which, in all provinces with the exception of Québec, meant that negotiations occurred in relation to the overall rate of increase of the schedule. It was for the profession to determine the relative values of each item in the schedule. Doctors and hospitals remained independent of direct control by the state.[416] The independence of doctors from hospitals is also clearly established in Canadian health law.[417]

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[412] P. O'Reilly, "The Canadian Health System Landscape" in D. Adams, ed., *Federalism, Democracy and Health Policy in Canada* (Kingston: Queen's University Press, 2001) 17 [O'Reilly].

[413] It is interesting that in the 1980s and 1990s, regionalization gave way to localism in Britain, whereas in Canada localism was replaced (eventually in all provinces and territories) with regionalism.

[414] Lahey, *supra* note 306.

[415] Tuohy, "Logics" *supra* note 35.

[416] The separation of the delivery system from government was later illustrated by *Stoffman v. Vancouver General Hospital*, where the Supreme Court of Canada held that the provisions of the *Canadian Charter of Rights and Freedoms* were not applicable as the government of British Columbia could not be said to control the hospital. *Stoffman v. Vancouver General Hospital* [1990] S.C.J. No. 125, [1990] 3 S.C.R. 483 (S.C.C.), although see *Eldridge v British Columbia (Attorney-General),* [1997] 3 S.C.R. 624 (S.C.C.).

[417] See, for example, *Yepremian v. Scarborough General Hospital,* [1978] O.J. No. 3457, 88 D.L.R. (3d) 161 (Ont. H.C.J.).

By the 1970s, the costs of funding the national insurance system had escalated and cost-control became a significant issue for policy debate. In the 1970s, it was first noted that although Britain spent less on health than Canada, the health outcomes of populations were very similar.[418] In practice, it appears that federal states generally spend more of the nation's gross domestic product (GDP) on health than non-federal states, possibly because of greater opportunities to cost-shift between government actors.[419] The *Federal–Provincial Fiscal Arrangement and Established Programs Financing Act 1977* reduced federal contributions to 25 per cent of the 1977 provincial expenditure on hospitals and doctors and tied subsequent increases to the GDP. Global budgeting based on case-based funding formulas for hospital services was introduced within provinces in an attempt to control costs, and changes to medical fee schedules were limited.[420] This resulted in the provinces having to spend more to support the health system. By 1979, the public rhetoric was that the health system was under-funded and that its principles were being undermined. Citizen groups mobilized to defend universal health insurance.[421] In 1979, the federal government convened a further review of the Canadian health system; the results of this review will be discussed in Chapter 5.

Convergences and Divergences

There were obviously some marked similarities, as well as some substantial differences, between the health systems in each jurisdiction by the end of the 1970s. But what is important is what the logics of the operations of each system(s) might illustrate about the future directionality and nature of regulation within that system when addressing patient-safety issues.

The nature of the health system in place in each jurisdiction is different, with Canada using an insurance-based model and Britain a model of national provision. Klein suggests that the provision of state-funded health insurance emphasizes the right of individuals to access healthcare, whereas a national model emphasizes the obligation of public authorities to make

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[418] Gray, *supra* note 306.
[419] Banting & Corbett, *supra* note 405 at 25–29.
[420] Gray, *supra* note 306; O'Reilly, *supra* note 412.

provision for the health of the community at large.[422] A systemic focus on individual rights to access healthcare may result in an increased focus on *access* or entitlement issues, at the expense of concern about other facets of the system. Indeed, the traditional focus of concerns for Canadian citizens is access – equality among persons, distance, travelling, and waiting times.[423] This is not to say that access is not of concern to the British public, who have indeed been concerned about the overt rationing of health services, nor is it to say that other issues are not of importance to Canadian citizens. However, the tensions occurring within the negotiation processes that occur between federal and provincial/territorial governments, governments and hospitals, and governments and health-providers focus attention on allocation issues in a manner unknown in Britain. The fact that there is no real parallel private system in Canada for the provision of "medically necessary" services, apart from heading across the border, also focused attention on equality and equity of access issues for *individuals* in a way unknown in Britain; in Britain, the national system places the focus on *government's* role and responsibility for the delivery of health care.

An insurance model is consistent with what some suggest are individual medical values – that the provision of medical and health services is based on an agreement, transaction, or contract, depending on your point of view, between a patient and a health (especially medical) professional.[424] Thus, insurance schemes may inherently retain a market orientation, with competition between players in the system providing some assurance of effectiveness, efficacy, and quality of services. In contrast, the NHS was seen as a triumph of socialist ideology inspired by egalitarian ideals,[425] and it has been described as "a model based on seeing health as a public good rather than an individual right."[426] Consistent with this philosophy, the relationship between health professional/provider and patient in the NHS was no longer to be mediated by liberal–individualist notions of a private contract between patient and health provider,[427] but rather through a quasi-contract between patients, the public, health professionals/providers and the state. State mediation in this relationship was

[421] Gray, *ibid.*
[422] Klein*, "New Politics", supra* note 306.
[423] Duncan, *supra* note 369.
[424] Klein*, "New Politics", supra* note 306.
[425] *Ibid.*
[426] *Ibid.* at 3.
[427] Porter, *Blood, supra* note 302.

paternalist and protective in intent to ensure the welfare of its citizens as a whole.[428] This separation points to the beginnings of a divergence between the systems. Market mechanisms with a liberal individualistic focus may result in a system that relies, at least to some extent, on those mechanisms, regulation by litigation initiated by individuals, and a reliance on collegial and corporatist mechanisms. Conversely, a less individualistic, more collectivist orientation may provide more interventionalist regulatory logic.

It is not just an insurance model, as compared to a national model, which may indicate differences between jurisdictions, but also payment methods through which health services are funded. Payment methods can be correlated by the degree of "organizational density" of public interventions in health.[429] At the less organisationally dense end of the spectrum are pure fee-for-service payments; then payments through private insurance with no cap on payment levels; private insurance with capped payments; public or semi-public insurance schemes; salary schedules allowing for individual merit increases; salary schedules linked to a combination of rank and seniority; and capitation.[430] In Canada, health services are generally clustered towards the middle and less organizationally dense end of the spectrum, whereas in Britain payment mechanisms are clustered towards the more highly organizationally dense end of the spectrum. The degree of organizational density evident in health systems organization may indicate a culture that is more or less likely to use increased regulatory and other forms of intervention to control activities within that sphere.[431]

The Canadian health systems do have some features in common with the NHS in that there is a distinct corporatist element within the health systems in each jurisdiction. Corporatism in this context refers to a merger of state and corporate power, a form of interest group politics or co-regulation, where the state structures a governance system to ensure participation by a specific group. The inclusion of group(s) within the governance structure of a sector or system provides the system with some legitimacy. It also gives the interest group in question a monopoly of access to the state and at least a modicum of power within

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[428] *Ibid.*

[429] Döhler, *supra* note 339.

[430] Freddi, "Rationality", *supra* note 342 in Freddi & Björkman, *supra* note 19 at 1.

[431] The converse may also be true. Light organizational density seen in the US health systems has resulted in a greater density of arms length regulation. In a non-health context, see Moss, *supra* note 5.

that system.[432]   A group is a politically representative organization which controls, or purports to control, people and activities within its jurisdiction, as facilitated or sanctioned by the state. The corporatist model is predicated, to a certain extent, on the interest group in question being a so-called "virtuous"[433] or "responsible"[434] actor. If corporatism is to be effective, the interest group embedded within the corporatist model must be able to control, as much as is possible, the practices and conduct of its members and ensure compliance with its norms, or else the implicit bargain at the heart of the corporatist agreement is void. In the health context in both jurisdictions, the corporatist approach can be seen through the inclusion of the medical profession in all stages of the decision-making processes within the sector, particularly in the consensus management structure that was explicit in Britain and implicit in Canadian health systems.

In both jurisdictions, accommodation with the medical profession was believed to be central to the establishment, viability, and sustainability of modern health systems. Tuohy's review of the NHS concluded that it was:

> a system that gave heavy weight to state authority and hierarchical mechanisms in budgetary matters, but left much discretion in clinical matters to individual medical professionals operating through collegial decision-making networks. In these respects it was a state-sponsored system of 'hierarchical corporatism.'[435]

This was epitomised by the sense "… that the doctor knew best not only in the consulting room but also in the corridors of Whitehall."[436]   Corporatism was reasonably highly developed as an informal process in the British NHS from its formation, and was formalised after the 1974 reforms. However, the corporate model in the NHS had a weakness in that the centralizing tendencies described above, and the statist tendencies described below, created the possibility, if not probability, that circumstances might arise where corporatism was declared antithetical to the public interest. This was especially so given the nature of the

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[432] Giaimo, *supra* note 306.

[433] J. Braithwaite, "Rewards and Regulation" (2002) 29 J.L. & Soc'y 12 [Braithwaite].

[434] R. Kagan & J. Scholz, "The 'Criminology of the Corporation' and Regulatory Enforcement Strategies" in K. Hawkins & J. Thomas, eds., *Enforcing Regulation* (Boston: Kluwer-Nijhoff, 1984) 67 [Kagan].

[435] Tuohy, "Logics" *supra* note 35 at 41.

[436] Kingdom, *supra* note 319 at 143.

relationships between the medical profession and the state, with most doctors being employees or independent contractors and thus, at least to some extent, under the control of their employer/contractor – whether the employer or contractor chose to exercise that control or not. Doctors were lower in a hierarchy in an employment sense, although the government chose for reasons of expediency to overlook that fact in what was then the public interest.

Tuohy suggests that "the central structural axis" of Canadian health systems was "an accommodation between the medical profession and the state …"[437] Tuohy suggests that Canada is perhaps the country in the world where the accommodation between the state and the profession is the most highly developed and most integral to the functioning of the system.[438] The Canadian health systems had elements of a liberal ideology; doctors, for example, are not employees of the state or of hospitals but independent entrepreneurs in private relationships with patients.[439] The implicit bargain between the state and the profession was first established in Saskatchewan, where the medical profession accepted the role of the state as a single payer, recognizing this would constrain their entrepreneurialism in so far as it came to price setting, although not in other respects, such as location of practice.[440] In return, the state recognized the continuance of professional autonomy in respect of clinical practice and practice ownership. The profession has more formal autonomy than it does in Britain, as the state is not an employer or a contractor but has a quasi-agency relationship with the profession.[441] As Tuohy puts it:

> [A]gency relationships between state and professional bodies entrusted physicians
> with making decisions about the provision of care within resource limits.
> Mechanisms of control within these structures relied heavily on hierarchical lines of
> accountability in budgetary matters and upon collegial networks among professionals
> in matters relating to the quality and appropriateness of care.[442]

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[437] Tuohy, "Logics" *supra* note 35 at 55.
[438] *Ibid.*
[439] Maioni, "Federalism", *supra* note 408.
[440] Giaimo, *supra* note 306; Tuohy, "Logics" *supra* note 35.
[441] Tuohy, *ibid* at 55.
[442] *Ibid.* at 164.

Doctors were placed at the heart of the decision-making system at all levels as a separate governance entity with considerable power and influence within service delivery and in terms of setting government policy.[443]   However, it is important to note that the nature of the accommodation with the profession varied in the different health systems: in British Columbia and Manitoba it was adversarial, in Québec it was statist, and in other provinces it was collaborative, albeit with episodes of conflict.[444]   Tuohy concludes that the Canadian health system(s) reflects the collegiality model of healthcare organization that gives predominant weight to medical professionals and to encouraging models of collegial governance between independent but mutually dependent policy actors.[445]   Although, as with Britain, the system is premised on accommodation and is corporatist in nature, the degree and quality of independence of the medical profession and doctors in the Canadian context creates a different dynamic – an agency relationship – which is more like a partnership between two equal parties.

Arguably, the agency dynamic established a preference for a co-regulatory model of regulation.   Co-regulation is a model where policy actors cooperate to create rules for a specific context.   Such negotiated policies pursue public and private interests.[446]   This co-regulatory framework is not just characteristic of the relationship between government and the professions, but also with hospitals, and is seen to some degree in the relationship between federal and provincial/territorial governments in the health context.   Thus governance trends in health systems in Canada incline towards reaching accommodations with other parties in the public interest.   Arguably, I suggest the deeper the co-regulatory corporatist relationship is embedded in the logic of the system, the harder it is to move to another other form of regulatory model.   Drawing again from path dependency, once a system starts down a path, it is difficult to reverse course.[447]

In both jurisdictions, corporatism may be challenged by any governance failures by the corporate partner.   In the patient-safety context, this raises a question about the adequacy of

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[443] *Ibid.*
[444] *Ibid.*
[445] *Ibid.*
[446] McDonald, "Working to Death" *supra* note 110.
[447] Pierson, *supra* note 47.

the medical profession's internal self-governance. In the NHS, there was no systematic peer review undertaken by any of the bodies representing the medical profession – the British Medical Association, the Royal Colleges, or the GMC – and any review within individual hospitals was driven by individuals and was sporadic at best.[448]   In Canada, peer-review systems were being developed by the profession – with the engagement and support of government. As discussed above, the real risk is that if a corporate partner is perceived to be shirking its governance responsibilities and to fall down on its side of the implicit bargain, it may find that the corporatist model comes under review.

Unlike Tuohy, Giaimo contends that the NHS was both corporatist *and* statist[449] and this constitutes another divergence between Britain and (most of) Canada. Statism is manifest in the NHS, argued Giaimo, through the role of the central state when it assumed responsibility for the provision of universal health care, financed through general revenue, and determined the national budget for healthcare.[450]   The state was at the centre of healthcare provision in Britain.

At the NHS's inception, government accountability for the NHS was considered critical because, as the then Secretary of State for Health Aneurin Bevan described it, "When a bedpan is dropped on a hospital floor, its noise should resound in the Palace of Westminster."[451] But, in practice, the chain of accountability within the NHS was flawed. In theory at least, the government, through mechanisms of parliamentary accountability, was publicly accountable for the operations of the NHS. The Secretary of State for Health was accountable through ministerial responsibly for his or her performance and for the performance of departmental employees. The difficulty faced by the state was that the NHS system was constituted in such a way that the central state could not prevent or respond to any deficiencies within the operations of the NHS because it had little or no power over the functions of local managers or doctors.[452]   In addition, it had little information about how hospitals actually spent their budgets and, even if it did have the information, information

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[448] Giaimo, *supra* note 306.

[449] *Ibid.*

[450] *Ibid.*

[451] Quoted in P. Day & R. Klein, *Accountabilities: Five Public Services,* (London: Tavistock, 1987) at 78 [Day & Klein].

[452] Giaimo, *supra* note 306.

systems could only measure inputs and outputs (e.g. numbers of hip surgeries performed), not outcomes (e.g. hip surgeries performed with low rates of complications reducing hospital stay times and increasing the prospect of rehabilitation), so there was no information about the quality or effectiveness of the services provided.[453] There were unclear lines of accountability within the hospitals, particularly after the 1974 reforms, after which no one single person could be held accountable for the failures of a unit.

Within the NHS, the requirements for political accountability clashed with the managerial and clinical accountabilities as constituted within that system. While the principle of localism served desirable policy ends, the realities of the statist model and the political consequences for governments in not being able to ensure effective accountability or to assert control over the operations of the NHS[454] could result in the principle of localism being revisited in the interests of greater control by the centre. This may particularly be so when it is coupled with pre-existing centralist regulatory tendencies within the NHS and the British governance model more generally. Reinforcing any centralizing, statist tendencies is the fact that the government owns the bricks and mortar of the NHS, and hospital doctors are employees of the state, with GPs and other primary health-providers being contractors to the state. Despite a commitment in principle to corporatism, employers and contractors have the power to create and enforce conditions of employment that regulate the conditions within and upon which an employee performs their job or the terms of the contract with independent contractors. Hence, the roots of a possible regulatory shift towards a greater role for the state in assuring the effective regulation of the health system may perhaps be seen.

With the exception of Québec, none of the Canadian health systems are statist in the same way in which statism manifested in the British NHS. The structures of the Canadian system make it quite clear that the federal government has limited power in the health arena, as, outside of the specific areas discussed earlier and in the next chapter, its health policy and regulatory influence is, in practice, limited to what it can negotiate or is prepared to negotiate with the provinces/territories. Likewise, although the provinces/territories have more

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[453] Klein, *"New Politics", supra* note 306 and Giaimo, *supra* note 306.
[454] Moran, *"Governing"* supra note 37.

regulatory leverage and responsibility, the lines between government, hospitals, and doctors are negotiated with co-regulatory partners. This is not to say that the pressures for political accountability were not as real and immediate as those experienced in the British system, because the history of many Canadian elections illustrates concerns about the management of health systems; it is to say, however, that the co-regulatory nature of regulation in this area may afford more scope for circumlocution. It is also to point out that the role of the state, again with the exception of Québec, as an actor within the health system is traditionally more limited than the expansive role assumed by the British government.

Additionally, consumerism was a more potent force within the Canadian health systems, as patients knew that doctors and hospitals were operationally independent of the state. Thus, politicians at all levels were to some extent shielded from some of the accountability for systems and individual failures, with patients looking towards the law to obtain redress and remedies. This, of course, is not to say that similar considerations did not occur in the British context – there, too, patients could and did seek legal redress; it is to say that the more expansive role of the state in Britain creates a different dynamic.

The divergence in statism between the two jurisdictions may be further reinforced by trends towards or away from centralization. Government control is also evident in the degree of centralization seen in the organization of the health system. Centralization has been identified as a key variable shaping health systems, as increasing centralization has been shown to lead to more cost controls and standardization within systems.[455] First, it is important to note that a state can have highly centralistic tendencies, while at the same time some elements of its system may be decentralized.[456] Levels of centralization may change due to changes in political norms and structures, and for other reasons. There are also varied contexts of decentralization. The constitutional level of decentralization is discussed in detail in the next chapter. In Canada, health is a provincial responsibility and inherently decentralized, whereas in the British unitary state it is inherently centralized. This is overly simplistic, as decentralization may also occur in operational and managerial contexts.

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[455] Hollingsworth, *supra* note 338 at 210.
[456] *Ibid.*

Operationally, both jurisdictions were decentralized. Britain favoured regionalization, and Canada localism, for service delivery. These are all variants of decentralization, and under the initial model the NHS was perhaps less decentralized than the Canadian provincial and territorial systems. However, the 1974 reforms to the NHS pushed decentralization further, establishing layers of governance actors at the regional, area, district and community levels. Importantly, these actors within the NHS were all government actors, created by and controlled by the government. In Canada, local actors constituted many private providers with, as discussed above, little in the way of organizationally dense funding mechanisms through which to control operations. Having said that, operational decentralization was an area of convergence between the systems.

In the managerial context, I suggest one sees more divergence. In the NHS, centralizing tendencies were a policy legacy from the Second World War that shaped the structure of the NHS. Despite the NHS having decentralized delivery systems, as Klein noted it tends towards being one of the most centralized health systems in the industrialized world.[457] Klein was referring to the heavy dependence on very rigid centralized planning, with even the 1974 reforms placing a heavy emphasis on this. The Canadian systems did not rely on central planning to the same extent.

If a health system's logic is towards a degree of centralization in its management, combined with statism, it may indicate a desire for control by the centre. This may mean that the central state is more likely to employ hierarchical regulatory mechanisms, such as direct regulation, in the traditional model. Co-regulatory systems acquire a different regulatory logic that may encourage the continuance of government-facilitated or -supported regulatory mechanisms that are not as coercive as direct regulation. This is not to say the direct regulation would not be used, but the logic of the system may incline towards the development and use of soft law mechanisms consistent with the 'New Governance' described in Chapter 1.

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[457] Klein, "*New Politics*", *supra* note 306.

Conclusion

The structures and logics of the respective health systems in each jurisdiction at the close of the 1970s had some similarities, but also some marked dissimilarities. These dissimilarities indicate the potential for future regulatory divergence in the face of a stressor that places accepted institutions and practices in question. The centralistic tendencies and statist structure of the British NHS are indicators of a system whose regulatory logic may direct it towards a more interventionalist regulatory framework if the implicit bargain inherent in its corporatist structure was perceived to have failed.

Conversely, co-regulatory decision-making frameworks are deeply embedded within all levels of the Canadian health system. The lack of statism inherent in the health systems in all provinces and territories, except arguably Québec, and at the federal level, and the systemic structures that preserve an independent, collegial and market-focused structure for healthcare delivery, indicate the future maintenance of co-regulatory processes. This is, of course, assuming that the corporatist bargain at the centre of the Canadian health system is maintained through effective governance within hospitals and by the medical profession, supported by governments and the public. However, it is not just the logic of health systems that creates points of possible regulatory divergence, but also in governance systems more generally. Accordingly, the next chapter examines differences in the broader governance frameworks within each jurisdiction, including issues of constitutional frameworks, politics, and differences in the habits of governance.

Chapter 4
Constitutions, Politics, and Culture: The More Things Change, The More Things
Stay the Same

Introduction

In the early 1980s, Britain and Canada had similar regulatory frameworks for patient safety. The contexts within which those regulatory frameworks were employed were, however, marked by significant points of divergence in relation to the underlying logics and norms informing regulatory systems. These divergences, as the path-dependency approach suggests, may pose major constraints to future policy and program developments.[458] As shall become clear in the next chapters of the thesis, these divergences would have consequences for the shape of each jurisdiction's regulatory framework for patient safety in the years to come. In this chapter, I examine three facets of contextual differences: constitutions, politics, and culture. Constitutional structures, political norms, or habits of governance, and the cultural milieu can function as explicit or implicit constraints on future change. The intention here is not to examine each facet in depth, as to do them full justice could be the subject of several theses, but rather to tease out the most salient features of each dimension as it relates, or may relate, to shifts in the regulatory arena post-1980.

My central argument in this chapter is that constitutional, political and cultural differences between Canada and Britain influence the future development of patient-safety law. This is not perhaps an altogether surprising conclusion, but is a point that warrants examination to assess why and how those differences might affect regulation. One of the most significant differences between the two jurisdictions is in respect of constitutional structures. It is obvious from the discussion in Chapter 2 that differing constitutional structures may see highly similar regulatory frameworks – again, this may not be a surprise considering that the regulatory roots of one jurisdiction, on the whole, originated from the other.[459] But it is also true that, in other contexts, one can see markedly dissimilar regulatory frameworks. A question at the heart of this chapter is: how might constitutional structures affect the

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[458] Kay, *supra* note 47.
[459] The influence of French law on law within Québec cannot be understated. It is also important to acknowledge that Indigenous Canadians have a body of law and custom.

direction and nature of regulatory change and, if so, what is its importance? In other words, what kind of difference do constitutions make?

Within constitutional structures, political systems operate with their own norms of practice or habits of governance. Although there are some similarities and shared political traditions between Canada and Britain, there are, I suggest, some relevant differences that influence how regulation is conceived and employed in each. Some of these differences are integrally connected to constitutional structures, indicating the interconnectedness of these areas. Another focus of this chapter is to ask: what are these differences and how might they influence regulatory culture?

Within and outside constitutions and politics lies culture. Although ascribing culture and values to a nation state is often speculative and risks gross over-generalization, culture influences and in turn is influenced by politics and constitutions and ultimately may influence the focus and shape of regulation. In this chapter, I also ask: what are the cultural factors relevant to patient safety in each jurisdiction and how might they shape regulatory direction?

In developing this argument, in the first section of this chapter I examine constitutional norms and practices in each jurisdiction. In the second section, I examine political systems and norms; and in the third and last section, I review culture in the context of health, regulation, and governance. In each section, I evaluate how the examined norms might affect regulatory directionality.

The Influence of Constitutional Frameworks

It is generally assumed that it makes a difference whether a nation has a federal or unitary structure in regard to public policy formation, policy output, and policy outcomes.[460] The shape and structure of institutions may influence the capacity of political actors to act, their perceptions of realistic policy alternatives, and their options and preferences.[461] Of the jurisdictions, Canada is a federal state and Britain, unitary. Federal states differ from unitary

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[460] D. Braun, "Territorial Division of Power and Public Policy-making: An Overview" in D. Braun, ed., *Public Policy and Federalism,* (Aldershot: Ashgate, 2000) 1 [Braun].

states in that federal systems tend to have strong supreme or constitutional courts, high barriers for constitutional amendment, and the power to govern is dispersed between different levels of government.[462]   In unitary states, national governments have more immediate authority than they do in federal states, as other levels of government lack formal or informal veto power against the actions of the central government.[463]   In contrast to federal states, some unitary states have unwritten constitutions or constitutions that are only partially enacted in law. Unitary states are said to have fewer institutional constraints on regulating and are more likely to initiate significant change.[464]

Theories of federalism identify institutional factors as determinants of government activity and policy-making.[465]   Federal states may face more institutional constraints for policy-making than unitary states.[466]   Traditionally, the literature has been dominated by the perspective that divisions in economic and political powers inherent in a federal structure operate to preserve the status quo and constitute a barrier to change.[467]   The British constitutional scholar A.V. Dicey noted, for example, that federalism maintains "the status quo in politics" and is therefore "incompatible with schemes for wide social innovation".[468]   A study of the development of social policy in Canada found evidence to support an argument that federalism slowed the development of the welfare state and then acted as a barrier to forces that sought to change it.[469]   This position suggests that federal systems are characterized by conflict and jurisdictional disputes, both of which promote delay. On this view, federal structures are generally considered a hindrance to social policy-making because of difficulties in achieving general consensus in a divided system.[470]   In the Canadian context, Tomblin noted:

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[461] Banting & Corbett, *supra* note 405.

[462] Braun, *supra* note 460.

[463] *Ibid.*

[464] See, for example, D. Adams, "Canadian Federalism and the Development of National Health Goals and Objectives" in D. Adams, ed., *Federalism, Democracy and Health Policy in Canada* (Kingston: Queen's University Press, 2001) 60 at 68 [Adams, "Canadian Federalism"].

[465] See, for example, Gray, *supra* note 306.

[466] Braun, *supra* note 460.

[467] See, for example, Gray, *supra* note 306.

[468] A.V. Dicey, *Introduction to the Study of the Law of the Constitution* (London: MacMillan, 1959) at 138-180 [Dicey].

[469] K. Banting, *The Welfare State and Canadian Federalism,* 2nd ed. (Montreal and Kingston: McGill-Queen's University Press, 1987) [Banting].

[470] Maoni, "Federalism", *supra* note 408.

Structural change does not always come easily (when circumstances change) because old, inherited, over-lapping, societal and State traditions make it very difficult to change direction. According to the logic of neo-institutional thinking, our complex and divided federal system makes it possible for old identities, visions and boundaries to survive and it limits what can be achieved, even when conditions change.[471]

However, some quantitative comparative studies have shown that constitutional factors have not been a relevant factor in explaining policy variation, although these studies have also been critiqued for not sufficiently nuancing the differences between federal and unitary states.[472] Hence, Braun asserts that differences between federal and unitary states should be understood in terms not of outcomes, but in modalities of action, of organization of power, and the games actors play.[473] In other words, constitutional structures may result in differences in how governments approach and address problems rather than the objectives and outcomes of government action.

Conversely, no lesser authority than Trudeau argued that federalism can enable radical policies in a way in which unitary systems do not.[474] In federal systems, political parties with new or even radical prescriptions for policy change may come into power in one jurisdiction, although not in all, and can introduce a seed of policy innovation and change that may slowly spread across the country.[475] An example of this is the Tommy Douglas government in Saskatchewan, which introduced the first universal health insurance program.

The broad conclusion of an extensive literature review by Banting and Corbett is that political institutions, such as constitutional structures, are never solely determinative of a policy or regulatory direction, as institutional structures interact with other factors – for example, ideology or economics – in a process of change,[476] but that the structures of some political institutions mean that some policy and regulatory directions are easier to pursue

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[471] S. Tomblin, "Creating a More Democratic Health System" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada: The Romanow Papers: Volume III* (Toronto: University of Toronto Press, 2004) 280 at 287-288 [Tomblin].
[472] Braun, *supra* note 460.
[473] *Ibid.*
[474] P. Trudeau, *Federalism and the French Canadians* (New York: St Martin's Press, 1968).
[475] Maioni, "Federalism", *supra* note 408.

than others. Therefore, in combination with other factors, constitutional structures may constrain political responses and shape resultant regulation. It is important then to examine how these structures might influence regulatory direction in each jurisdiction.

Canada

General Framework

The constitution of Canada divides legislative and executive power between federal and provincial governments.[477] Pre-confederation Canada was a series of internally self-governing colonies, administered by colonial authorities that were answerable to the government in Britain. Accordingly, as Duncan et al note, British colonial rule of what is now Canada created a number of semi-autonomous entities with an engrained ethos of local reliance.[478] Post-confederation, the relationships between the provinces (and territories) and the federal government have been shaped by that sense of independence, regional autonomy, and geography.

Smiley notes that the Canadian Constitution contemplated a centralized federal system, as what were then regarded as the major functions of government were vested in the federal government.[479] However, as the role of government expanded as a result of the transformation from a classic liberal to welfare state, the provinces' and territories' role and functions under the Constitution have become increasingly central to the operation of the modern state. This is due to the broad interpretation by the courts (and especially the Judicial Committee of the Privy Council) of the provincial heads of legislative power to encompass much of the legislative capacity needed to build the welfare state.[480]

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[476] Banting & Corbett, *supra* note 405; Maoni, *ibid.*

[477] *Constitution Act, 1867* (U.K.), 30 &31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5 [*Constitution Act, 1867*; *Constitution Act, 1982* being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11 [*Constitution Act, 1982*]. The *Constitution Act, 1867* created a federal union of several British colonies and defined much of the operations and functions of government including its federal structure, and the operations of the House of Commons and Senate and of the justice system. Sections 91-95 establish areas of federal, provincial and shared jurisdiction. The *Constitution Act, 1982* repatriates the Constitution from Britain, establishes the supremacy of the Constitution, establishes the *Charter of Rights and Freedoms* and creates mechanisms for amending the Constitution.

[478] Duncan, *supra* note 369

[479] D. Smiley, *Canada in Question: Federalism in the Eighties* (Toronto: McGill University Press, 1980).

Canada has been described as being a "very" federal state.[481] There is a greater degree of decentralization in Canada than many other federal nations – perhaps, as Gray suggests, reflecting Canada's greater "cultural, economic and linguistic diversity".[482] Governance within Canada occurs along a continuum ranging from sectors where there is a large degree of federal unitarianism to what might be termed disentangled sectors where each order of government acts independently.[483] Much of Canadian politics is dominated by the politics of federalism and inter-governmentalism.[484] As the Supreme Court of Canada noted:

> The principle of federalism recognizes the diversity of the component parts of Confederation, and the autonomy of provincial governments to develop their societies within their respective spheres of jurisdiction. The federal structure of our country also facilitates democratic participation by distributing power to the government thought to be most suited to achieving the particular societal objective having regard to this diversity.[485]

From the outset, the question of how to balance the powers of the provincial (and more latterly the territorial) governments and the federal government was contentious. As Maioni notes, the division of powers in the *Constitution Act 1867*[486] and the *Constitution Act 1982*[487] set the parameters for federal relations in Canada.[488] These Acts set up an environment marked by continuing tension. This tension was manifest in a constitutional framework where a tendency towards centralization, implied by the allocation of economic and residual powers to the federal government, confronted a decentralizing tendency, evident in the broad responsibilities over social affairs accorded to the provinces and territories.[489]

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[480] M. Jackman, "Constitutional Jurisdiction Over Health Care in Canada" (2000) 8 Health L.J. 95 [Jackman]; *Canada v. Attorney General, supra* note 370.

[481] See, for example, Gray, *supra* note 306; G. Skogstad, "Canada: Dual and Effective Federalism, Ineffective Problem-Solving" in D. Braun, ed., *Public Policy and Federalism* (Aldershot: Ashgate, 2000) 57 [Skogstad].

[482] See, for example, Gray, *supra* note 306 at 4.

[483] T. McIntosh, "Introduction: Restoring Trust, Rebuilding Confidence – The Governance of Health Care and the Romanow Report" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada*, vol. 3 (Toronto: University of Toronto Press, 2004) 3 [McIntosh].

[484] *Ibid.*

[485] *Reference Re Secession of Quebec*, [1998] 2 S.C.R. 217 at para. 58.

[486] *Constitution Act, 1867, supra* note 477.

[487] *Constitution Act, 1982, supra* note 477.

[488] See, for example, Maioni, "Roles and Responsibilities", *supra* note 404. The division of powers is primarily established in the *Constitution Act, 1867, supra* note 477 s. 91 (federal) and s. 92 (provincial).

[489] Maioni, "Roles and Responsibilities", *supra* note 404.

Canada has gone through periods of centralization and decentralization in terms of the exercise of political power, but the overall trend appears to be towards decentralization.[490] Centralization appeared to be a stronger force in the early 20th century from the 1930s to the 1950s, when "the centralist perspective was the dynamic initiating force in Canadian constitutional politics. Centralism was never stronger than during this quarter century."[491] This of course can be attributed to the need for cooperation between different orders of government to address the challenges of the Great Depression and the Second World War. This period gave way in the late 1950s and 1960s to an era of 'cooperative federalism', 'collaborative federalism', 'executive federalism', 'accommodative federalism', or 'flexible federalism'.[492] This era saw the provincial and territorial governments working with the federal government employing various informal federal–provincial mechanisms of accommodation (including Medicare). Despite the emphasis on cooperation, however, others wryly note that "Nevertheless, this 'cooperative' federalism results just as often in competition and conflict as in cooperation and coordination."[493]

However, despite this ostensible cooperation, disagreements about the role of federal, provincial and territorial governments were ongoing. This was especially so during the late 1960s and through the 1970s as a consequence of the rise of nationalist sentiments and the election of a nationalist government in Québec in 1976, and the election of a Conservative government in Alberta that was determined to challenge federal incursions into energy and natural resources policy-making.[494] One provincial official was quoted by O'Reilly as saying:

> At the heart of the matter … regarding roles and responsibilities is federal unilateral intervention in provincial fields of social jurisdiction … This issue is not one of

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[490] Banting & Corbett, *supra* note 405.

[491] P. Russell, *Constitutional Odyssey,* 2nd ed. (Toronto: University of Toronto Press, 1993) at 62 cited in H. Leeson, "Constitutional Jurisdiction over Health and Health Care Services in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3*,* (Toronto: University of Toronto Press, 2004) 50 at 54.

[492] H. Leeson, "Constitutional Jurisdiction over Health and Health Care Services in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3 (Toronto: University of Toronto Press, 2004) 50 [Leeson].

[493] R. Pelletier, "Intergovernmental Cooperation Mechanisms: Factors for Change?" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3 (Toronto: University of Toronto Press, 2004) 127 at 129 [Pelletier].

jurisdictional clarity; it is one of … federal interference with the priorities of provincial governments.[495]

The 1960s saw a period of decentralization where the balance of power moved to the provinces and territories due to the federal government's reliance on cooperation. Conversely, it also saw the introduction of many of the pillars of the welfare state due to the federal government's willingness to use its spending power, a shift that might be considered in the direction of centralization.

Subsequent federal attempts in the 1970s at prioritizing national cost-sharing programs, for example Medicare, attracted accusations from some quarters of direct intrusion into provincial jurisdictions (recentralization).[496] Generally, as O'Reilly noted, the provinces and territories feared that any new delivery programs initiated by federal government were the thin edge of the wedge of increasing federal power.[497] Centralization also attracted criticism from provincial and territorial governments, as these governments believed that they had a better sense of policy priorities because of their proximity to people and services and their sensitivities to regional, local, economic, linguistic, and cultural differences.[498]

Tensions also became manifest in respect of shared-cost programs, such as Medicare, especially once the recession of the 1970s and changing economic policies saw the federal government move to place limits on the levels of funding directed towards shared-cost programs.[499] One issue was that the federal government might partially fund programs, but the provincial and territorial governments responsible for implementing those programs bore the blame for any or all failings, even those caused by funding shortfalls.[500] Certainly, discord between the different governments is a characteristic of governance in Canada,

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[494] McIntosh, *supra* note 483; O'Reilly, *supra* note 412.

[495] P. O'Reilly, "The Federal/Provincial/Territorial Health Conference System" in D. Adams, ed., *Federalism, Democracy and Health Policy in Canada* (Kingston: Queen's University Press, 2001) 107 at 118 [O'Reilly, "Conference"].

[496] *Ibid.*

[497] *Ibid.*

[498] Adams, *supra* note 464.

[499] See discussion in Chapters 3 and 5. See, for example, O'Reilly, *supra* note 412; Lahey, *supra* note 306.

[500] O'Reilly, *supra* note 412.

particularly in the second half of the 20th century[501] – if nothing else because, as Pelletier notes, "[i]t is not a genuine partnership between equals, but an uneven relationship between politicians …"[502]

A dominant feature of Canadian federalism is so-called executive federalism, which Skogstad describes as:

> … the norm and practice of consultation and negotiation among national, provincial and territorial officials and ministers on matters of public policy where the interests and responsibilities of the two levels of government overlap.[503]

A reliance on the executive to create policy is also a characteristic of the Westminster parliamentary model in which the executive plays a dominant role in governance. This is manifest in the Canadian government system at the intergovernment level, with the mechanisms of cooperative (or less cooperative) federalism concentrating power in the hands of government ministers and officials. Some suggest that this type of system results in Canadian citizens assuming the role of "spectators" in a dialogue occurring between the members of the executive of two levels of government,[504] often shrouded in secrecy with little transparency. Some note that the levels of disagreement between the two levels of government are such that both sides engage in communication strategies intending to tell the public their version of the disagreement in an attempt to leverage public support.[505] While this does not result in citizen participation, it does inject a little more transparency, even if self-serving, into the process.

With each province and territory having internal sovereignty, there are, not unexpectedly, differences between them as to why, what, and how to regulate. As the Supreme Court noted, differences between provinces "are a rational part of the political reality in the federal process."[506] Canada's federal system may lend itself to less dramatic regulatory change and

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[501] Especially in respect of health, see Kenny, *supra* note 97.
[502] Pelletier, *supra* note 493 at 147.
[503] Skogstad, *supra* note 481 at 57.
[504] Tomblin, *supra* note 471 at 290.
[505] See, for example, *ibid* at 289.
[506] *Haig v Canada*, [1993] 2 S.C.R. 995, at 1047.

relative stability over time (of course these trends are not absolute.)[507]   In some applications, the slow pace of provincial reforms may function as a rough process of evidence-based decision-making, as provinces get the benefit of 'trying before they buy' through watching the experience of innovations in other provinces. It perhaps limits the national impact of any knee-jerk regulatory changes made in response to local political imperatives. There are a number of examples of this in the health context. The development of Medicare is a case in point. The basic model was developed in Saskatchewan, adopted in a few other provinces, and then was followed by federal enabling legislation (see discussion in Chapter 3). It was subsequently adopted by individual provinces until all had implemented it. Regionalization (discussed in Chapter 5) provides another example in the health context. This differs from the previous example in that there was no federal greasing of the wheels; rather, health system regionalization was adopted in various forms by one province after another, based to a large extent by learning from and copying the experiences of other provinces.[508]

Canadian Federalism and Healthcare

In respect of health, the *Constitution Act 1867* is a reflection of its times, given that at the time of its enactment health was seen as a personal responsibility and a private matter.[509] Although, except as subsequently discussed, health was not specifically addressed in the *Constitution Act 1867*, it does not mean that no provision was made for these types of matters. However, it also seems that the *Constitution Act 1867* reflects the view that the continued development of the infrastructure of a health system(s) was a priority that provincial governments needed to support.   Under the Constitution, the provinces are allocated responsibility for "the Establishment, Maintenance, and Management of Hospitals, Asylums, Charities, and Eleemosynary Institutions in and for the Province, other than Marine Hospitals."[510]   More generally, provinces are also responsible for "all matters of a local or private nature …"[511], "property and civil rights …" (interpreted as including the regulation of

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[507] Tuohy, "Logics" *supra* note 35.

[508] D. Philippon & J. Braithwaite, "Health System Organization and Governance in Canada and Australia: A Comparison of Historical Developments, Recent Policy Changes and Future Implications" (2008) 4:1 Healthcare Pol'y e168.

[509] A. Braën, "Health and the Distribution of Powers in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3 (Toronto: University of Toronto Press, 2004) 25 [Braën]; Leeson, *supra* note 492 and Maioni, "Roles and Responsibilities", *supra* note 404.

[510] *Constitution Act, 1867, supra* note 477 s. 92(7).

[511] *Ibid.* s. 92(16).

professionals, including health professionals)[512], and education.[513] The federal government was assigned more limited responsibilities for health-related issues, reflecting the view that health as a general legislative domain was not a matter of concern for the central government. Accordingly, the Constitution gave the federal government the important but specific responsibility for "Quarantine and the Establishment and Maintenance of Marine Hospitals."[514] Other broader powers came to be understood to have application to health, particularly the criminal law,[515] the spending powers,[516] and (in limited circumstances) the general peace, order, and good government power.[517] For the most part, the federal role has been focused on public health under the criminal law power (dealing with matters such as tobacco, firearms and hazardous substances) and on the use of the spending power to achieve provincial participation in Medicare. The federal government delivers very little in the way of health programs directly to Canadian citizens, other than its constitutional responsibilities to provide services to First Nations and Inuit communities, the Canadian military, prisoners in federal prisons, and 'aliens'.[518]

Outside of these specifics, the Canadian Constitution does not clearly distribute responsibility for health to the provincial, territorial, or federal governments. Health is an issue that is subject to negotiation between sometimes-competing interests according to the nature or scope of the issue at hand and the political sensitivities at play. The Supreme Court of Canada has concluded:

> In sum 'health' is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending in the circumstances of each case on the nature or scope of the health problem in question.[519]

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[512] *Ibid,* s. 92(13).
[513] *Ibid,* s. 93.
[514] *Ibid,* s. 91(11).
[515] *Ibid,* s. 91(27).
[516] *Ibid,* s. 91(3).
[517] *Ibid,* s. 91.
[518] *Ibid,* s. 91(11). See discussion in Jackman, *supra* note 480; S. Coughlan & D. Darling, "The Canadian Legal System" in J. Downie, K. McEwen & W.MacInnis, eds., *Dental Law in Canada* (Markham, Ont.: LexisNexis, 2004) 1.

Given the relative uncertainties in this area, and the tensions discussed in the previous chapter inherent to the health insurance framework, it is perhaps not surprising that health is often an area of great contention between the federal, provincial, and territorial governments – so much so that some suggest that intergovernmental conflict, particularly over Medicare, often obscures and distracts from other debates about healthcare in Canada, including such matters as the quality and safety of healthcare in Canada.[520]   As Maioni notes:

> In effect, intergovernmental discussions in health care have become stymied by the relentless spotlight on a statute that regulates fiscal transfer programs, making it difficult if not impossible to coherently address issues of governance and long-term sustainability in health care.[521]

Johnson also notes that "many reforms and improvements, namely, macro-level policy discussions, do not get done because of federal–provincial disagreement and deadlock."[522]

The relationship between the different levels of government in respect of health is mediated through the mechanisms of collaborative federalism through regular conferences between first ministers, deputy ministers, and officials.[523]   Accordingly, the health system is also characterized by executive federalism.

> With the rise of a symbolic, high-stakes political game, health became an important intergovernmental issue. The governments responded in a predictable way, by seizing control of the issue. As a consequence, the public and other interests likely had fewer opportunities to control the health agenda or discourse.[524]

Negotiations between these parties are generally conducted behind closed doors by the executive branches of government. The agendas of these regular meetings are rarely

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[519] *Schneider v The Queen* [1982] 2 S.C.R. 112 at 142, Estey J [*Schneider*].
[520] McIntosh, *supra* note 483 at 3; Maioni, "Roles and Responsibilities", *supra* note 404.
[521] Maioni, *ibid* at 184.
[522] C. Johnson, "Health Care Politics and the Intergovernmental Framework in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3 (Toronto: University of Toronto Press, 2004) 199 at 200 [Johnson].
[523] Pelletier, *supra* note 493.

divulged, let alone the deliberations that occur during these meetings.[525] Pelletier examined the agendas of the ministerial and deputy ministerial meetings occurring in the late 1990s and early 2000s. He established that most of the items dealt with matters of public concern at that time: tainted blood, health human resources, smoking, public health, homecare, and medical equipment, indicating a degree of responsiveness.[526] The fact that, of all the safety issues that could have been on the agenda, only public health and blood made it indicates the centrality of those issues (see discussion in Chapter 6) and that for the Canadian public and politicians the quality and safety of health services more generally were not a central concern. It may of course also reflect the reality of the federal government's limited responsibility for the delivery and regulation of health services.

Canada's federal system may lend itself to less dramatic regulatory change and relative stability over time.[527] The last word might be left to Johnson, who is of the opinion that "Federal–provincial relations, both harmonious and discordant, have facilitated *and* constrained policy change" in Canadian healthcare.[528]

Britain

Britain is a unitary state where national government makes policy for and regulates the nation. Constitutionally, there is no question of power-sharing with other levels of government unless the central government chooses to do so. While the Westminster parliament can and from the 1990s did delegate powers to regional parliaments as it saw fit, it may revoke such powers by a simple parliamentary majority at its pleasure and hence it remains a unitary state.[529] Despite this devolution, the government did not delegate responsibility for all aspects of governance to regional parliaments; it retained many key powers at the national level. Primarily, the national devolved aspects of social policy and other matters of local application or interest. While some powers were devolved to regional

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[524] Tomblin, *supra* note 471 at 289.

[525] Pelletier, *supra* note 493.

[526] *Ibid.*

[527] Tuohy, "Logics" *supra* note 35.

[528] Johnson, *supra* note 522 at 201 [emphasis original].

[529] H. Döring, "Ambiguous Centralism and Occasional 'Federalism by Stealth' – Great Britain" in D. Braun, ed., *Public Policy and Federalism* (Aldershot: Ashgate, 2000) 177 [Döring].

parliaments in Scotland, Wales, and Northern Ireland, England is still governed in a unitary manner by the central state.

Britain's constitutional structure is further muddied by its membership from 1973 of the European Community, which became in 1993 the European Union, a quasi-federal supranational structure.[530] In the health context, the practical effect of this is that now Britain's sovereignty over health governance may be affected by the European Union's treaties and directives. An example from the post-1980 period is the *Working Hours Directive.*[531] Due to devolution throughout the 1990s, Britain obtained the vestiges of federalism, while retaining a unitary status constitutionally.

The powers of a unitary state to enact abrupt policy (and regulatory) change are well illustrated in the healthcare context, and indeed in social policy more generally. As discussed in more detail in Chapter 3, in the years following the Second World War the introduction of the welfare state and the NHS constituted significant, radical, and rapid changes to existing norms of social policy. As significant, rapid, and radical were the, in some sectors, overnight introduction of new governance norms by the Thatcher government in the early 1980s, some of which are discussed in Chapter 5. In respect of these reforms, consultation was limited, and many of these changes were simply rammed through parliament in the teeth of any public opposition. Outside of the social policy sphere, the introduction of the highly unpopular poll tax by the Thatcher government provides another cogent example. The introduction of a flat rate community charge levied upon all adults to replace residential property taxes occurred forthwith as it benefited traditional conservative voters.[532] There

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[530] It is also important to note that in 1950 Britain became a signatory of the *Convention for the Protection of Human Rights and Fundamental Freedoms,* 4 November 1950, 213 U.N.T.S. 221 at 223, Eur. T.S. 5 [European Convention on Human Rights], an initiative of the Council of Europe. Once in force, this convention enabled citizens to appeal to the European Court of Human Rights if they believed their rights pursuant to that convention had been infringed. It was not until 1998, with the enactment of the *Human Rights Act 1998* (U.K.) c. 42 that these rights were incorporated into British law. See, for example, R. Horton, "Health and the UK Human Rights Act 1998" (2000) 356:9236 Lancet 1186 [Horton].

[531] EC, *Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organisation of working time,* O.J. L. 307/18; EC, *Council Directive 2000/34/EC of the European Parliament and of the Council of 22 June 2000 amending Council Directive 93/104/EC concerning certain aspects of the organisation of working time to cover sectors and activities excluded from that directive,* [2000] O.J. L. 195/41; see discussion in McDonald, "Working to Death" *supra* note 110.

[532] See, for example, P. Smith, "Lessons from the British Poll Tax Disaster" (1991) 44:4 National Tax J. 421 [Smith].

were widespread demonstrations and at least one riot in the weeks leading to the enactment of the new tax, but it was duly passed on schedule in the teeth of any opposition.[533] It was not, however, to last long. Mrs Thatcher lost her leadership of the Conservative Party (and her Prime Ministership), in part due to this issue, and the tax was subsequently repealed by her successor.[534]

In respect of health, government in the late 1990s rapidly devolved the management of the NHS to regional parliaments (with the exception of England), although the regulation of health professionals through government-sanctioned self-regulation by the health professions remains the purview of the national government.[535] The retention of the power to regulate the health professions at the national level is significant, as it keeps a significant degree of power to regulate the operations of the NHS at the national level – health professionals, after all, are an integral part of the operations and functioning of the NHS. The impact of devolution on the NHS is a matter of debate. This thesis examines the period 1980–2005, and it appears that only towards the end of this period, beginning from 2004, did some differences begin to emerge in the organization and management of the four NHSs – there was little change from the pre-established norms in respect of quality and safety.[536] Some attribute this relative stability in the post-devolution period to the substantial policy inheritance of each NHS and the high level of coordination seen between the four regions.[537] Stability was not a characteristic of the NHS prior to devolution (see discussion in Chapter 5).

Britain and Canada

In short, the different constitutional structures in each jurisdiction may, in accordance with other factors, predispose a government to regulate or not. In Canada, a federal structure may result in slow, incremental, negotiated change, which may involve reform by agreement

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[533] *Ibid.*

[534] *Ibid.*

[535] Health professional regulation remains a reserved power; see, for example, *Scotland Act, 1998* (U.K.), c. 46, Sch. 5, Pt II, Head G, G.2.

[536] See, for example, K. Woods, "Health Policy and the NHS in the UK: 1997-2002" in J. Adams & P. Robinson, eds., *Devolution in Practice: Public Policy Differences within the UK* (London: Institute for Public Policy Research, 2002) 25 [Woods]; S. Greer, *The Four Way Bet: How Devolution has led to Four Different Models for the NHS* (London: The Constitutional Unit, University College of London, 2004).

and co-regulation at the intergovernmental level. It also may create an environment where matters that can be the subject of intergovernmental agreement are few. These matters may be ones where interconnectedness is crucial, such as the development of information systems, public health (including the operation of the blood system), and questions about levels of funding provided for health services – but also provincial governments operate in a largely unitary fashion for matters that do not touch upon federal concerns or raise any necessity for intergovernmental consistency.

In contrast with Canada, where most healthcare issues are either provincial or shared issues, traditionally in Britain most healthcare issues have, at least until the 1990s, by definition, been national issues, to be nationally regulated by a majority government in a unitary state if required. Even with some devolution of powers from the 1990s, a long history of a centralized service and regulation means that issues, especially in respect of quality and safety, may not, at least initially, be regarded as truly regional or local. With few barriers to initiating comprehensive regulatory change if a problem arises, a culture may be created in which the enactment of such regulation is almost reflexive.

In the context of a comparative examination of patient-safety regulation, it might be suggested that a comparison between Britain and Canada is asymmetrical. The constitutional authority over healthcare is vested in the provinces, and some might say that the comparison therefore should be between Britain, the unitary state, and the provinces as unitary entities of governance. This may especially be argued given the possible parallels between the oversight exercised over Britain by organs of the European Union and the Council of Europe, including the European Court of Human Rights, and over the Canadian provinces by the federal government of Canada and the Supreme Court of Canada.[538] In making the distinction between a unitary state and a unitary entity, I highlight that provinces are not nation states no matter how similar their constitutional structure to a nation. A further complicating factor is that financing is a divided responsibility in Canada, while it is the

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[537] Woods, *ibid.*

[538] See, for example, *Chaoulli v. Quebec (Attorney-General),* [2005] S.C.J. No. 33; [2005] 1 S.C.R. 791 (S.C.C.) [*Chaoulli*].

responsibility of the unitary government in Britain. The federal context in Canada cannot be ignored.[539]

Constitutions, although important, do not exist in isolation; they are embedded in a broader governance context – the political life of each jurisdiction. What might be termed the habits of governance in each jurisdiction provide a context that may also indicate current and/or future divergence, and this is examined in the next section of this chapter.

Politics and Governance

Politics, and what may be termed the habits of governance, in each jurisdiction also warrant examination as factors that might indicate the future directionality of regulatory choices – after all, regulation is the product of the politics.[540] There are a number of similarities in respect of the political norms and habits of governance in each jurisdiction, again not surprisingly given that Canada was a British colonial possession; but there are also some differences.

Although their constitutional make-up may be different, the political systems in each jurisdiction are similar in that both are Westminster-style democracies. Moe and Caldwell suggest that a Westminster government is an institutional arrangement that generally establishes a democratically elected single party government headed by a strong leader, with strong party discipline, to keep dilemmas of public choice at bay.[541] However, the tenets of Westminster-style democracy may be moderated in some circumstances. As discussed in the previous section, in Canada it may be affected by the impact of federalism, and in Britain by its membership of the quasi-federalist European Union and its devolution of some powers to regional parliaments.

Westminster-style democracy may also be moderated by the nature of politics in each system. The Westminster model is predicated on a single-party government, and certainly the history

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[539] I thank Bill Lahey for this insight.

[540] Kenny, *supra* note 97 at 68.

[541] T. Moe & M. Caldwell, "The Institutional Foundations of Democratic Government: A Comparison of Presidential and Parliamentary Systems" (1994) 150 J. Institutional & Theoretical Econ. 171 at 189 [Moe].

of each jurisdiction (in Canada at the provincial and federal levels) has generally seen the election of single-party governments mostly functioning as majority, and more rarely minority, governments.

While second chambers operate at the federal level in Canada and in Britain, there are limitations on the ability of the British House of Lords (traditionally dominated by conservative forces due to its, until recently, hereditary membership) to institute any veto, delay, or unacceptable amendments to legislation, and any such attempts may be overridden by the House of Commons.[542] The formal limitations on the Canadian Senate are only in relation to constitutional amendments and originating bills relating to appropriations of public funds.[543] However, informally the Senate's weak legitimacy as a body appointed by government means it does little in this regard. Hence, in Britain a majority government may create regulation in spite of opposition from within and outside government. This is similar to the pattern seen at the provincial level of government in Canada, at least in respect of matters which are solely within provincial powers.

The degree of party discipline inherent in the Westminster system may also be a significant point of difference. Across Canadian politics, one saw a high degree of party cohesiveness and discipline, meaning that parliamentarians were required to vote along party lines.[544] In contrast, while party discipline was reinforced in the British system, the oftentimes large numbers of backbench members of parliament meant that party discipline on occasions faltered and backbenchers could and did break from the determinations of their party.[545] While this tendency towards ill-discipline in Britain did not bring governments down, it created a context where political positions were the subject of in-party contest. It also created a situation where backbenchers had more freedom to raise issues of concern to their electorates in public forums even if the issues did not align with formal party policy. In Britain, members of parliament could play a more significant and public role than their

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[542] See *Parliament Act, 1911* (U.K.), 1 & 2 Geo. V., c. 13 which allowed a delay of three parliamentary sessions or two years before the House of Commons could override the House of Lords, amended to two parliamentary sessions or one year in *Parliament Act, 1949* (U.K.) 12, 13 & 14 Geo. VI., c.103.

[543] *Constitution Act, 1867, supra* note 477.

[544] Maioni, *supra* note 384.

[545] *Ibid.*

Canadian counterparts in raising issues and making claims that fan the flames of scandal (discussed further in Chapter 6).

The constitutional model in Canada often requires bargaining between provinces, territories, and the federal government.[546] The features and conditions of Canadian policy-making at the intergovernmental level emerged from this constitutional reality.[547] In some facets of Canadian politics, the norms of the intergovernmental model are in part replicated. At the provincial level, policy-making often, although not inevitably, proceeds through a process of negotiations between the provinces and other key actors or stakeholders. In the health context, for example, such negotiations proceed between the provinces and medical associations.[548] Some commentators describe the current system of governance as having a "… well deserved reputation for elitism, behind the scenes approach to interest group politics, and concentrated executive-corporate power ...".[549] Indeed, the system in Canada often, although not invariably, involves what amounts to a process of co-regulation where policy actors cooperate to create new rules within a specific context.[550]

However, it is not only constitutional structures that shape habits of governance. In Britain, there was a tradition of governments having a particular interest in resolving disagreement through incorporating interest groups in the process of decision-making in a formal manner.[551] Although the approach adopted in Britain never saw the levels of integration displayed in true corporatist governance systems (for example Germany),[552] it was a great deal more formalized than processes in Canada, and had a greater reach across sectors. It is suggested that this greater degree of formal corporatism as a mode of governance in Britain was the result of historical factors, including the rise to power of a social democratic government (the Labour Party), and the strength of the organized labour movement. These factors were not seen to the same extent in Canada, as while social democratic parties were highly influential in some provinces, notably Saskatchewan, they had limited impact in others

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[546] T. Marmor, K. Okma & S. Latham, *National Values, Institutions and Health Policies: What do they Imply for Medicare Reform? Report 5* (Ottawa: Commission on the Future of Health Care in Canada, 2002) [Marmor].
[547] Tuohy, "Logics" *supra* note 35.
[548] Marmor, *supra* note 546; Tuohy, "Logics" *supra* note 35.
[549] Tomblin, *supra* note 471.
[550] McDonald, "Working Hours" *supra* note 110.
[551] Klein*, "New Politics", supra* note 306.

and only contained impact at the federal level because of their third-party status.[553] Additionally, organized labour remained comparatively weak in Canada,[554] whereas the unions were a dominant and powerful force in Britain, at least until they were smashed by the Thatcher government in the reforms described in Chapter 5. While there is a tradition of accommodation within the health system in Britain, importantly such accommodation occurs within a centralized framework as the maintenance of hierarchy has also long been a characteristic of British governance structures.[555]

Both jurisdictions support the legitimacy of government regulation in areas of social policy, and indeed consider this a core role of government.[556] This commitment to statism may emerge from post-war world-view Keynesian ideas about the role of the state in the economy, the legacy of reconstruction, and the transition "from warfare state to welfare state"[557] seen across much of the industrialized world. Both jurisdictions then are generally statist (especially in comparison with the US) in that they agree that government could and should be involved in matters of social policy. In the context of social policy, King notes:

> Conservatives in the other four countries [Canada, Britain, France, and Germany] are also not consistently anti-statist in attitude; on the contrary they often express a highly exalted view of the role of the state in economic and social life.[558]

But in only one jurisdiction (Britain), with the possible exception of Québec, does one see a true statist culture. A characteristic of British culture, especially post-World War II, was to favour the rights of the wider society over the individual person[559] and a belief in the efficacy and effectiveness of centralized state planning.[560]

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552 Moran, "Governing" *supra* note 37; Maioni, *supra* note 384.

553 Maioni, *ibid.*

554 *Ibid.*

555 Tuohy, "Logics" *supra* note 35.

556 See, for example, Maioni, "Roles and Responsibilities", *supra* note 404; Tuohy, "Logics" *supra* note 35; R. Klein, *The New Politics of the NHS: From Creation to Reinvention* 5th ed. (Oxford and Seattle: Radcliffe Publishing, 2006) [Klein*, New Politics,* 5th ed]; Moran, "*Governing*"*supra* note 37.

557 Maioni, *ibid* at 173.

558 A. King, "Ideas, Institutions and the Policies of Governments: A Comparative Analysis: Part III" (1973) 3:4 Brit. J. Pol. Sci. 419 [King, "Ideas"].

559 Horton, *supra* note 530.

Conversely, in Canada, although statism is certainly a part of the ethos of governance, its impact is varied, perhaps because of the proximity of the United States. It is commonly suggested that the Canadian perspective on governance is encapsulated by a phrase contained within the *Constitution Act, 1867*[561] referring to "peace, order and good government."[562] Canada embraces the role of government in the working of its society and acknowledges its legitimate role in maintaining order, a position similar to Britain.[563] But it is also suggested, perhaps controversially, that there is a shared North American neoliberal vision manifesting in a commitment to an individualistic social order.[564] It is further suggested that this commitment acts to shape government regulation to focus on the rights and entitlements of individuals, while also engaging with social policy concerns which touch upon the community (usually in the context of ensuring equality). Canada's commitment to individualism is seen in the emphasis on individual rights within social policy. For example, the design of Medicare is that government finances what were to remain private transactions between patient and health professional and/or health-provider. While this commitment is not manifested to the extent of the libertarian extremes seen in the US, it was stronger than was seen in Britain. The commitment to individualism in Canada was, however, tempered by a concern for equality as a foundational core principle of governance in Canada. A concern for equality is present throughout government policy, actions, and debates at all levels of government, particularly in respect of health.[565]

There is also some difference between the jurisdictions in terms of their organizational density which can be differentiated by examining the level of market or state dominance.[566] Döhler suggests three ideal types of welfare state: 1) a mainly market-based model with no comprehensive public health insurance; 2) a restricted market model with national health insurance model where a sector of health-providers has retained market mechanisms; and 3) a state-dominated model.[567] In respect of health, Canada fits within model two and Britain model three, suggesting that Britain has a high level of organizational density, compared with

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[560] Klein*, New Politics,* 5th ed.*, supra* note 556.
[561] *Constitution Act, 1867, supra* note 477.
[562] Duncan, *supra* note 369; Kenny, *supra* note 97.
[563] Kenny, *ibid.*
[564] Tomblin, *supra* note 471.
[565] Duncan, *supra* note 369.
[566] Döhler, *supra* note 339.

Canada's medium level. This has implications for the nature and type of regulation employed by the state, with greater regulation being required or likely when there is a greater level of organizational density.

Some conclude that the lesson of examinations of British policy change is that strong centralized state structures can sometimes lead to greater departures from the established policy path – "… wholly new trajectories are made more easily possible by strong structures."[568] For health policy, the result could be radical change to established systems and structures, if deemed politically necessary; and these comments are also applicable to provincial governments in Canada, again with the caveat that the radical change must relate to matters within provincial power. The logic of political norms may mean that, in Britain, governance forms may incline towards what might be termed government paternalism, or what became known in the Thatcher era as the 'nanny state'.[569] Canada's governance structures may be more predicated on the empowerment of individuals, with a graduated level of state regulation, often – at least in the health context – working closely with responsible institutional actors.

Culture

Cultural approaches to public policy seek to explain stability and change in terms of the rise and fall of cultures. Cultural approaches focus on incidences where a dominant culture that sustains current policy (including regulatory) norms is subverted by a counter culture that challenges policy and regulatory stability and promotes change.[570] These dynamics apply in respect of regulation as much as they do in relation to other state activities. Culture is important, as Licht et al note, because:

> In addition to constraining the development of more specific institutions, the prevailing informal institutions in a society may also serve as sources of motivation for and justification of such institutions … Culture … operates as a constraint

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[567] *Ibid.*

[568] D. Wilsford, "Path Dependency or Why History Makes it Difficult but Not Impossible to Reform Health Systems in a Big Way" (1994) 14:3 J. Pub. Pol'y 251 at 265.

[569] See, for example, R. Cottam, "Is Public Health Coercive Health?' (2005) 366:9497 The Lancet 1592.

because it encompasses the unwritten, unspoken rules of the game, and it coordinates people's epistemics and expectations.[571]

Culture is another factor that may shape responses to issues and influence regulatory directionality.

There are many definitions of 'culture', but there is also general agreement that key elements of culture are shared values and beliefs.[572] According to Kenny, "values are understood to be relatively enduring beliefs about the ends or goals of social institutions and the virtues they *ought* to embody",[573] and "[v]alues directly define what is desirable and create taken-for-granted perceptions of what is "natural" in social relations."[574] Values may create political communities and guide actions, and can unite or constitute a people.[575] Values do not necessarily indicate preferences for particular institutions or structures – all values may do is speak to which interest should be protected over another, not how that should be done.[576] Suggesting that a country has specific cultural traits becomes increasingly problematic when it may be argued that many societies are less heterogenous and more diverse than they may have been in the past – although a counter argument is that the forces of globalization to some extent weaken cultural differences between nations.[577] Hence, the analysis in this section focuses on emerging cultural trends that may be indicative of why societies choose one policy direction (or form of regulation) over another. I then assess what can be discerned about the different values and attitudes towards health and health services in each jurisdiction. I discuss the movement to post-trust and risk societies, and the possible implications of this for regulation.

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[570] C. Wilson, "Policy Regimes and Policy Change" (2000) 20:3 J. Pub. Pol'y 247.

[571] A. Licht, C. Goldschmidt & S. Schwartz, "Culture Rules: The Foundations of the Rule of Law and Other Norms of Governance" (2007) 35 J. Comp. Econ. 659 [Licht].

[572] *Ibid.*

[573] Kenny, *supra* note 97.

[574] Licht, *supra* note 571.

[575] Marmor, *supra* note 546.

[576] *Ibid.*

[577] See, for example, D. Held, A. McGrew, D. Goldblatt & J. Perraton, *Global Transformations: Politics, Economics and Culture* (Stanford, California: Stanford University Press, 1999); J. Inda & R. Rosaldo, "Introduction: A World in Motion" in J. Inda & R. Rosaldo, eds., *The Anthropology of Globalization: A Reader* (Oxford: Blackwell Publishers, 2002) 1.

In terms of values associated with healthcare, there are some marked similarities but also some divergences between Britain and Canada. Both jurisdictions acknowledge the efficiency of the market to manage market goods, but healthcare (or at least some forms of healthcare) is understood to be a public good.[578] The question is the degree or the extent to which these viewpoints are held. Any universal health funding program is concerned with enabling the access of all users to certain forms or levels of healthcare and hence is concerned, to a degree, with equality. The formation of the NHS was part of the enactment of a comprehensive welfare state that was concerned with ensuring universal access to a range of social services. In the health context, the NHS was designed to ensure universal access to a minimum level of health services with a broader ambit of coverage than was seen in Canada, for example, including dental services and long-term care. The process for implementing the NHS saw the nationalization of health-facilities across the country to provide a system where government funded, managed, regulated, and provided health services. In Britain, there was no moral imperative based on concerns about equality to limit economically privileged persons' access to privately provided healthcare. Indeed, part of the 'stuff their mouths with gold' bargain at the inception of the NHS was a guarantee that the consultants could retain the ability to treat private patients using NHS facilities. Britain accordingly has a two-tier system, with a private system working in parallel with a public system. In Britain, the acceptance of a parallel private system with its possibilities for queue-jumping is an accepted logic of the system. A renunciation of the market in the provision of healthcare is not a central value for the British public, as long as all can access services through a public not-for-profit system, even if that involves delays or rationing. The NHS, however, provides equal access to a broader range of services than in seen in Canadian jurisdictions so its functional commitment to equality may be greater than is seen in Canada.

Canadian jurisdictions gradually enacted insurance plans so that governments funded universal access to medically necessary medical and hospital services. Government funding of access to other forms of health-related goods or services varied across the provinces, resulting in less functional equality in terms of accessing a range of services than was seen in Britain. Initially, the Canadian system was also two-tiered in that private services could be provided by doctors and health facilities. It was not until the enactment of the *Canada Health*

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[578] Kenny, *supra* note 97.

Act[579] in 1984 that a concern for equality within the relatively narrow sphere of medical and hospital services became an overarching priority. The Medicare program was redesigned at the federal level to limit the possibilities of private provision of so-called medically necessary services in the provinces and territories (as discussed in Chapter 5).[580] Access to medically necessary services was to be based on need, resulting in a one-tier delivery system within this sphere. Other broad areas of health service delivery – for example, long-term care and dentistry – continue to be largely market based. The increasing resistance to private provision of medically necessary services within Canadian health systems probably owes as much to a reaction to the inequalities seen in the US as it did to commitments to equality.[581] But the concept of restricting private provision of medically necessary services, and hence a renunciation of market values in this narrow sphere of healthcare provision, has become a central value for Canadians.[582] As such Canada's commitment to equality, at least insofar as it relates to access to medically necessary services, is arguably greater than in Britain. In respect of medically necessary services Canada has mandated equality, while the British NHS displays, at best, limited inequality.[583] Equality appears to have different meanings in each jurisdiction, meanings derived from its political and social contexts. For this reason, a commitment to equality expresses itself differently in the institutional structures in each country.

These differences also flow to the nature of the welfare state in each jurisdiction. While Canada is clearly what Esping-Andersen's typology terms a liberal welfare state, the categorisation of Britain within the typology has been more questionable.[584] After the Thatcher reforms, the case for Britain's inclusion in the typology as a liberal welfare state is stronger, prior to this the characteristics of the British welfare state straddled across the liberal and social democratic models. This is a significant point because the liberal model sees a greater emphasis on "individual initiative and opportunity, where social policy is more

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[579] CH Act, *supra* note 401.

[580] The ability to privately provide medically necessary services was limited during the period examined by this thesis. The impact of *Chaoulli, supra* note 538*,* which may weaken the single-tier system in Canada, is outside the purview of this thesis.

[581] See, for example, L. McFarlane & C. Prado, *The Best Laid Plans: Health Care's Problems and Prospects* (Montreal and Kingston: McGill-Queen's University Press, 2002) [McFarlane]; Kenny, *supra* note 97.

[582] See, for example, Romanow, "The Future" *supra* note 303.

[583] I thank Bridget Lewis for this insight.

residual in nature and associated with the role of the market."[585] Conversely, the social democratic model focuses on the state provision of welfare, based on universalism, with a significant engagement in the management of the labour market in respect of wage bargaining and to reduce unemployment.[586] Britain, then, prior to 1980, had a welfare state model which placed a lesser premium on individuals in favour of society more generally. The role of the state in the British model was more paternalistic in its nature.

It is not just values associated with health services that may be important indicators of change, but also general social values. It is posited by a number of theorists that a period of cultural change is occurring, suggesting the emergence of a 'post-trust society'[587] where individuals and communities are increasingly expressing distrust, or suspicion, of traditional and established institutions of social order, such as governments, professions, religious institutions, and other social edifices. Misztal, for example, described "the emergence of a widespread consciousness that existing bases for social cooperation, solidarity and consensus have been eroded."[588] Societies, some argue, have moved from unconditional trust in the actions of important social and policy actors to conditional trust or moderated distrust.[589] Giddens suggests that changes in the conditions of modernity, including globalization and risk perception, create uncertainties that impact upon social trust.[590] Beck argues that the rationality of modern society requires consideration of the possibility of future damage, both as a consequence of our risk-taking actions and of the risk-taking actions of others, and this involves trust or mistrust.[591] Furedi echoes this view and argues that the prevailing culture exhibits an absence of trust in humanity and that people's actions are regarded as at least

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[584] The other is conservative (continental Europe). Esping-Andersen, *supra* note 39. This typology is not without its critics, who argue that there are more than three models.

[585] Maioni, *supra* note 384 at 1.

[586] The other is conservative (continental Europe). Esping-Andersen, *supra* note 39.

[587] See, for example, Lofstedt, *supra* note 61.

[588] Misztal, *supra* note 71 at 3.

[589] O. Quick, "Outing of Medical Errors: Questions of Trust and Responsibility" (2006) 14:1 Med. Law Rev. 22 [Quick].

[590] A. Giddens, *The Consequences of Modernity* (Cambridge: Polity Press, 1990).

[591] Beck, "*Risk Society*", *supra* note 6.

potentially dangerous.[592] In contrast, O'Neil suggests that in actuality we trust more than, or at least as much as we always have, but our trusting mechanisms have changed.[593]

Increasingly, trust is no longer unquestionably given but must be earned and maintained through mechanisms of public accountability. Douglas suggests that this is a facet of a culture increasingly driven by the need to assign responsibility or, as she would suggest, attribute blame to any or all actions that result in harm.[594] As O'Neill and others note, the instruments that mediate relationships between institutions and the public can foster trust or, conversely, undermine it creating the conditions for mistrust.[595] As Rowe and Calnan describe it:

> changes in trust are driven by the dialectical relationship between trust, power, governance and accountability, so that each affects the other in a continuing iterative process.[596]

How this dialectical relationship may have unfolded in Britain and Canada during the 1980s, 1990s, and early 2000s is discussed in subsequent chapters. Briefly, although the post-trust trend affects both jurisdictions, I suggest it has had a greater impact in Britain. This is because the widespread institution of audit mechanisms within the British public sector was integrally tied to the widespread and wide-reaching incorporation of the principles of the New Public Management (NPM) into the public sector and the creation of what Power terms an audit society.[597] This, as discussed in Chapter 5, was also deeply embedded in the NHS. Additionally, as discussed in Chapter 6, widespread failures of the traditional regulators (especially health professions' regulators) within the health system in Britain provoked mistrust of these actors and of existing regulatory frameworks.

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[592] F. Furedi, *Culture of Fear: Risk-taking and the Morality of Low Expectations* (London & Washington D.C.: Cassell, 1997).

[593] O. O'Neill, *A Question of Trust: The BBC Reith Lectures 2002* (Cambridge: Cambridge University Press, 2002) [O'Neill].

[594] Douglas, *supra* note 5.

[595] O'Neill, *supra* note 593.

[596] Rowe, *supra* note 62 at 379.

[597] M. Power, *The Audit Society: Rituals of Verification* (Oxford: Oxford University Press, 1997) [Power].

Some suggest that Canada, too, is influenced by the post-trust society paradigm, in that a decline in deference to authority and a loss of trust in elected officials and in government institutions may be increasingly observed.[598] In contrast to Britain, I suggest that trust in what might be termed the deliverers of health services largely remained intact in Canada, but the trust vested in the actions of provincial, territorial, and federal governments took a beating from a public increasingly tired of the infighting over budgets and concerned about the toll successive funding decreases and restructuring was taking on the ability of Canadian health systems to provide quality care in a timely manner.[599]

Sociocultural theorists also suggest that risk is an increasingly important cultural construct. While sociocultural theorists are divided in how they theorize risk, they all, to a greater or lesser extent, agree that risk has, to quote Lupton, "become an increasingly pervasive concept of human existence in western societies"[600] which organizes, monitors, and regulates societal actors. Theorists describe a transformation in human consciousness from seeing risks as a matter of fate and faith to seeing risks as a consequence of human failure.[601] Beck, for example, suggests that dangers and hazards are increasingly seen as humanly generated and therefore as controllable.[602] Douglas suggests that these attitudes provide scope for a society where someone must inevitably be to blame.[603] Perceiving risks as the consequences of human failures has regulatory consequences. As discussed in Chapter 6, perceptions about the scope and nature of risks to the public may influence regulation. However, also important are societal attitudes about responsibility for risk management, a question integrally connected to questions of trust in institutional actors. The public perception of risk may raise questions about the rightful role of government: is it government's responsibility to actively and aggressively regulate risk to protect its citizens? Or is risk management a process that should be facilitated by government action in a co-regulatory paradigm with institutional actors and individuals?

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[598] Kenny, *supra* note 97; Pelletier, *supra* note 493; S. Brooks & L. Miljan, *Public Policy in Canada: An Introduction,* 4th ed. (Don Mills, Ont.: Oxford University Press, 2003).

[599] See, for example, Romanow, "The Future" *supra* note 303; Tuohy, "Logics" *supra* note 35.

[600] Lupton, *supra* note 5 at 25.

[601] Giddens, "Risk Society" *supra* note 6.

[602] Lupton, *supra* note 5 at 65.

[603] Douglas, *supra* note 5.

Conclusion

After examining the governance systems in Britain and Canada, I adapt Marmor et al's conclusion that:

> many of the core structural differences in national health care arrangements are the product not of differences in fundamental social values but of differences in political superstructure, of differing accommodations of clashing interests, and of the historically contingent "accidental logics" of established social institutions[604]

Constitutionally, Canada's federal structure shares power between the federal government, provinces, and territories. Intergovernmental governance often occurs through processes of executive federalism – where policy-making and regulation occur through negotiation, accommodation, and consensus. Even when it is clear that provinces or territories have jurisdiction, reforms may occur in a slower, perhaps more considered, way as states and territories learn from the experiences, and perhaps radical change, of others. As Canada is a federal society, as well as a federal state, it is unsurprising that these norms should also flow through to the provincial and territorial level where co-regulatory models – where government reaches consensus and accommodation with key societal groups to co-regulate practice – remain a common aspect of governance. Canada also has a tradition of lesser organizational density in the regulation and management of social policy.

In Britain, unitary constitutional structures, coupled with a strong Westminster democratic tradition, make for a culture where the enactment of regulation is relatively simpler. While in practice government often preferred to reach some form of accommodation with other actors, especially in respect of implementation – through the institution of quasi-corporatist arrangements, notably with organized labour – there was also a tradition of state dominance and centralization. A greater degree of organizational density was seen in Britain requiring greater regulation. British public policy, especially in the health context, focused more centrally on benefiting the population, rather than having an individual focus, hence was more paternalistic in nature and resulted in a greater role for the state.

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[604] Marmor, *supra* note 546 at 4.

The contention in this chapter is that factors such as constitutional structures and political and cultural norms create a background trajectory that constrains, or at least is highly influential, in determining future choices about forms of regulation used to regulate certain issues. These factors are not in and of themselves sufficient, however, to predicate change and influence a process begun through a confluence of other factors – and it is these other factors that are subject to examination in Chapters 5 and 6 of this thesis. As I acknowledged at the beginning of this chapter, to do justice to matters of constitutions, politics, and culture could be the topic of several theses. While this chapter discusses some of these issues, it does not pretend to do so in any depth; but the analysis in this chapter is sufficient to enable me to assert that there are both some convergences and divergences in constitutional, political, and cultural norms between the jurisdictions, and some of these divergences are sufficient to provide a partial explanation as to why a particular regulatory direction may be chosen in the future.

Chapter 5
Mistrust, Markets, and Modernization: Moments of Change

Introduction

To recap the argument so far, the pre-1980 period saw a remarkable convergence between Canada and Britain as to which regulatory instruments to employ in respect of patient-safety issues. However, the design of the health systems and the constitutional, political, and social norms in each jurisdiction were distinct, and this established conditions through which divergences could emerge. In this chapter I examine the period from 1980–2005 and evaluate how changes to accepted political norms may affect the design of regulatory frameworks and use of regulatory instruments.

The beginning of the 1980s saw a transformation in the accepted norms of governance within the public sector, a transformation that ultimately spread across the world. The label affixed to these shifts was the New Public Management or NPM. The tenets of the NPM resulted in reappraisals of the forms and functions of the public service in Britain and Canada. The impact of the introduction of the NPM, and the scope and extent of its introduction, on the management of patient safety within the health systems in Britain and Canada requires evaluation. As Aucoin notes, "[c]hanges in public management are not merely changes to administrative processes and practices; they are also changes to governance itself."[605] Put differently, the rise of NPM approaches mark shifts in political norms. These shifts can provide the impetus for a fundamental re-evaluation of the purpose, intent and necessity of regulation.

The central argument of this chapter is that the differing impacts of the NPM on the management of patient safety in British and Canadian health systems constituted an important point of divergence between jurisdictions in respect of regulating patient safety. More specifically, the chapter asserts that the modes of governance of the NHS were more deeply penetrated by the tenets of NPM, much more so than was seen in Canadian health systems. In the NHS context, the principles of the NPM affected not only the management of the NHS, but also clinical concerns with a resultant lessening in professional autonomy.

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[605] Aucoin, *supra* note 39 at 3.

There were significant variations in the adoption of the NPM across Canadian governments, attributable to the Canadian federal system.[606] Generally, the NPM was somewhat influential in many Canadian health systems with respect to their management and financing. The clinical realm remained largely untouched and professional autonomy preserved.

In the first section of this chapter, I offer a fuller description of the NPM. The second section of this chapter analyzes events in Britain, focusing most attention on the Conservative governments of Margaret Thatcher and John Major in power from 1979 to 1997. It was the Conservatives whose ideological convictions saw the precepts of the NPM deeply embedded into the British public sector. The section also briefly discusses the approach of Tony Blair's 'New Labour' government in power from 1997 which, to some extent, modified some of the effects of the NPM on the NHS, but left undisturbed much of its core structure. I turn then to an analysis of the impact of the NPM on Canadian health systems in the third section of this chapter.

What is the NPM?

The NPM is associated with neoliberal economic theories that emanated from the Chicago School of Economics in the 1970s. In general, these theories advocate a lessening of the role of government, outside of monetary policy, a demand for good governance by governments (e.g. fiscal conservatism, debt reduction, inflation control), and an advancement of the role of free markets in governance.

Emerging from these general principles is a prescription for the management of the public sector, now known as the NPM. A full analysis of the NPM is neither possible nor necessary for the purposes of the argument being advanced in this chapter and in this thesis. However, for definitional purposes a brief outline of many of the central operating premises of the NPM must be made.

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[606] See, for example, K. Murray, "The Realignment of Government in the Provinces" in C. Dunn, ed., *Provinces*, 2nd ed. (Toronto: University of Toronto Press, 2006) 415.

Economic stagnation, high unemployment, and increasing fiscal deficits in the 1970s and 1980s placed governments, to quote Campbell, "under stress".[607] The stress fuelled debates about sustainability of the welfare state internationally and about the proper role of the state and the market in providing social services.[608] It raised questions about the hitherto accepted economic theories of Keynesian economics that underlay the welfare state.[609] It is suggested by some that economic stress resulted in the introduction of a new model to manage the public sector – the NPM.[610] It is suggested by others that the dominance of the NPM can be attributed to the rise of the 'New Right' political ideology and government.[611] Others suggest that existent mechanisms for the governance of the private sector had proved unsatisfactory or that new technology required new modes of management.[612] Whatever the reasons for its influence, it proved a dominant force for changes to modes of governance during this period.

While there is some disagreement as to exactly what constitutes the NPM because of the many and varied contexts within which it has been applied, some general themes emerge.[613] To minimize the role of government and maximize the operation of the free market, one sees the privatization or commercialization of many public enterprises that are deemed outside the core business of government and the increased contracting out of public services to private providers. One also sees the imposition of restraints on public expenditure so debt may be curtailed and inflation contained, and so that state debt may be reduced.[614] Within the management of the public sector, one may also see the separation of policy development from funding and delivery of services. This is closely linked to the concept of regulatory capture, which is to say the possibility that regulators may be influenced by close

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[607] C. Campbell, *Governments Under Stress*, (Toronto: University of Toronto Press, 1983) cited in Aucoin, *supra* note 39.

[608] Marmor, *supra* note 546.

[609] In a nutshell, Keynesian economics embraces the role of government in the management of a mixed economy to ensure that macroeconomic ends are achieved. For a more detailed explanation, there are a number of books and articles on this theme; for example, J. Stein, *Monetarist, Keynesian & New Classical Economics,* (Oxford: Blackwell, 1982).

[610] Aucoin, *supra* note 39, but see C. Hood, "The 'New Public Management' in the 1980s: Variations on a Theme" (1995) 20:2-3 Acc. Org. & Soc'y 93 [Hood].

[611] See, for example, C. Pollitt, *Managerialism and the Public Services: The Anglo-American Experience*, 2nd ed. (Oxford: Blackwell, 1993) [Pollitt, *Managerialism*]. But see Hood, *ibid.*

[612] See discussion in Hood *ibid.*

[613] See, for example, Hood, *ibid*; Aucoin, *supra* note 39; Pollitt, *Managerialism*, *supra* note 611; C. Hood, "A Public Management for All Seasons?" (1991) 69:1 Pub. Admin. 3 [Hood, "Public Management"].

[614] See, for example, Hood, *supra* note 610; Aucoin, *supra* note 39.

associations with the regulated, such that the regulators may not act in the public interest. Regulatory capture may also arise if the elected ministers of state become subordinate to the interests and agendas of the bureaucracy, raising the possibility of a 'Yes Minister' scenario.[615] Hence, contestability of advice and independence from partisan interests become key concerns of the NPM. One also commonly sees the introduction of private-sector management practices into the public sector, including, for example, the increased use of contracts and performance indicators, enhanced accountability mechanisms, and the monitoring and oversight, not just of financial matters, but also of the effectiveness, efficiency, quality, and responsiveness of service delivery.[616] Also one may see the devolution of management authority within agencies or organizations. There is some tension between some tenets of the NPM, for example, between the centralization inherent in any contracting process and the decentralizing premise of devolution.[617]

The principles and practices of the NPM spread across the world through the 1980s and 1990s, although in different forms and with different intensity in other Western democracies, and this variance raises challenges when making comparisons between jurisdictions.[618] Christensen and Lægreid, for example, argue that the tenets of the NPM are filtered, interpreted, and modified through national factors.[619] National factors include the instrumental actions of politicians and administrators and the nation's (or province or territory's) political–administrative history (its culture, style of governance, and traditions), resulting in a variance between nations (and levels of government within federal states).[620] Some assert that both Britain and Canada are in the group of countries in which the NPM

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[615] This classic BBC comedy ran from 1980 to 1984 and portrayed a minister's agenda for reform being constantly thwarted by the machinations of the civil service. It was said to be Prime Minister Thatcher's favourite television program.

[616] See, for example, Hood, *supra* note 610; Aucoin, *supra* note 39; M. Moran, "Not Steering but Drowning: Policy Catastrophes and the Regulatory State" (2001) 72:4 Pol. Q. 414 [Moran, "Policy Catastrophes"].

[617] T. Christensen & P. Lægreid, "New Public Management: The Effects of Contractualism and Devolution on Political Control" (2001) 3:1 Pub. Manage. Rev. 74 [Christensen]; Hood, "Public Management", *supra* 613.

[618] See, for example, Hood, *supra* note 610; Aucoin, *supra* note 39; C. Hood, "Contemporary Public Management: A New Global Paradigm?" (1995) 10:2 Pub. Pol'y & Admin. 104 [Hood, "New Global Paradigm"].

[619] Christensen, *supra* note 617.

[620] *Ibid.*

had the greatest impact.[621] It is also generally agreed the NPM saw the greatest uptake in the unitary governments of Britain and New Zealand.[622] Others contest that Canada had a high uptake of the NPM, suggesting that, while it could not be said that Canadian governments were unaffected by the tenets of the NPM, the impact of the NPM was generally somewhat limited at both the federal and provincial/territorial levels.[623] This view acknowledges that there were some provinces within Canada where the tenets of the NPM penetrated more deeply, in particular Alberta and Ontario.[624] Accepting, for argument's sake, that Canada and Britain are in the group of countries where NPM had the greatest penetration into governance structures, a closer examination of what actually occurred in these jurisdictions illustrates considerable variations – despite the reforms being presented in similar terms and supporting similar general administrative principles.[625]

Britain

The Conservative Years

The election of the Conservative Thatcher government in 1979 marked the election of a government fiercely committed to a particular ideology – that of neoliberalism, a market driven approach to economic and social policy. As a government, its primary policy objectives were to revive market liberalism and to radically revise and roll back the role of the state. The Thatcher government opposed 'big' government and state-led egalitarianism and was deeply suspicious of the influence of the welfare state on society.[626] The impact of the British economic crisis on the Conservatives was said to have "… produced a desire to be seen to 'stand up to' vested interests and a mode of making policy that dismissed the importance of consultation and compromise."[627] To achieve these ends, there was a movement away from the previous reliance on consensus-building mechanisms, such as royal

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[621] Hood, *supra* note 610; Christensen, *supra* note 617.   However, see Aucoin, *supra* note 39, who argues that the NPM was not all that influential in Canada.

[622] Hood, *supra* note 610; Christensen, *supra* note 617.   However, see Aucoin, *supra* note 39.

[623] Aucoin, *ibid.* See also Canada, Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons* (Ottawa: Minister of Supply and Services, 1993).

[624] See, for example, E. Glor, "Has Canada Adopted the New Public Management?" (2001) 3 Pub. Manage. Rev. 121 [Glor].

[625] Christensen, *supra* note 617.

[626] Hood, *supra* note 610.

[627] Moran, "Policy Catastrophes", *supra* note 616 at 425.

commissions, as the basis of policy development, towards small, fast-acting task forces or review panels drawn from the core executive, or from outsiders.[628]

With a solid majority of votes in the House of Commons and Conservative domination of the House of Lords, the Thatcher government had the capacity to pursue its chosen policy direction. The only limitations were concerns for its prospects of re-election, concerns blunted by its genuine ideological commitment to the reforms it was implementing.[629] In pursuit of its objectives, "Thatcherites were convinced that a dramatic break with many institutions and policies was necessary…"[630] In some contexts, however, the strategy of government was to retain its institutions intact but to change their operational dynamics.[631] The extent of this break from existent institutions and policies is critical in appraising the modes and instruments for subsequent regulation.

The vision of the Conservative government was of a strong centralized state with strong individualistic consumers making decisions in a free marketplace. The emphasis was on the role of government, not as a provider of services, but as policy-maker and regulator. To employ a favoured metaphor: government was to steer, not row.[632] Klein notes the paradox at the heart of this new governance agenda – to reduce the role of the state, the power of the state had to be strengthened, because it remained a truism that free markets required regulation,[633] and hence power was increasingly centralized in state agencies. Although decentralization of service delivery in the NHS was continued and indeed developed in subsequent reforms, such decentralization occurred in the context of greater controls imposed by the central state, first in respect of financial matters and ultimately in regard to performance, including the provision and governance of social services.

The NHS was not initially targeted by the Thatcher government for major reforms to its structure or institutions, apart from limited reforms in 1982 that saw the partial

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[628] *Ibid.*
[629] Tuohy, "Logics" *supra* note 35.
[630] A. Gamble, "The Thatcher Decade in Perspective" in P. Dunleavy, A. Gamble & G. Peele, eds., *Developments in British Politics,* (New York: St Martin's Press, 1990) 333 at 336; see also Moran, "Policy Catastrophes", *supra* note 616, who refers to a radical transition.
[631] Klein*, New Politics, supra* note 306.
[632] Moran, "Policy Catastrophes", *supra* note 616.

reorganization and further decentralization of the regional system. This replaced the 90 Area Health Authorities with 192 District Health Authorities (DHAs). This ensured that decisions were made as close to the point of delivery as possible. The boards of regional health authorities (RHAs) and DHAs reflected the ideological convictions of the government. Boards comprised representatives of the senior management of the authority and non-executive members appointed by the Secretary of State (primarily on the basis of their business skills). The formal representation of consultants, GPs, and nurses on governing bodies was ended. The reforms, at least in some senses, represented a revolt against expertise, as there was less scope within the management of the DHAs for the role of the expert (i.e. health professionals).[634] But the reforms may have also represented an attempt to subsume one form of expertise (clinical) with another (managerial/technocratic). The NHS also collaterally felt the impact of the general reforms through the imposition of constraints to the global budgets allocated to the NHS.[635]

The internal management of the NHS did, however, become a focus of government attention. Sir Roy Griffiths, a prominent businessman, was charged to lead a team of businessmen to review NHS management practices to determine how its internal efficiency could be improved. Its 25-page report provided to government in 1983 was a catalyst for much change. At the heart of its recommendations was the wry observation that "In short if Florence Nightingale were carrying her lamp through the corridors of the NHS today she would almost certainly be searching for the people in charge."[636] It recommended the introduction of clearer management structures and of performance targets against which managers would be held accountable.[637] The Griffiths Review also criticized the NHS's consensus management structure, suggesting that too many people were involved in decision-making resulting in significant decision-making delays, and suggested that decision-

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[633] Klein, *New Politics, supra* note 306.
[634] *Ibid.*
[635] P. Day & R. Klein, "Britain's Health Care Experiment" (1991) 10:3 Health Affairs 39 [Day, "Health Care Experiment"].
[636] NHS Management Inquiry, *NHS Management Inquiry Report*, (London: Department of Health and Social Services, 1983) [Griffiths Report]. See discussion in BRI Inquiry, "Learning from Bristol", *supra* note 287; Tuohy, "Logics" *supra* note 35; R. Klein, *The Politics of the National Health Service,* 3rd ed. (London: Longman, 1995) [Klein, *Politics,* 3rd ed.].
[637] Griffiths Report, *ibid.*

making processes should be rationalized.[638] The NHS was said to lack direction, despite the issuance of many directives.[639] Further, the review identified that it was uncertain whether the NHS produced the right kind of services and whether the quality of such services was adequate, as little or no quality evaluations occurred. The review noted in particular that outputs were not measured, there was little or no clinical or economic evaluation of service provision, and that the NHS did not know how well it was meeting the needs and expectations of the people it served.[640] It recommended that service provision and resource usage be evaluated.

While the focus of the review was on managerial issues, its reference to evaluating clinical services was a marked departure from traditional practice, where clinical matters within the NHS had been the sole responsibility of the medical profession.[641] That these questions were even raised was perhaps a first step towards placing some limitations upon the power of the medical profession within the NHS, in effect enhancing the power of the state.[642] The review's recommendations, to review and restructure management systems to appoint managers at every level of the NHS to provide leadership and enhance accountability, were consistent with the NPM ideology that was more broadly being imposed upon the public sector at that time.[643]

The implementation of the Griffiths recommendations was government's effort, for the first time, to measure and assess managerial performance.[644] However, managers continued to play a constrained role in an institution where a parallel management and operations structure remained in place for the medical profession. Despite the Griffith review, attempts to build a unified management structure within the NHS foundered, and the relationships between managers and clinicians did not fundamentally alter.[645] The review resulted in the

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[638] *Ibid.*
[639] Klein*, New Politics, supra* note 306.
[640] Griffiths Report, *supra* note 636.
[641] See discussion in Chapter 2.
[642] Klein*, New Politics, supra* note 306.
[643] Tuohy, "Logics" *supra* note 35.
[644] *Ibid.*
[645] See, for example, the events in Bristol, discussed in Chapter 6, where the maintenance of a parallel management structure saw a CEO fail to intervene in the face of concerns of an unacceptably high death rate for children undergoing some forms of paediatric heart surgery. BRI Inquiry, "Learning from Bristol", *supra*

introduction of performance indicators to enable the comparison of the relative performance of NHS Trusts; it was thought that this might lead to pressure by management to change clinical behaviour.[646]   Performance measures, at least in respect of measuring throughput, were adopted in the mid-1980s, but the activities of doctors generally remained outside of the managerial purview.[647]   After the Griffith review, managers still lacked the necessary information, and perhaps the will, to challenge clinical dominance, [648] although it is also fair to say that the emphasis on and strengthening of managerial power within the NHS increasingly was seen to weaken the power of the professions.[649]

By its third term in office, the Thatcher government was prepared to undertake more serious reforms, propelled in part by what Klein described as the political perception that the medical profession had breached its "implicit concordant" or its bargain with the state.[650] The terms of the implicit bargain were that the medical profession would remain quiescent about changes to the NHS in return for the retention of managerial and clinical autonomy. Prime Minister Thatcher may have viewed the sustained criticism by doctors of the budgetary limitations imposed upon the NHS under the Thatcher government as an implicit revocation of the concordant.[651]

Accordingly, in 1987, a review of the NHS was undertaken by a small working group chaired by the Prime Minister and including four cabinet ministers and two policy advisers. In a break from the tradition of accommodation and corporatism, there were no formal terms of reference, limited consultation, and no representation from the medical profession or from the management of the NHS.[652]   What emerged from the review was a commitment to the establishment of an internal market within the NHS.[653]   This was consistent both with neoliberal ideology concerned about regulatory capture (discussed in more detail later) and

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note 287 and *General Medical Council v Roylance* (No 2) [2000] 1 AC 311 [Roylance]. See also Tuohy, "Logics" *supra* note 35.

[646] Harrison & Schulz, *supra* note 352 at 198.

[647] Tuohy, "Logics" *supra* note 35.

[648] *Ibid.*

[649] See discussion in BRI Inquiry, "Learning from Bristol", *supra* note 287; Day, "Health Care Experiment", *supra* note 635.

[650] See discussion in Chapter 2. See also Klein*, "Politics", 3rd ed.supra* note 636 at 177; Day, "Health Care Experiment", *ibid.*

[651] Day, "Health Care Experiment", *ibid*; Klein*, "New Politics", supra* note 306.

[652] Day, "Health Care Experiment", *ibid.*

with reforms that had been or were being implemented in other parts of the British social services system. These reforms to the NHS were based to a large extent on the work of an American economist, Alain Enthoven, who had earlier critiqued the NHS for, in his view, failing to reward efficiency and innovation.[654] This failure to institute appropriate incentives resulted, according to Enthoven, in a system that encouraged hospitals to export patients, while not rewarding hospitals (usually teaching hospitals) that imported patients.[655]

General practitioners were always weakly controlled by government and hence had limited accountability within the NHS because of their status as independent contractors. The Conservative government, cognisant of this problem, imposed a new contract in them in 1989.[656] This strengthened their accountability to the state by requiring them to carry out certain contractual obligations. Family Health Service Authorities could monitor the terms of these contracts, as well as oversee referral and prescription patterns.

Working for Patients, a White Paper issued by government in 1989, and incorporated into the *NHS and Community Care Act 1990*, set out the framework for reform.[657] The framework included a split between purchasers and providers of services. Henceforth, District Health Authorities (DHAs) would purchase health services from hospitals and other providers. General practitioner fundholding was also introduced, where GPs with large practices (over 11,000 patients) could be allocated a budget to purchase health services (hospital and other community services) for their patients, as well as to pay for their own services. This would, in theory at least, create an internal market which would see competition on the basis of price and quality for funding. Hospitals could remain directly managed by a DHA or convert to NHS Trust status. NHS Trust status would give hospitals greater operational control as they would no longer be overseen by Regional Health Authorities and a further decentralization of the health system to the local level. In addition, NHS Trusts would hold the contracts of consultants who worked there, although pay would remain centrally

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[653] Tuohy, "Logics" *supra* note 35.
[654] The irony of asking an American economist, when the US health system is one of the least efficient in the world, to provide advice on improving efficiency in the NHS, one of the most efficient health systems in the world, escaped few commentators. A. Enthoven, *Reflections on the National Health Service,* (London: Nuffield Provincial Hospitals Trust, 1985) [Enthoven].
[655] *Ibid.*
[656] Day, "Health Care Experiment", *supra* note 635.

negotiated. This potentially gave the NHS Trusts greater control over medical professionals. On the other hand, NHS Trusts were required to include medical professionals in their governance structures, as a condition of gaining self-governing status, reinforcing the accommodation with the profession. The state gave with one hand and took away with the other trying to manage the relationship with doctors so as to avoid a direct confrontation with the medical profession while implementing highly controversial reforms.

The introduction of the internal market was, at least in theory, also designed to clarify the responsibilities of some actors and strengthen accountability.[658] Klein notes that the internal market reforms aimed to transform the relationship between players in the market from trust to contract.[659] Importantly, contracts are also a tool that gives more formal and hierarchical control to the contractor, as part of the contractual process involves setting precise targets and expectations around service provision, service quality, and accountability.[660] Some suggest that, at least initially, service agreements generally did not play a significant role in respect of judgements about clinical quality or appropriateness, as the quality-focused standards within those agreements were largely procedural; for example, they addressed matters such as waiting times.[661] While this is, or was, a correct view and some contractual terms were and are procedural, the development of systems to monitor not just outputs (i.e. number of hip surgeries performed) but also outcomes (i.e. rates of post-surgery infections of those undergoing hip surgery) has enabled service quality to be monitored more comprehensively.

The White Paper also heralded the introduction of medical audit processes within the NHS. Medical audit was defined in the White Paper as "a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome for the patient".[662] From 1989, the Department of Health supported the development of medical audit practices within trusts and DHAs by

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[657] U.K., Department of Health, *Working for Patients* (London: HMSO, 1989) [*Working for Patients*].

[658] Tuohy, "Logics" *supra* note 35.

[659] Day, "Health Care Experiment", *supra* note 635; R. Klein, "The NHS Reforms So Far" (1993) 75 Annals R.C.Med. 74 at 77 [Klein, "NHS Reforms"].

[660] Christensen, *supra* note 617.

[661] Tuohy, "Logics" *supra* note 35.

[662] *Working for Patients, supra* note 657 at 39.

providing £40 million per annum in earmarked funds for five years.[663] From 1990, as a matter of policy, all doctors within the NHS were required to take part in systematic processes of medical audit. The medical audit models initially established within the NHS were described by Harrison and Pollitt as an internal medical model, controlled by the profession, not by NHS management.[664] Thus, medical audit, to some extent, represented the continuation of the accommodation between the medical profession and the state, whereby the profession retained control and autonomy of the practice of its profession. However, in this case the state put mechanisms in place to ensure that processes were in place to audit service quality and to that extent the autonomy of the profession was limited as the state required compliance. Monitoring would take place retrospectively, be conducted by doctors, and aimed at modifying behaviour by education. It would also be confidential, with only aggregate data passed to managers.[665]

Clinical guidelines would be increasingly used to guide practice, although enforcement would rest with the profession, not line managers.[666] Increasingly, it was written into contracts that providers must have established procedures for clinical audit, or that all medical staff must participate in audit; and some contracts particularized specific topics to be addressed by audit programs.[667] However, such contractual provisions may have been ineffective as, in general, at least in early iterations of contracts, there were no sanctions available for breaches, and any monitoring of compliance tended to be retrospective, reactive, and paper based.[668] Tuohy's conclusion was that "[c]ontracting, then, did not generally provide a vehicle for the monitoring of clinical performance …".[669] However, the increasing sophistication of such contracts, and the development of better information systems, suggests that, increasingly, contracts may have become a vehicle to monitor clinical performance.

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[663] Tuohy, "Logics"*supra* note 35.

[664] S. Harrison & C. Pollitt, *Controlling Health Professionals: The Future of Work and Organisation in the NHS* (Buckingham: Open University Press, 1994).

[665] Tuohy, "Logics" *supra* note 35.

[666] *Ibid.*

[667] *Ibid.*

[668] M. Rumsey *et al.*, *The Role of the Commissioner in Audit: Findings of a National Survey of Commissioning Authorities in England* (London: CASPE Research, 1994) at 28.

[669] Tuohy, "Logics" *supra* note 35 at 181.

Although these reforms established a market element into the structure of the health services, they still preserved to some degree the clinical arena as an autonomous zone for collegial decision-making (at least by members of the medical profession). Tuohy suggested that as a result there was little real change in the balance between state actors and the medical profession: "[t]he resilience of traditional patterns of relationships among the actors in the British health care arena derived from the centrality of trust-based relationships in the functioning of the system."[670] Others note that quasi-market competition did in fact, over a period of time, transform the relationships between medical professionals, patients, and managers, as the service agreements negotiated under this model addressed the issue of effectiveness and quality.[671] Additionally, a significant effect of *Working for Patients* was to, "persuade the medical profession to accept more collective responsibility for the way in which individual members exercise their craft."[672] The signal sent to the medical profession is that they have bounded autonomy when actions are taken because the state required it and when there are audit and oversight mechanisms in place to monitor compliance.

As discussed above, the possibility of capture was a focus of the NPM. The corporatist structures within many sectors of the British public sector were a cause of great concern to the conservative governments. As discussed in Chapter 3, the structure of the NHS, with its formal accommodation with the medical profession in the process of decision-making, was such as to automatically raise the hackles of the Thatcher government. Reforms to the NHS constituted the third wave of the Thatcher government's global attack on corporatism in government – the first being reforms to industrial relations, the second to education.[673] Indeed, a hallmark of the Thatcher era is said to be its attacks on the power of established professional groups (as well as local authorities).[674] It is notable that many of these groups were traditionally opposed to the Conservative party or threatened its power.[675] However, it was not just self-interest that drove these reforms; it was also ideological conviction. Indeed, the trust formerly vested in the medical profession to act in a manner consistent with the

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[670] *Ibid.* at 201.

[671] See, for example, R. Flynn, "Clinical Governance and Governmentality" (2002) 4:3 Health, Risk & Soc'y 155 [Flynn].

[672] Klein*, Politics,* 3rd ed.*supra* note 636 at 243.

[673] Tuohy, "Logics" *supra* note 35.

[674] Klein*, Politics,* 3rd ed.*supra* note 636 at 137.

public interest was now in question because of concerns about capture – in this instance, that the private commercial interests of the medical profession were outweighing the public interest.[676] These concerns were particularly seen in respect of the operations of the professional regulatory bodies. As Davies notes: "[t]here was no doubt, however, that the statutory bodies were a thorn in the side of a New Right government …".[677] The political costs of any direct confrontation with the medical profession were potentially so great that the Conservative government chose not to do so, despite its ideological commitments.

But Davies suggests that a confrontation did in fact occur, albeit through an indirect attack on the power, privileges, and autonomy of the medical profession.[678] This occurred by strengthening the accountability mechanisms implicit in employment relationships, promoting audit and risk management within the NHS, and establishing regional education bodies through the *NHS and Community Care Act 1990*.[679] The impact of the reforms was summed up by Klein:

> [T]here is a new emphasis on holding clinicians and others accountable for their performance. A system hitherto based on trust – on the view that consultants and others, by the very nature of their professional status, can be trusted to manage resources put at their disposal – is turning into a system where justification is required. … The NHS has always relied on trust; hence, of course, the inadequacy of so much information in the past. If clinicians and other health professionals can be trusted to do the best for their patients, why bother to collect information about their activities?"[680]

However, any changes to government-sanctioned self-regulation by the health professions were, at this time at least, relegated to the sidelines of reform. In some senses, they may have been deemed unnecessary. Klein notes:

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[675] C. Davies, "The Demise of Professional Self-Regulation: A Moment to Mourn?" in G. Lewis, S. Gewirtz & J. Clarke, eds., *Rethinking Social Policy,* (London: Sage, 2000) 276 [Davies, "Demise"].
[676] *Ibid.*
[677] *Ibid* at 282.
[678] *Ibid.*
[679] *Ibid.*
[680] Klein, "NHS Reforms", *supra* note 659 at 77.

One of the hallmarks of the Thatcher government was precisely that it challenged the power of the trade unions and the professions. In a sense, the medical profession was given warning that it no longer had a veto on public policy and that more rigorous self-regulation was the only alternative to greater managerial control.[681]

Another general focus of the NPM was to make government institutions, particularly in the social services, more responsive to their users – who were re-branded during this period as 'consumers' or 'clients'. For Conservative governments, such responsiveness was an important characteristic of the private-sector norms they were trying to instil in the public service.[682] The re-branding, if you will, of social and health services as products, has attracted a number of powerful critiques.[683] It has been suggested that the use of business language (such as 'provider' and 'consumer') to describe healthcare tapped into a widely shared cultural understanding of what the public expected from a business in terms of service, quality, and safety.[684] The public's increased expectations are coupled with legal rights and remedies if products or services are unsatisfactory.[685]

It is a chicken-and-egg question as to whether these changes – instituted as part of an ideological shift – presaged, accompanied, or were the result of an accompanying shift in social or cultural values. This cultural shift could be seen in trends towards consumerism and, in the health context, in the transformation in the nature of healthcare relationships. Patients moved from being passive recipients of treatment and care, paternalistically offered by medical professionals, to partners in a care-and-treatment relationship with a medical professional. The public was no longer ready to accept passively what was given to them;

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[681] R. Klein, "Why Britain is Reorganising Its National Health Service – Yet Again" (1998) 17:4 Health Affairs 111 at 124 [Klein, "Reorganising NHS"].
[682] Aucoin, *supra* note 39.
[683] J. Childress, *Practical Reasoning in Bioethics* (Bloomington, Ind.: Indiana University Press, 1997); R. Malone, "Policy as Product: Morality and Metaphor in Health Policy Discourse" (1999) 29:3 Hastings Center Report 16 [Malone].
[684] See, for example, Malone, *ibid*.; B. White, F. McDonald & L. Willmott, "Health Law: Scope, Sources and Forces" in B. White, F. McDonald & L. Willmott, eds., *Health Law in Australia,* (forthcoming, Sydney: Thomson, 2010) 3 [White].
[685] *Ibid.*

consumerist rights began to dominate public discourse.[686] Consumerist values of difference and choice are "increasingly accepted by a self-reliant 'contented majority' confident that they can control their own lives."[687]

The Conservative government's approach saw the replacement of the public service ethics with a new managerialist doctrine where the citizen became a consumer and managers ran a business accountable through a market-like process, rather than democratic accountability.[688] But, as Bauman notes, consumer rights in a contract culture are fundamentally out of step with many of the values that underpin the welfare state, such as democratic accountability.[689] As such, these trends imply a revision, not only of the management practices of the public sector in its dealing with consumers, but also of regulatory frameworks and accountabilities.

In the health context these trends translated into pressure to institute regulatory reforms to enhance the rights of patients in their dealings with the NHS and health professionals to make the latter more responsive to patient concerns (complaints). The introduction of the NHS Patients Charter by the Conservative government in 1991 is a case in point. The charter contained broad guarantees at the level of principle, in addition to ten rights and nine standards of practice, many of which related to waiting times or service quality. Although the charter had no legal force, it was bolstered by the introduction of performance measures to try to ensure that the charter was meaningful. Providers were required to produce annual reports containing data about how they met, or did not meet, the standards. But a consequence of this focus on quality and responsiveness to consumers may be that, as Klein notes, the power of the healthcare workers had to be 'smashed'. [690] The move to ensure responsiveness and service quality seems to have further reinforced the impetus for enhanced power, control, and oversight over the medical profession within the NHS.

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[686] E. Annandale & D. Field, "Medical Sociology in Great Britain" in W. Cockerham, ed., *The Blackwell Companion to Medical Sociology* (Malden, MA & Oxford: Blackwell, 2005) 246.

[687] *Ibid.* at 253.

[688] H. Dean, "Managing Risk By Controlling Behaviour" in P. Taylor-Grooby, ed., *Risk, Trust and Welfare,* (Basingstoke: MacMillan, 2000) 51.

[689] Z. Bauman, *Work, Consumerism and the New Poor,* (Buckingham: Open University Press, 1998).

[690] Klein*, New Politics, supra* note 306 at 116.

<u>'New Labour'</u>

The year 1997 saw the election of the Blair Labour government. Symptomatic of the degree of integration of many of the tenets of the NPM into governance norms was that many of the reforms instituted by the previous Conservative government were retained and even strengthened by the Labour government, as part of its 'third way'. The 'third way' was an attempt to marry the economic policies of the 'New Right' with some of the social policies of the Left. One of the intentions of the third way was to focus on being pragmatic, not ideological.

In the health context, the advent of the Labour government saw "both rhetorical emphasis and practical action … now firmly located around issues of health care quality …".[691] A number of reasons have been suggested for this switch of focus. These include: increased evidence of what works in clinical practice; widespread variations in clinical practice and outcomes; a number of high-profile failings of care (discussed in Chapter 6); the emergence of data systems that enabled closer monitoring of performance; the need to contain costs; and, perhaps above all, the necessity for a new government to find an issue "around which to articulate public concern over the NHS which could serve as a focus for health care reform."[692] The Labour government also encouraged the development of social consensus through extensive consultation requirements structured into policy development processes – a process that has been termed 'open governance'.[693]

The underlying principles of these reforms remained very similar, however, to those underlying the Conservative government reforms: to increase the mechanisms for control over clinical matters to enhance and improve performance and strengthen accountability mechanisms within the NHS. Again, the logic was towards centralization, to support a strong, accountable state.

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[691] H. Davies & R. Mannion, "Clinical Governance: Striking a Balance Between Checking and Trusting" in P. Smith, ed., *Reforming Markets in Health Care: An Economic Perspective* (Buckingham: Open University Press, 2000) 246 at 247 [Davies & Mannion].

[692] *Ibid.* at 248.

[693] See, for example, B. Salter & M. Jones, "Change in the Policy Community of Human Genetics: A Pragmatic Approach to Open Governance" (2006) 34:2 Pol'y & Pol. 347; U.K., Cabinet Office, *Modernising Government* (London: HMSO, 1999).

The new government did remove some of the elements of the internal market, and health authorities, trusts and GPs were encouraged to collaborate rather than compete.[694] In other respects, Labour took the internal market a step further by developing primary care organizations (PCOs), consortia of general practices, which could enter into service agreements with providers of hospital and community care services. The 1997 White Paper also emphasized the importance of accountability for the quality of performance outcomes as measured by performance indicators.[695] It introduced the concept of clinical governance, essentially an accountability framework for clinical practice, and required NHS Trusts and PCOs to introduce clinical governance mechanisms.[696]

The *Health Act 1999* enacted the reforms heralded in the White Paper.[697] The new regulation was interventionalist in nature in contrast to the previous "light touch" used to address clinical matters.[698] The intervention is for the most part focused on clinical care.[699] 'Quality' was a watchword of the reforms, and the Act created a duty of quality:

> It is the duty of each Health Authority, Primary Care Trust and NHS trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals.[700]

This meant that every NHS Trust must institute a clinical governance framework. As part of clinical governance, they must have policies for managing risk and improving quality, including reinvigorating clinical audit, strengthening risk-management procedures, mechanisms to implement the National Service Frameworks, National Institute for Clinical Excellence Guidelines, frameworks for staff to report concerns about poorly performing

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[694] U.K., Department of Health, *The New NHS: Modern, Dependable,* (London: HMSO, 1997) [*The New NHS*]; *Health Act 1999* (UK) c. 8 [*Health Act 1999*].
[695] Tuohy, "Logics" *supra* note 35.
[696] Flynn, *supra* note 671; K. Walshe, *et al.*, *Clinical Governance: From Policy to Practice* (Birmingham: Health Services Management Centre, University of Birmingham, 2000) [Walshe, "*Clinical Governance*"]; Davies & Mannion, *supra* note 691.
[697] *Health Act 1999*, *supra* note 694; *The New NHS, supra* note 694.
[698] A. Davies, "Don't Trust Me, I'm a Doctor: Medical Regulation and the 1999 NHS Reforms" (2000) 20:3 Oxford J. Legal Stud. 437 [Davies, "Trust"].
[699] *Ibid.*.
[700] *Health Act 1999, supra* note 694, s. 18(1).

colleagues, and development courses.[701]   National Service Frameworks (NSF) were developed for major care areas; they were essentially evidence-based guidelines for clinical practice. The National Institute for Clinical Excellence (NICE) was established in 1999 to set standards and create guidelines for quality healthcare. The NSF and the activities of NICE also undermined clinical autonomy in that the professions no longer had a monopoly over setting the standards for the profession; instead, these processes were centralized in government agencies. Acceptance and uptake of these guidelines was auditable by the Commission for Health Improvement, as well as being a relevant consideration in any litigation.   The advent of clinical governance has been heralded as representing a "fundamental shift in the relationship between the state and the medical (and other health care) professions."[702]

Pursuant to the reforms, the clinical performance of NHS Trusts would be henceforth evaluated by a newly established Commission for Health Improvement, a non-departmental government body.[703] Its responsibility was to provide advice and information to NHS Trusts and PCOs, review their arrangements to monitor and improve quality, and conduct investigations of the management, provision, or service quality.[704] In part, it did this through a regular process of inspections. Klein notes:

> These instruments [NSF and the Commission for Health Improvement] pose a potentially major threat to the medical profession. They challenge the notion at the heart of medical autonomy: that performance can be judged only by peers.[705]

This Labour initiative was heralded as "the latest of many attempts in the NHS to exercise greater managerial control over clinical activities"[706] and as "revolution" in the way that the British medical profession was regulated.[707] It was, however, also a logical extension of the

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[701] Davies, "Trust", *supra* note 698.
[702] Flynn, *supra* note 671 at 155.
[703] *Health Act 1999, supra* note 694, s. 19. The National Care Standards Commission was established in Britain under the *Care Standards Act 2000* to monitor long-term care facilities and other private health facilities.
[704] *Health Act 1999 supra* note, s. 20(1).
[705] Klein, "Reorganising NHS", *supra* note 681 at 122.
[706] S. Gillam, "Clinical Governance: Implementing the White Paper" in R. Klein, ed., *Implementing the White Paper: Pitfalls and Opportunities* (London: The King's Fund, 1998) 66 at 68 [Gillam].
[707] Davies, "Trust", *supra* note 698.

previous government's move to impose private-sector governance requirements onto the public sector and thereby to increase accountability. In so doing, it imposed another layer of governance requirements, focusing on clinical performance, upon the NHS and upon those who work there. In short: "the government appears to take the view, however, that the profession cannot be trusted to perform this work without the oversight of government regulators."[708] In addition to this, Davies suggests "It is the cost factor that explains the shift from a self-regulatory paradigm to an interventionalist, managerial one."[709] He notes that the proportion of NHS resources allocated to dealing with negligence claims was increasing. It was suggested that it might be more cost effective to weed out poorly performing doctors than to absorb the increasing costs of legal action.[710]

The National Clinical Assessment Authority (NCAA) was established by regulation in 2001 as a special health authority.[711] Its purpose was to provide support to health authorities, primary care trusts, hospitals and community trusts facing concerns about the performance of an individual doctor or dentist by providing advice, carrying out assessments, and offering education and mediation services. This was another mechanism used to strengthen the powers of NHS management to address concerns about professional performance. In creating a parallel process, government avoided the necessity of revisiting government-sanctioned self-regulation. The program's functions were explicitly linked to the GMC's performance-related assessment powers,[712] which constituted additional implicit pressure for the GMC to undertake its performance-related functions adequately as this independent agency was, so to speak, looking over its shoulder.

There was a third round of reforms occurring from 2001–2003 based on two reports: *Building a Safer NHS for Patients: Implementing an Organisation with a Memory*[713]and *A First Class Service:*

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[708] *Ibid.* at 446.

[709] *Ibid.* at 447.

[710] *Ibid.*

[711] *The National Clinical Assessment Authority (Establishment and Constitution) Order 2000*, S.I. 2000/2961.

[712] J. Allsop, "Regaining Trust in Medicine: Professional and State Strategies" (2006) 54:4 Curr. Socio. 621 [Allsop, "Regaining Trust"].

[713] U.K., Department of Health, *Building a Safer NHS for Patients: Implementing an Organisation with a Memory,* (London: Department of Health 2001) [*Building a Safer NHS*].

Quality in the New NHS.[714] One key action was to establish a National Patient Safety Agency (NPSA) in 2001 with a mandate to prioritize patient safety within the NHS.[715] Although this agency had few ostensible powers, it instituted a number of programs that aligned with NHS goals, with tighter scrutiny of safety and quality issues within the NHS, including the reporting of adverse events.

The *National Health Service Reform and Health Care Professions Act 2002* slightly reorganized the health system again by giving Primary Care Trusts broader purchasing authority and renaming Health Authorities as Strategic Health Authorities. The Act also focused on patient and community participation in public decision-making in the NHS by establishing patient forums for each NHS Trust and Primary Care Trust, and a Commission for Patient and Public Involvement in Health. The commission's mandate was to provide advice about arrangements for public involvement in decision-making and to oversee and support the patient forums.

The theme of mistrust of the health-professional regulators continued under the Labour government. Government had made it clear that professional regulatory bodies were on notice that they must improve their performance:

> Recent events have dented public confidence in the quality of clinical care provided
> by the NHS. The challenge for the professions is to demonstrate that professional
> self-regulation can continue to enjoy public confidence.[716]

Perhaps this form of associational self-regulation – i.e. the imposition of pressure to try to compel improved performance from self-regulatory actors[717] – was deemed insufficient, as government subsequently added a layer of meta-regulation above the mechanisms of government-sanctioned self-regulation. Meta-regulatory mechanisms are where a government agency is given an extended mandate or is created to oversee the exercise of

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[714] U.K., Department of Health, *A First Class Service: Quality in the New NHS* (London: Department of Health, 1998) [*A First Class Service*].
[715] *The National Patient Safety Agency (Establishment and Constitution) Order 2001*. S.I. 2001/1743 and *The National Patient Safety Agency Regulations 2001*, S.I. 2001/1742 [National Patient Safety Regulations].
[716] *A First Class Service, supra* note 714 para. 3.44.
[717] See discussion of associational self-regulation in McDonald, "Working to Death" *supra* note 110.

government-sanctioned self-regulatory regulatory powers to ensure that they are exercised in the public, not private, interest.[718] Meta-regulation is then ideologically consistent with the NPM as it guards against regulatory capture and can be considered an expression of distrust, or at least concern, that the regulatory actor(s) in question are no longer "responsible"[719] or "virtuous" political actors.[720] In particular, the government established the Council for Healthcare Regulatory Excellence (originally known as the Council for the Regulation of Health Care Professionals) (CHRE) to oversee all health-professional regulatory agencies within Britain.[721]

The *Health and Social Care (Community Health and Standards) Act 2003* established the Commission for Healthcare Audit and Inspection (the Healthcare Commission) and abolished the Commission for Healthcare Improvement and the National Care Standards Commission (both agencies only having been established in 1999 and 2000 respectively).[722] The Healthcare Commission, similarly to its predecessor, audits and oversees the operations of NHS facilities to encourage improvement in the provision of healthcare by and for NHS bodies.[723] The Act also established NHS Foundation Trusts, a status to be achieved by NHS Trusts with an exemplary record of quality and performance. Foundation Trust status confers even greater autonomy on management and the community. Section 45(1) of the Act strengthens the quality duty previously established in the *Health Act 1999* to have general application across the NHS: "It is the duty of each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided by and for that body."

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[718] See, for example, McDonald, "Working to Death" *supra* note 110; Gunningham, *supra* note 116.

[719] Kagan, *supra* note 434.

[720] Braithwaite, *supra* note 433.

[721] It was established pursuant to *National Health Service Reform and Health Care Professions Act 2002* (U.K.), 2002, c. 17, s. 25-29 partly as a result of a recommendation made by the BRI Inquiry (see discussion in Chapters 6 and 7) [*Health Care Professions Act*].

[722] The government and others involved in the health sector became concerned that the sector was being overregulated by a plethora of regulatory agencies with sometimes overlapping responsibilities which were poorly coordinated, bureaucratic, and whose operations placed too great a burden on front-line health-providers. In 2003, the Minister of Health announced that the Health Select Committee would review the aims and functions of 'arms length' regulatory agencies in the health sector. In 2004, a report recommended that many of these 'arms length' agencies be merged to streamline their functions and to save significant amounts of money. U.K., Department of Health, *Reconfiguring the Department of Health's Arm's Length Bodies,* (London; Department of Health, 2004).

[723] *Health and Social Care (Community Health and Standards) Act 2003* (U.K.) s. 48 [*Health and Social Care Act*].

The tenets of the NPM comprehensively penetrated the NHS under successive governments and fundamentally altered its governance arrangements. The key difference between the Labour and Conservative governments was the degree to which they embraced marketization, but in other respects reforms remained largely consistent with the tenets of the NPM. In so doing, the reforms were consistent with the internal logic of the NHS, as they contributed to the maintenance and expansion of control by the centre. This is irrespective of the greater devolution and decentralization from regional to district to local levels of responsibility during this period, as the devolution was accompanied by the imposition of increasingly detailed financial, managerial and clinical expectations upon all actors within the NHS. Recentralization was re-branded as rational public policy.[724] These contractual expectations were subject to monitoring, auditing, and evaluation by state agencies, supplemented by public reporting of results.

It is the degree to which the NPM affected clinical autonomy that is the most striking divergence between Britain and Canada. In Britain, the Conservative government, at least, was deeply suspicious of professional control as it threatened the supremacy of the state, in the sense of determining the priorities for the health system and delimiting the budget for healthcare. But for all governments fears of capture by a powerful interest group were at the heart of many of the reforms to the NHS. Hence, a key part of the reforms instituted as part of the implementation of the NPM was to create mechanisms to control and limit the autonomy of the professions. These mechanisms included the end of formal corporatist arrangements within the NHS, a greater oversight and control of doctors by NHS management, specific accountabilities for budgetary and clinical decisions and clinical outcomes, as well as specific performance expectations, including compliance with government-generated standards for practice.

It has been suggested that the commitment to mechanisms of audit and accountability seen, not just within the NHS but across the British public sector, has resulted in the emergence in Britain of what Power calls an "audit society" where the regulatory preoccupation is to

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[724] T. Marmor, "Fads in Medical Care Policy and Politics: The Rhetorics and Reality of Managerialism" (Lecture presented as part of the Rock Carling Fellowship Annual Lecture, 2001) cited in C. Tuohy, "Agency, Contract and Governance: Shifting Shapes of Accountability in the Health Care Arena" (2003) 28:2-3 J. Health Pol. 195 [Tuohy, "Agency"].

monitor performance.[725] A distinctive factor of the emerging regulatory state is the declining willingness to trust social actors to comply with rules and a resort to more open scrutiny, inspection, and audit; hence, the growth of the audit society and the increased resources devoted to audit and accountability.[726]

Canada

As noted earlier, there are some challenges with assessing the degree of penetration of the NPM in federal states, due to the multiple layers of government: in Canada thirteen provincial or territorial governments and the federal government (fourteen jurisdictions in total). For the purposes of the argument in this chapter, I am assessing the degree of penetration of the NPM into the management of health systems, so there will only be a limited analysis of the federal level.[727] Analysis of events in the federal sphere will only occur to the extent that tenets of the NPM influenced the Medicare program. As a global comment, Canadian health systems showed both structural and institutional stability, and no major policy change like the institution of the NHS's internal market occurred.[728]

Federal Government

At the federal level, in 1979 elections brought to power, as a minority government, the Progressive Conservative Party headed by Joe Clarke. Some commentators noted: "Before his victory on 22 May 1979, Clarke sounded like a Canadian counterpart to the 'iron lady' [Thatcher]", but the reality was anything but – attributable to the minority status of his government.[729] During its brief stint in power, the Clarke government commissioned Justice Hall, the architect of Medicare, to review Canada's health insurance programs. This review occurred as a result of sustained criticism from the Liberals of the Progressive Conservative's policy of tolerance of extra-billing. Thus the review was designed to shore up support for the government and, as such, political considerations required the use of a consensus-

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[725] Power, *supra* note 597.

[726] Power, *supra* note 597.

[727] There is little to no attention paid in the literature to the impact of NPM on Canadian territories; accordingly, the focus of attention will be on developments in the provinces.

[728] Tuohy, "Logics" *supra* note 35.

building device, like an external review, undercutting commitment to the full gamut of NPM reforms. The review's scope was somewhat limited, in that although Justice Hall was to review health insurance programs, the implicit limits were to undertake such a review within the current regulatory framework. The Clarke government's commitment to NPM foundered in the face of political reality, despite a persistent minority view that provincial insurance programs should be repealed in favour of a market-based system similar to the US system.[730] A market-based system was, unsurprisingly, roundly rejected by Justice Hall, who said Medicare should be sustained. He was also critical of the trappings of the market-based system that had been retained – for example, extra billing – and suggested that fees should be independently determined and any form of user-pays system should be resisted.[731]

By the time Justice Hall reported back, the Clarke government was but a memory, and a Liberal government, led by Pierre Trudeau, was back in power. Trudeau introduced only some of the elements of the NPM, as part of a program of 'rational management', focusing primarily on the risk of ministers being captured by bureaucrats.[732] Certainly, there was no interest in opening Medicare to the free market. Federal and provincial relations remained strained on healthcare, due to general tensions on constitutional reform and other matters (discussed in Chapter 3), perceptions that the federal government was not assuming its fair share of the burden, and resistance from some to the recommendations of the Hall Report.[733] The tensions were exacerbated when the Trudeau government moved to limit its financial exposure to ever-increasing Medicare costs by moving from 50/50 cost-sharing to block grants, 100 per cent cash transfers were replaced by a mixed system of cash transfers and tax points, and the introduction of an escalator.[734]

Discord over the direction of the Medicare program continued, with some provinces, particularly Alberta, strongly advocating for a more user-pays model in line with the tenets of the NPM that advocate a greater reliance on market mechanisms and increasing privatization

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[729] C. Campbell, *Governments Under Stress* (Toronto: University of Toronto Press, 1983) cited in Aucoin, *supra* note 39 at 11.
[730] Gray, *supra* note 306.
[731] *Ibid.*
[732] Aucoin, *supra* note 39.
[733] Gray, *supra* note 306.
[734] Lahey, *supra* note 306.

of services formerly provided by government. In 1983, the Alberta government acted on those convictions by raising Medicare premiums by 47 per cent and announcing the introduction of a $20 per day charge for in-patient hospitalization.[735] The actions of the government of Alberta were said to have spurred the federal government into action, with constitutional law experts asserting that the federal government could legitimately enforce compliance with the conditions of the hospital and medical insurance programs.[736]

In 1983, the Trudeau government published a white paper, *Preserving Universal Medicare*, that focused on the issue of imposing user charges on patients.[737] The White Paper suggested the introduction of new legislation to rationalize and strengthen the current legislation in this area, arguing it would preserve Medicare by ensuring its basic principles.[738] The *Canada Health Act* (CHA) was introduced and passed unanimously in 1984.[739] Five principles underpinned the shape of the Medicare scheme. It rejected a market base for the provision of doctor and hospital services, by requiring the health insurance program in each province or territory to be managed by a non-profit authority accountable to government[740] and by discouraging extra billing and user charges by threatening non-payment of the equivalent amount of the federal contribution.[741] The ban on extra billing struck at a part of the medical profession's autonomy by removing a symbol of their fiscal independence. However, other than adherence to the five conditions of portability, public administration, universality, comprehensiveness, and accessibility, the CHA does not prescribe how health services ought to be delivered within the provinces.[742] The impact of this, especially given the high-profile nature of the extra-billing debate, was to draw a line under the possibility of importing free-market principles unless the government concerned was prepared to deal with the (no doubt considerable) public fall-out.

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[735] Gray, *supra* note 306.
[736] *Ibid.* This view is disputed; see, for example, Petter, *supra* note 373; Choudhry, *supra* note 373; Choudhry, "Social Policy", *supra* note 373.
[737] Canada, Health and Welfare Canada, *Preserving Universal Medicare: A Government of Canada Position Paper,* (Ottawa: Health and Welfare Canada, 1983).
[738] Gray, *supra* note 306.
[739] CH Act, *supra* note 401.
[740] *Ibid,* s. 8(1).
[741] *Ibid*, ss. 18-20.
[742] It is, of course, disputed as to whether the federal government has the power to do this. Petter, *supra* note 373; Choudhry, *supra* note 373; Choudhry, "Social Policy", *supra* note 373.

The CHA also, in a manner of speaking, confirms the existent forms of accommodation as a mechanism of governance in health systems across Canada. For example, s. 12(2) of the CHA notes that disagreements between provinces and negotiating bodies from the profession over payment schedules should be referred for binding arbitration. In so doing, it acknowledges that formal accommodation with the medical profession will continue, hence Tuohy's comment that " … although the passage of the Canada Health Act constituted an undeniable symbolic defeat for the medical profession, there were significant tangible and structural gains for the profession as the result of the legislation."[743] While the CHA removed flexibility in respect of billing, the CHA did not address other aspects of professional autonomy such as location, scheduling, labour and other inputs, volume, and mix of services. In enacting the CHA, the focus of the federal government appeared to be to defend the boundary between the private and the public sectors – a course of action anathema to strict interpretations of the NPM.[744] Reaffirming central responsibility for national standards in respect of the public financing of doctor and hospital services gave the Trudeau government an opportunity to preserve it and leave the provinces to negotiate the practicalities with the still-powerful medical profession.[745]

A Progressive Conservative majority government was elected and held office between 1984 and 1993, led by Brian Mulroney and later Kim Campbell. These governments pursued a range of organizational and managerial changes, but "in comparison to the other three systems [Australia, New Zealand, and Britain], Canada appeared to fall short of the mark."[746] The impact of NPM-style reforms in respect of the CHA was limited to the progressive constraint of financial contributions under the Medicare program, in the interests of paying off debt, a process commenced in the late 1970s by the Trudeau government.[747] For example, total federal contributions declined from 40 per cent in 1975 to 33 per cent in 1994, and changed from 100 per cent conditional cash payments to, in 1974, about 50 per cent in the form of unconditional tax points.[748]

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[743] Tuohy, "Logics" *supra* note 35 at 94.
[744] *Ibid.*
[745] Gray, *supra* note 306.
[746] Aucoin, *supra* note 39 at 13.
[747] Tuohy, "Logics" *supra* note 35.
[748] *Ibid.* at 92.

The 1993 election of the Liberals, under Jean Chrétien, saw the new government undo many of the NPM-style reforms initiated by the Mulroney and Campbell governments and, in the health context, its focus again was to defend the boundaries between private and public sectors.[749]   But it also continued the program of fiscal austerity, with the Chrétien government's 1995 budget unilaterally reducing federal contributions to the provinces.[750]   It announced a National Forum on Health in 1994 to "develop a new vision for Canada's health system for the 21st century."[751]   But the development of the forum was marred by federal–provincial disagreement, with the provinces unhappy at what they saw as a continuing federal incursion into provincial powers.[752]   Ultimately, the forum was boycotted by the provinces, although some sent observers along to various meetings. The forum's 1997 report was a solid endorsement of the structure of Medicare – funding for medically necessary services, single-payer model, the five principles, and partnership.[753]   As with the Hall review, "[i]n short, the National Forum on Health, unlike the review of the NHS in Britain … solidly endorsed the structural balance and the institutional mix of the existing system."[754]

Somewhat reversing the fiscal austerity that was a characteristic of the NPM (a reversal also seen in Britain), by 1999 the federal government agreed to restore federal funding for Medicare to 1995 levels.[755]   In return, the provinces agreed to allocate all that funding to 'core' healthcare services and programs and expressed their commitment to the Medicare principles. All provinces except Québec also entered into a social union framework with the federal government. The framework saw the provinces reiterate their commitment to the principles of Medicare, refer disagreements to a dispute-resolution mechanism,[756] and the federal government committed to only introducing cost-sharing programs with the agreement of at least six provinces.[757]   This represented what one might term the last gasp of

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[749] Gray, *supra* note 306.

[750] Lahey, *supra* note 306.

[751] Canada, National Forum on Health*, Canada Health Action: Building on the Legacy: Final Report,* **(**Ottawa: Health Canada Communications, 1997) [National Forum on Health].

[752] Tuohy, "Logics" *supra* note 35.

[753] National Forum on Health*, supra* note 751.

[754] Tuohy, "Logics" *supra* note 35 at 96.

[755] Both economies had markedly strengthened by this period.

[756] The dispute resolution mechanism was never placed in legislation or even in an agreement between federal, provincial, and territorial governments, and has never been used.

[757] Tuohy, "Logics" *supra* note 35.

NPM at the federal level in the health context. Subsequent federal-level reviews of the Medicare program (Kirby and Romanow) were not solely motivated by NPM-related concerns.[758] In the context of patient-safety-related reforms, it is also interesting to note that these reports focused primarily on issues of access to services and sustainability. The Kirby Report did, however, recommend the responsibility for funding medical services be devolved to the regional level. While this recommendation has not been actioned, it may constitute a threat to professional autonomy as fee negotiations for medical services have traditionally occurred at the provincial level and hence may threaten the nature of the bargain with the medical profession.[759]

The Provinces

After the introduction of the CHA in 1984, the provinces, on the whole, complied with the requirements in the CHA to eliminate, or limit, extra billing and/or user charges. Post the CHA, Ontario experienced significant challenges negotiating with the medical profession, unhappy with losing extra-billing privileges and with the compensation on offer from the province.[760] This resulted in a strike. But despite some provinces disagreeing with the CHA, the political stigma of being seen to not comply with the Medicare principles appeared too politically risky for provincial governments, in the face of continued public support for Medicare.[761]

The 1990s saw the ideological differences between provinces cast into greater relief. Some, like Ontario and Alberta, had governments committed to the neoliberal ideology that underpinned the NPM and which included reducing the role of the state in the funding and organisation of healthcare. Others remained resistant to the NPM and determined to retain an expansive role for the state in ensuring access to healthcare. These differences mainly emerged in the context of disagreements about Medicare.

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[758] Canada, Senate Standing Committee on Social Affairs, Science and Technology, *The Health of Canadians – The Federal Role – Volume Six - Recommendations for Reform,* (Ottawa: Standing Senate Committee on Social Affairs, Science and Technology, 2002) [Senate, "Health of Canadians"]; Romanow, "The Future" *supra* note 303.

[759] Senate, "Health of Canadians" *ibid*, see also Saskatchewan, Saskatchewan Commission on Medicare, *Caring for Medicare. Sustaining a Quality System*, (Regina: Government of Saskatchewan, 2001) [Fyke Commission].

[760] Gray, *supra* note 366.

[761] Tuohy, "Logics" *supra* note 35.

In the 1990s, in the context of broad governmental agendas at both federal and provincial levels to reduce deficit spending (a key element of the NPM), governments embarked on measures to contain public health expenditures.[762] After first trying, and failing, to control medical budgets i.e. payments to doctors, provinces reduced hospital budgets by instituting case-based funding to encourage efficiency. In addition, in the mid-1990s, all provinces instituted a program of hospital restructuring, including hospital closures and the reduction of bed numbers. [763] The 1990s saw most federal and provincial governments adopt an NPM-driven agenda, at least in terms of its fiscal aspects.[764] Governments across Canada agreed that balancing the budget was an absolute priority, and cutting taxes and paying down debts were essential to economic growth.[765] The period 1992–1997 saw substantial cuts to program spending by the federal government and by provincial governments.[766] Some provinces passed anti-deficit laws, and from 1992 provinces reduced health spending, a trend reversed in 1997.[767] In the health context, real per-capita spending decreased by 7.2 per cent from 1990–1996, while total per-capita spending increased by 1.7 per cent.[768]

The most remarkable change was state-led horizontal restructuring – or regionalization.[769] In all provinces bar Ontario, forms of regional structures were established to manage the hospital sector. Ontario resisted the regionalization trend.[770] While it did establish district health boards, they were advisory and had no budgetary power. This changed the organizational structure of the health system in Ontario but did not significantly change how it operated.[771] In Ontario, hospitals continued as self-governing bodies, so the relationship between the state and hospitals did not really alter.[772]

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[762] *Ibid.*

[763] *Ibid.*

[764] L. Imbeau, K. Chenard & A. Duda, "The Conditions for a Sustainable Public Health System in Canada" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* Vol. 3*,* (Toronto: University of Toronto Press, 2004) at 224 [Imbeau].

[765] *Ibid* at 224.

[766] *Ibid* at 224.

[767] *Ibid* at 224.

[768] Tuohy, "Logics" *supra* note 35.

[769] *Ibid.*

[770] At least it resisted until 2006, when it began to introduce regionalization.

[771] Tuohy, "Logics" *supra* note 35.

[772] *Ibid.*

In all other provinces, power was devolved from provincial health ministries to regional bodies, including the discretion to allocate health resources (within a global budget allocated by the provincial health ministry), and some planning and policy functions.[773] The regional bodies could either directly assume the responsibility for the operation of hospitals or could contract with the hospitals for service provision.[774] Either way, the regional bodies could establish performance targets, strengthen accountabilities, and increase monitoring. However, the changes in governance norms when the state imposed a centrally planned structure on local hospitals meant that hospitals lost autonomy. As Lavis notes, "[t]his change of governance altered a key element of the core bargain with hospitals: their autonomy as private institutions."[775] Although regionalization involved devolution from the provincial ministries of health to quasi-independent regional bodies, the process of requiring such structural change involved an assertion of government power.[776] Implementing legislation reinforced the accountability of the regional bodies to government.[777] In no instance did the responsibility of a regional board include anything related to the management of doctors[778] – hence Lavis's conclusion that "[r]egionalization also had little apparent effect on the core bargain: physician services were excluded from regional funding envelopes in every Canadian province."[779]

By the mid-1990s, there was a sense that Medicare could be in jeopardy.[780] A 1996 Ontario poll showed that 46 per cent of respondents believed that the quality of care at their local hospital had worsened over the previous year.[781] This may have been due to the bad press resulting from overcrowded emergency rooms, long waiting lists, crises in cancer care, restructuring, and hospital closures.[782] These factors "caused much public confusion and

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[773] Maioni, "Roles and Responsibilities", *supra* note 404; Lahey, *supra* note 306.
[774] Lahey, *supra* note 306.
[775] Lavis, *supra* note 386 at 271.
[776] Lahey, *supra* note 306; Tuohy, "Logics" *supra* note 35.
[777] Lahey, *ibid.*
[778] Tuohy, "Logics" *supra* note 35 at 100.
[779] Lavis, *supra* note 306 at 272.
[780] See, for example, T. Marmor, *supra* note 546.
[781] Cited in Tuohy, "Logics" *supra* note 35 at 103.
[782] S. Glouberman & B. Zimmerman, "Complicated and Complex Systems: What Would Successful Reform of Medicare Look Like?" in P. Forest, G. Marchildon & T. McIntosh, eds., *Changing Health Care in Canada,* vol. 2*,* (Toronto: University of Toronto Press, 2004) 21 [Glouberman]; O'Reilly, *supra* note 412; Adams, *supra* note 464 at 66.

cynicism."[783]   The governmental debates about Medicare became increasingly acrimonious and dysfunctional, which also acted to undermine public confidence in the system.[784]   As the Romanow Commission's interim report put it: "Canadians are tired of the finger-pointing and 'hollering from a distance' while both parties squabble over fundamental directions and funding."[785]   The general unhappiness with the system still has at its heart concerns over physical access to healthcare services.[786]

The accommodation with the medical profession that underpins the medical aspects of the health insurance schemes in each province was discussed in more detail in Chapter 3. Some attribute the stability of the structures of Canadian health to the nature of the long-term accommodation between the state and the medical profession, an accommodation established on even more favourable terms than the accommodation at the heart of the NHS.[787]   Central to this accommodation was the commitment to maintain professional autonomy in exchange for acquiescence to the introduction of health insurance programs in each province. Where the introduction of the tenets of the NPM in Britain saw a sustained assault on all aspects of the medical profession's interface with the health system (fiscal, managerial, and clinical), this pattern was not repeated in Canada. With the exception of a brief period in Ontario (discussed further below), the ideologically based suspicion of the medical profession as a quasi-union and/or an agent of regulatory capture did not seem to exist in Canada and did not compel reforms to anywhere the same extent as occurred in Britain. Equally, medical professionals in Canada were never on the same footing vis-à-vis the state as their British counterparts as they were at best agents of government. Hence, Canadian doctors had much more independence than their British counterparts being neither independent contractors in a contractual relationships with the state nor employees. While some professional autonomy was indeed curtailed in Canadian jurisdictions in the name of fiscal responsibility, the managerial and clinical spheres of professional autonomy remained, for the most part, untouched. Attempts to curtail professional autonomy did create some

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[783] Adams, *ibid.* at 66.
[784] McIntosh, *supra* note 483.
[785] Canada, Commission on the Future of Healthcare in Canada, *Shape the Future of Health Care: Interim Report,* by R. Romanow (Ottawa: Commission on the Future of Health Care in Canada, 2002) at 40 [Romanow, "Interim"].
[786] Duncan, *supra* note 369.
[787] Tuohy, "Logics" *supra* note 35.

strain between the state and the medical profession in Canada, with the profession opposing what they perceived as state attempts to gain control over physician supply, scope of coverage, payment mechanisms, and clinical protocols.[788]

The Medicare wars of the late 1970s and 1980s in which the medical profession confronted the federal and some provincial governments, as well as consumer and public interest groups, pointed to a change in the nature of the accommodation with the medical profession within Canada and its relationship with the state and the public. One doctor noted: "The physician must realise that he is no longer the total master of his destiny and that he cannot speak with absolute authority, especially in matters pertaining to health care delivery."[789] Governments during this period were more willing to "flex their legislative muscle to take unilateral action if necessary, but more typically to establish a 'shadow' within which their negotiations with the profession would proceed."[790]

As discussed in Chapter 3, Canadian doctors, or their agents, negotiated a fee schedule for the reimbursement of services on a fee-for-service basis. Generally, it is notoriously difficult to contain the growth of fee-for-service models because of built-in incentives for professionals to increase utilization to maximize their incomes – something that has significant consequences for budgets.[791] In the 1990s era of fiscal constraint, highly influenced by the tenets of the NPM, this proved somewhat problematic for governments, and the first small steps were taken to try to address the issue. Thus, in the 1990s the terms of the accommodation between the state and the profession were progressively elaborated to constrain the entrepreneurial discretion of doctors.[792] Limitations on extra billing have previously been discussed, but there were other ways in which the state sought fiscal control or at least influence over the medical profession.

The initiatives first focused on issues of over-utilization of or over-billing Medicare. In the late 1970s and early 1980s some provinces established committees to review the utilization

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[788] O'Reilly, *supra* note 412.
[789] M. Richter, "A Doctor Looks at his Profession: What Went Wrong?" (1986) 135 CMAJ 524.
[790] Tuohy, "Logics" *supra* note 35 at 230.
[791] Lahey, *supra* note 306.
[792] Tuohy, "Logics" *supra* note 35.

profiles of individual doctors to determine whether they were over-billing Medicare.[793] The bodies all were reactive in nature, responding to extreme outliers rather than conducting regular audits. With one exception (Québec), the bodies were set up under the aegis of professional bodies. For example, in Ontario, the utilization body was administered by the College of Physicians and Surgeons of Ontario (CPSO), and in British Columbia, the British Columbian Medical Association; only in Québec was utilization review considered the proper responsibility of government. It is perhaps telling that opinion polls in Québec indicated higher levels of support for state activism than in any other region in Canada[794] and, as discussed in Chapter 3, the statist tradition is strongest in that province. With the exception of Québec, the mechanisms employed to address this issue respected and retained the autonomy of the profession to self-govern.

The question of the fees that doctors could charge was traditionally negotiated between the profession and the province. The nature of the relationships between these parties varied across Canada. For example, British Columbia, Ontario, Alberta, and Manitoba used a collective-bargaining model which saw the employment of increasingly confrontational tactics. Relations were particularly adversarial in British Columbia where a populist political culture, a polarized partisan environment, and an adversarial human relations system combined to create discord.[795] The British Columbian government was the first to try to establish control over the distribution of doctors by refusing to issue billing numbers to doctors seeking to practise in areas deemed over-serviced. A successful challenge was made to this policy on the ground that it impeded mobility rights.[796] In Ontario, the relationship between the state and profession was closer, going beyond medical remuneration. Relationships were reasonably collegial in most of the other provinces.[797] Québec was again alone having a highly formalized and structured process for negotiations. These processes

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[793] *Ibid.*
[794] *Ibid.*
[795] *Ibid.*
[796] See *Mia v British Columbia (Medical Services Commission)* (1985), 17 DLR (4th) 385 (BC SC); *Wilson v British Columbia (Medical Services Commission),* [1988] BCJ 1566 (BC CA); *Waldman v British Columbia (Medical Services Commission),* [1989] BCJ 2014 (BC CA) but see where such challenges were unsuccessful *Canadian Egg Marketing Agency v Richardson* [1998] 3 S.C.R. 157 (SCC); *Rombaut v New Brunswick (Minister of Health and Community Services),* [2001] NBJ 243 (NB CA) 2001. See also discussion in D. Greschner, "How Will the Charter of Rights and Freedoms and Evolving Jurisprudence Affect Health Care Costs?" in T. McIntosh, P. Forest & G. Marchildon, eds., *The Governance of Health Care in Canada,* vol. 3 (Toronto: University of Toronto Press, 2004) 83.
[797] Tuohy, "Logics" *supra* note 35.

of negotiation did not do much to contain budgets, so most governments acted unilaterally to institute a global budget for the payment of doctors, thus capping, to an extent, utilization.

But once these global budgets were established, the details still had to be negotiated with the professions. In parallel with the introduction of global budgets, many provinces determined that the relationship between the provinces and the medical profession needed to be formalized (as had been the case in Québec since the 1980s). In the 1990s in Alberta, British Columbia, New Brunswick, Newfoundland, Nova Scotia, Ontario, and Prince Edward Island, bipartite joint management committees with equal representation from government and the medical profession were established.[798] The committees formalized the accommodation at the heart of the Canadian health systems, cemented the corporatist nature of the management system within Canadian health systems, and arguably expanded the influence of the medical profession in policy-making. These management committees negotiated fee structures for the provision of medical services within global budgets, newly introduced to try to contain utilization.[799] In Britain, action was taken to remove corporatism due to fears of capture; in Canada, the corporatist bargain was formalized and strengthened.

Although the focus of much attention was indeed fees and utilization, so as to contain cost overruns, increasingly clinical effectiveness and quality became an issue of concern for governments. However, in Canada incursions by the state into clinical care were fiercely and on the whole successfully resisted. Professional bodies sought to pre-empt government intervention in the area of developing clinical guidelines, but most governments chose to establish joint profession–government taskforces or specialized arms-length bodies to develop them.[800] In Québec, issues of clinical effectiveness, including the formulation of practice guidelines, were dealt with by the professional regulatory body.[801] In Ontario, joint committees were developed between the province and the profession to deal with aspects of practice other than utilization, including the formulation of clinical guidelines. The Task Force on the Use and Provision of Medical Services was established in Ontario in 1988. It

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[798] *Ibid.*
[799] Lahey, *supra* note 306.
[800] Tuohy, "Logics" *supra* note 35.
[801] *Ibid.*

issued two guidelines, but in 1991 was replaced by a joint management committee. Also in Ontario, an Institute for Clinical Evaluative Sciences was established to conduct research to assist with developing clinical guidelines, but it was never really effective because of the physician-services budget cap and budget reductions.[802] The 1995 election of an ideologically driven Conservative government in Ontario, with a deep distrust of unions, saw government assume unprecedented powers in respect of the schedule, supply, and distribution of physicians.[803] After some conflict, the parties agreed to establish joint committees in respect of matters like clinical guidelines. In Saskatchewan, the Health Services Utilization and Research Commission was established in 1992 at arms length from government, with significant professional engagement, to produce clinical guidelines.[804] While these bodies may have produced guidelines there was no monitoring of uptake, or any requirement by the state to incorporate guidelines into professional practice. Governments may have seen guidelines as a method to standardize practices and improve quality. However, clinical guidelines played a minimal role in clinical practice in Canada; but the mechanisms to develop them proved a source of conflict, as the profession saw any attempt by the state to develop them as an incursion into professional autonomy.[805] The monitoring of medical performance remained firmly with hospital medical staffs and the profession more generally.

While governments' concerns about fiscal issues compelled them, to some extent, to place constraints on the medical profession's autonomy, they chose to use mechanisms that maintained, to a large extent, the corporate bargain struck with the profession. Attempts by the provinces to assume a greater role in regard to clinical effectiveness and quality were broadly ineffective, with the medical profession retaining its autonomy in this area. While the lack of strong anti-professional ideology generally seen in Canada may have been one factor mitigating against the reduction of clinical and managerial autonomy, there are also other possible explanations. These include that the form of NPM embraced in the context of Canadian health systems tended not to be strongly preoccupied with the possibilities of third-party capture by the medical profession, whereas the converse was true in Britain. But

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[802] *Ibid.*

[803] *Ibid.*

[804] *Ibid.*

[805] *Ibid.*

an explanation may also go back to the logics of the system established during the founding of health insurance programs, where doctors are not employees or contractors of the state, and their agency relationship with government creates a sustained logic of anti-intervention in areas where the profession can legitimately claim expertise.

During this period, many governments commissioned reviews of their health systems.[806] These reviews predominantly focused on issues related to access, funding, and sustainability. There were a number of common themes emerging from these reports, including advocating a move to community care, reallocation of functions between healthcare personnel, decentralization of decision-making to regional councils, and a broadening of focus of the health system to adopt a 'determinants of health' approach.[807] The focus was primarily on restructuring in the hospital sector through increasing horizontal integration, reducing bed numbers and, to some extent, building capacity for community-based care.[808] Traces of NPM ideology can be found in several of these reports and was particularly evident in the significant differences between the reports as how the desired outcomes should be achieved.[809]

As for the provinces, no matter what the strength of the ideological conviction about NPM was within particular provinces, "[n]one, however, called for or embarked upon major structural or institutional change to its health care system", [810] and no report raised radical alternatives to the basic model.[811] The closest to do so emerged from Alberta in 2001 and focused on issues of efficiency, choice, and responsiveness – all NPM tenets – to make an argument for greater penetration of the market into healthcare.[812] However, its recommendations were not pursued. In general, Canadian health systems withstood the lure

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[806] Quebec, Clair Commission, *Les Solutions Émergentes. Commission d'étude sur les Services de Santé et les Services Sociaux,* (Quebec: Ministère de la Santé et des Services Sociaux, 2000) [Clair Commission]; Fyke Commission, *supra* note 759; Ontario, Ontario Health Services Restructuring Commission, *1996-2000. Looking Back, Looking Forward: A Legacy Report,* (Ottawa: Health Services Research Foundation, 2000) [Ontario Restructuring Commission]; Alberta, Premier's Advisory Council on Health, *A Framework for Reform: Report of the Premier's Advisory Council on Health,* (Edmonton: Alberta Health, 2001) [Mazankowski Report].

[807] See discussion in Lahey, *supra* note 306; Tuohy, "Logics" *supra* note 35.

[808] Tuohy, *ibid*

[809] See, for example, Lahey, *supra* note 306.

[810] Tuohy, *supra* note 35 at 97.

[811] Marmor, *supra* note 546.

[812] Mazankowski Report, *supra* note 806.

of market incentives and managed care which led to substantial modifications of the health systems in other countries.[813]

The reviews occurring in the 2000s (two at the federal level and three provincial reviews – Alberta, Saskatchewan and Québec – again with the exception of Alberta), suggest that the neoliberal agenda and the NPM concerns have waned and evidence-based decision-making is gaining ground.[814] Thus the focus, while still overwhelmingly on access and determinants of health, has been broadened to also include concerns about effectiveness and quality. Four of the reports recommended the creation of independent quality agencies to monitor and report about quality and effectiveness-related issues.[815]   Quality agencies were subsequently introduced in Alberta, Saskatchewan, and Ontario.[816]

In Canada, reforms based on the NPM were important in the health system context, insofar as they touched upon maters of fiscal control. Hence, there was great penetration of the tenets of the NPM in terms of the impositions of budgetary constraints and controls. The processes of regionalization saw increased control by the centre at the expense of local actors, and the imposition of contracts and other mechanisms to monitor and require performance by hospitals. It is clear, however, that despite a few relatively timorous attempts, there was no serious incursion into clinical autonomy; and indeed, that the corporatist accommodation with the profession was, to a certain extent, strengthened. The greater impact of an NPM-inspired renegotiation of the accommodation with the medical profession was in the context of fiscal policy and medical entrepreneurialism.

Conclusion

While the full spectrum of the tenets of the NPM became deeply embedded in the governance of the health system in Britain in terms of financial, managerial, and clinical issues, the same could not be said for Canada. In Canada, despite the ideological convictions

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[813] Banting & Corbett, *supra* note 405.

[814] Adams, *supra* note 464.

[815] Fyke Commission, *supra* note 759; Romanow, "The Future", *supra* note 303; Senate, "The Health of Canadians *supra* note 758; Mazankowski Report, *supra* note 806.

[816] *Health Quality Council of Alberta,* Alta. Reg. 130/2006; *Health Quality Council Act,* S.S. 2002, c. H-0.04 as amended by S.S. 2002, c. R-8.2; *Commitment to the Future of Medicare Act,* S.O. 2004 c. 5.

of some governments, in the context of the health system the impact of the NPM was limited primarily to matters relating to budgets and expenditure. The clinical autonomy of the medical profession was never seriously threatened, and in fact the logic of the system promoted the further development of the corporatist system through joint working committees addressing a range of issues. The impact of the NPM was a turning point that marked a change in the logic of governance within the NHS that had significant implications for the British approach to patient-safety regulation. The logic of the systems in Canada remained largely intact, and the NPM did not prove a pivotal turning point in that system.

Chapter 6
Dead Babies and Deviant Doctors: Scandals and Regulatory Realignments

Introduction

The last chapter argued that broad shifts in political norms shape the context of regulatory changes. This chapter considers a second contextual dimension that promotes regulatory realignment, namely, the emergence of scandals. Two emblematic images are particularly potent in fostering regulatory realignments: infant fatalities and deviant doctors, cases that epitomize the threat posed to the most vulnerable on the one hand, and the responsibility imposed on the most trusted on the other. These images are sadly redolent of many of the scandals discussed in this chapter.

That critical events drive change is not a new insight.[817] The policy literature indicates that health-related scandals that resonate in the public consciousness can precipitate a cycle of regulatory shifts.[818] Scandals may lead to public inquiries, public inquiry may result in new safety measures, and new safety measures result in novel or increased regulation.[819] Fundamentally, regulation as Moran describes it "is the response to the now instinctive reaction that 'something should be done about it'."[820] Hutter and Lloyd-Bostock concur:

> Emotions are aroused by news of serious injury or tragic death, especially where there are large numbers of victims. The power of accidents to command attention and arouse emotion in turn has social consequences. Accidents create expectations and

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[817] See, for example, B. Jones, *Reconceiving Decision-making in Democratic Politics: Attention, Choice and Public Policy* (Chicago: University of Chicago Press, 1994) [Jones]; I. Butler & M. Drakeford, *Social Policy, Social Welfare and Scandal: How British Public Policy is Made* (Basingstoke & New York: Palgrave MacMillan, 2003 [Butler & Drakeford]; B. Turner & N. Pidgeon, *Man-made Disasters* (Oxford: Butterworth-Heineman, 1997); C. Wells, *Negotiating Tragedy: Law and Disasters* (London: Sweet & Maxwell, 1995) [Wells, *Negotiating Tragedy*].
[818] Butler, *ibid*; N. Stanley & J. Manthorpe, "Introduction: The Inquiry as Janus" in N. Stanley & J. Manthorpe, eds., *The Age of the Inquiry: Learning and Blaming in Health and Social Care* (London and New York: Routledge, 2004) [Stanley & Manthorpe].
[819] A. Alaszewski & K. Coxon, "Restructuring Health Care: Developing Systems to Identify Risk and Prevent Harm" in A. Petersen & I. Wilkinson, *Health Risk and Vulnerability* (London & New York: Routledge, 2008). [Alaszewski & Coxon]
[820] M. Moran, *The British Regulatory State: High Modernism and Hyper-Innovation* (Oxford: Oxford University Press, 2003) at 26 [Moran, *British Regulatory State*].

demands for action. Not only must some response be made; it must be seen to be made.[821]

If the public comes to believe that regulatory agencies are not sufficiently responsive to scandals, before or after the scandal emerges into the public spotlight, regulators may lose the public's trust. Without trust, regulatory actors may lose legitimacy.[822] The impetus to legitimize the health system and regulators within that system is an integral objective of regulatory change in this context.

Canada and Britain each saw major health scandals between 1980 and 2005, but with respect to the cases in question, there was no straightforward or consistent pressure for regulatory change. In Britain, as Alaszewski and Coxon note, the cycle of scandal, inquiry, demand for change, and resultant reform has been particularly evident in health and welfare services.[823] In Canada this is not the case. This divergence needs explanation. The central argument developed in this chapter is that differences between Britain and Canada offer significant insights into how a scandal shapes or does not shape major regulatory changes. There is much more to the story than conventional regulatory theory would suggest.

A more nuanced analytical framing is necessary to classify scandals. More specifically, I suggest scandals should be classified, not in terms of their nature, but in relation to the extent to which they: 1) raise public and political perceptions about risk and its management; 2) illustrate a perceived threat to trust in the health systems and to actors within that system; and 3) engender concerns that accountability mechanisms have failed. In the cases where all three factors are evident, public and political demands for greater regulatory control will result in the enactment of regulatory reforms. Scandals that are contained, that are effectively managed by traditional actors, and where accountability functions are perceived to be reasonably effective, will not result in demands for state dictated regulatory change, although alternate types of transformation might ensue. Based upon the development of this

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[821] B. Hutter & S. Lloyd-Bostock, "The Power of Accidents: The Social and Psychological Impact of Accidents and the Enforcement of Safety Regulations" (1990) 30 Brit. J. Crim. 409 at 410 [Hutter & Lloyd-Bostock].
[822] P. Almond, "Regulation Crisis: Evaluating the Potential Legitimizing Effects of 'Corporate Manslaughter' Cases" (2007) 29:3 Law & Pol'y 287 [Almond]; Wells, *Negotiating Tragedy*, supra note 817.
[823] Alaszewski & Coxon, *supra* note 819; Butler & Drakeford, *supra* note 817.

scandal matrix, I conclude that scandals in the NHS were of a particular character that created a powerful mandate for change in the regulatory framework of the health system. This resulted in a system of greater controls and a movement of real regulatory powers from professions and institutional actors to the state and newly created state agencies. In contrast, in Canada, scandals generally did not align with the scandal matrix and therefore the traditional regulatory framework from 1980 remained largely intact.

What the comparative analysis in this chapter illustrates is that scandals might be necessary, but not wholly sufficient, precipitators of state directed regulatory change. In rare cases, some scandals alone are a sufficiently powerful force to create an impetus for change. But most often the achievement of significant regulatory change requires additional compelling political and/or policy rationales – some of these were discussed in the previous chapter.[824] Scandals may give government the moral authority to act swiftly and comprehensively to create new regulatory frameworks or to significantly renew and revise existing frameworks.[825] In the absence of scandals or the risk of them, risk is not brought to life for the public, there is reduced external pressure for change and there is a lesser likelihood of regulatory change.[826]

In developing this argument, this chapter begins by discussing the analytical orientation informing the analysis used in this chapter, which builds upon the existing literature on scandals and public policy, and in particular what we know about approaches to examine not just why scandals can cause reforms but how the nature of scandals may drive the form of any subsequent law reform. I then describe and analyze health-related scandals between 1980 and 2005 in Britain and Canada. Scandals were identified from analysis and reports in the secondary literature and the media.[827]

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[824] See, for example, M. Rajeev Gowda, "Integrating Politics with the Social Amplification of Risk Framework: Insights from an Exploration in the Criminal Justice Context" in N. Pidgeon, R. Kasperson & P. Slovic, eds., *The Social Amplification of Risk* (Cambridge: Cambridge University Press, 2003) 305 [Gowda]; Butler & Drakeford, *supra* note 817.

[825] C. Davies, "Regulating the Health Care Workforce: Next Steps for Research" (2004) 9: Suppl. 1 J. Health Serv. Res. Policy 55 [Davies, "Regulating the Health Care Workforce"].

[826] Hutter & Lloyd-Bostock, *supra* note 821 at 418.

[827] The scandals identified in this chapter of the thesis were judged to be significant because they had national impact. National impact was assessed in a variety of ways: all of the cases discussed in this chapter had some form of external inquiry (most involving some form of public inquiry); the cases were discussed in the national

Analytical Orientation: Dissecting a Scandal

A scandal is an event that had national impact, inasmuch as that event was externally investigated, was covered by the national media, and discussed in the relevant professional and/or academic literature. There may have been other events giving rise to local scandals, but my interest is how public discourse is framed in relation to a scandal that receives major attention and debate. Researchers have presented theories as to why events become scandals, and while this question is not the focus of this thesis, it must of necessity inform analysis as to the circumstances in which scandals contribute to regulatory change.

Best suggests that three layers of actors must make claims to transform events into scandals.[828] The event must enter into public discourse through the actions of people drawing upon the nature of the event to generate public concern. Best suggests that the first claims are made by victims and interest groups (primary claim-makers), the second by the media (secondary claim-makers), and the third by the public (tertiary claim-makers).[829] Without the engagement of all layers of claim-makers, to a greater or lesser extent, an event does not become a scandal. Conversely, counterclaims-makers, powerful players with institutional interests to protect, also play a significant role in Best's typology, as they try to limit events from developing into scandals or to mute their force by making a series of counterclaims about the event, or participants in the event, to protect their own interests. These techniques include: 1) mobilizing denial; 2) suggesting that violations are minor or understandable from a perspective of expert knowledge; 3) placing the blame on a solitary bad apple; and 4) instituting reverse deniability processes. Reverse deniability is when superiors blame subordinates and subordinates protect superiors by not passing on information either in the belief that superiors do not need to know or that the issue can best be managed at a lower, more expert level.[830] In a nutshell, Best suggests that the impact of scandals on public perceptions is the result of issue mobilization by claim-makers, a mobilization that often, although not inevitably, involves contestations with counterclaims-makers.

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media; the cases were discussed in prominent journals of the professions, including health management journals and the like.

[828] J. Best, *Threatened Children: Rhetoric and Concern About Child Victims* (Chicago: Chicago University Press, 1990) [Best].

[829] *Ibid.*

Other theorists working from a risk-analysis perspective also try to explain why there are differences in the way in which risks are conceptualized and responded to, both within differing domains of risk within a single state, or in the same domain of risk between states.[831] For example, the Social Amplification of Risk Model (SARF) suggests that information about events is communicated between a variety of actors in ways that elevate or diminish its significance, depending upon that person's/institution's interests, the current social-political–cultural environment, and so on.[832] Issue mobilization is undoubtedly a central reason why events or incidents become scandals. Certainly, the role of patients, families, the media, and public inquiry processes have been critical in focusing attention on scandals within the NHS. Similar patterns can be seen in Canada.

While these typologies are useful in explaining why events become scandals, the next step is to explain why some scandals result in policy change and others do not. Some approaches examine the nature of the scandal to determine characteristics that are more likely to see that event act as a fulcrum for demands for policy change.[833] These approaches suggest that a number of factors determine whether a scandal will act as a driver for policy change, including: 1) the numbers harmed or killed; 2) the identity of the victims (i.e. their degree of vulnerability); 3) whether the incident shatters established preconceptions about, for example, health-providers; 4) whether there has been a pattern of conduct over time; and 5) whether an independent inquiry has been constituted as a result of these actions.[834] The SARF model, described above, also attempts to explain this, but it has been critiqued for not

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[830] Butler & Drakeford, *supra* note 817.

[831] R. Kasperson *et al.*, "The Social Amplification of Risk: A Conceptual framework" (1988) 8:2 Risk Anal. 178 [Kasperson, "A Conceptual Framework"]; O. Renn, "Risk Communication and Social Amplification of Risk" in R. Kasperson & P. Stallen, eds., *Communicating Risks to the Public: International Perspectives* (Dordrecht: Kluwer Academic Press, 1991) 457 [Renn]; R. Kasperson & J. Kasperson, "The Social Amplification and Attenuation of Risk" (1996) 545 Acad. Pol. Soc. Sci. 95 [Kasperson, "Social Amplification and Attenuation of Risk"]. See also N. Pidgeon, R. Kasperson & P. Slovic, eds., *The Social Amplification of Risk* (Cambridge: Cambridge University Press, 2003) [Pidgeon].

[832] Murdock, Petts, and Horlick-Jones suggest six major sets of players within the field of action: government and state agencies; opposition parties; campaigning groups; corporations; scientific and expert communities; and the media, although they do not assume that these actors' privileged positions are fixed, or indeed monolithic. G. Murdock, J. Petts & T. Horlick-Jones, "After Amplification: Rethinking the Role of Media in Risk Communication" in N. Pidgeon, R. Kasperson & P. Slovic, eds., *The Social Amplification of Risk* (Cambridge: Cambridge University Press, 2003) at 156 [Murdock, "After Amplification"].

[833] Butler & Drakeford, *supra* note 817; Stanley & Manthorpe, *supra* note 818.

[834] *Ibid.*

engaging with the political elements of this question. Gowda notes these types of analyses are "fundamentally a *political* account of how people and societies deal with risks and risk-related incidents."[835] Further, Gowda suggests that scandals may not cycle into regulatory change "simply because the salient risk incidents which result in problem identification are not coupled with politically viable solutions that would result in significant policy action."[836] As Gowda suggests, models such as SARF must be accompanied by an appreciation of political, policy, environmental, and contextual factors.

Some regulatory theorists posit a link between risk perception, trust, and policy acceptability, and there is some empirical evidence to support this assertion.[837] In the introductory chapter to this thesis, I built upon this policy change cycle by suggesting that a concern for effective accountability is also a relevant (and conceptually different) part of this cycle, particularly in the context of health-related scandals. In this chapter I build upon this to develop a classificatory scheme for analysing scandals. There are three elements that contribute to policy acceptability: 1) discourses about risk and how risk is framed in relation to scandal; 2) how public trust in health professionals, health system regulators, the health system and patient safety regulation is defined in relation to scandal; and 3) the adequacy of accountability regimes within which a scandal is located. Accountability, as is discussed later in the chapter, is a key variable in health policy. A combination of concerns about risk, trust, and accountability may result in a perception that current policies are not acceptable and that greater regulatory controls on the health system and its actors are both necessary and desirable.

Scandal Classification

The policy cycle, described above, trust-risk-accountability-acceptability, provides a basis upon which to classify scandals and their regulatory impact. A consideration of risk perception requires the analysis of the incidence and aggregation of scandal, its scale, location, and nature, who was affected, how the scandal was communicated to the public, and the responses, if any, to the scandal. A consideration of trust involves examining

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[835] Gowda, *supra* note 824 at 306 [original emphasis].
[836] *Ibid* at 313.

societal attitudes and the narratives of scandal – what these scandals tell the public about whether and to what extent to trust health professionals, hospitals, other health-providers and systems, and regulatory actors. A consideration of accountability involves analysis of whether existent accountability mechanisms (prospective and retrospective) created the conditions for effective accountability. At the last, I examine any resultant demands for greater control that may emerge from scandals, specifically considering what, if anything, was deemed to need greater control, by whom, and how.

Risk

A risk "is not a static, objective phenomenon, but is constantly constructed and negotiated as part of the network of social interaction and the formulation of meaning."[838] At a cultural level, sociocultural theorists suggest that an understanding of the concept of risk in modern Western societies is central to an understanding of how those societies function. While sociocultural theorists are divided in how they theorize risk, they all, to a greater or lesser extent, agree that risk has, to quote Lupton, "become an increasingly pervasive concept of human existence in western societies"[839] which organizes, monitors, and regulates societal actors. Giddens describes a transformation in human consciousness from perceiving risks as a matter of fate and faith to seeing risks as a consequence of human failure: "it is a society increasingly preoccupied with the future (and also with safety) which generates the notion of risk."[840]

The concept of 'risk' must also be central to any consideration of healthcare and healthcare delivery. It has long been recognized that there is a risk of harm to persons who receive health services. Although it was not until the 17th century that mathematical theories of probability and modern scientific techniques developed, researchers throughout history have linked adverse health effects to different types of hazardous activities, principally by way of observation.[841] The risks associated with the provision of health services were 'objectively' confirmed by empirical analysis after the development of statistics and epidemiology, first in

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[837] For a general overview, see discussion in Poortinga, *supra* note 64.
[838] Lupton, *supra* note 5 at 29.
[839] *Ibid* at 25.
[840] Giddens, "Risk Society" *supra* note 6 at 27.
[841] Covello, *supra* note 5.

the 19th century in respect of hospital/health- professional-acquired infections,[842] then in the late 20th century in respect of adverse events in hospitals.[843] Individuals and groups have historically employed a number of regulatory strategies to manage such risks, most saliently the development and use of the common law and direct regulation through law-making.[844] But knowing of the objective possibility of risk and hearing a narrative of risk play out in the lives of real people are two different things. The narratives told in scandals bring risk to life for the public in a manner which cannot be matched by an empirical study as such studies lack emotive power. A higher consciousness, or perception, of risk may result in demands that the perceived risk be subject to greater control, often through regulation.

Incidence and Aggregation of Scandals

As a preliminary comment, to promote systemic change in long-established institutional and regulatory structures, aggregation may be an important factor. Scandals may, on aggregate, foster a greater perception of the risk that problems occur within and across systems, and are not one-off, aberrant events. A caveat to this, however, is that the nature of some single scandals is so compelling that these individually may result in significant regulatory change. For example, Dr Harold Shipman, a British GP, was convicted of the murder of fifteen patients and is believed to have murdered as many as 245, becoming one of the worst serial killers in history.[845] As an event to raise public perceptions of the risks associated with healthcare, this case was unparalleled. Dr Shipman's actions and the systemic failures of people and systems around him to identify concerns about his practice prompted, among other things, changes to the regulatory frameworks around dispensing narcotics and death certification. The impact of this scandal on its own was significant in respect of increasing public perceptions of risk and ultimately resulting in significant regulatory change.

An aggregation of scandals may raise risk perceptions and promote a fundamental reappraisal of the established regulatory framework. The larger the numbers of scandals, and therefore

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[842] Ayliffe, *supra* note 67.

[843] See, for example, Baker, "Adverse Events", *supra* note 2; Brennan, "Adverse Events" *supra* note 2; Wilson, "Quality", *supra* note 2; Vincent, "Adverse Events", *supra* note 2; Schioler, *supra* note 2; Davis, *supra* note 2.

[844] See, for example, Covello, *supra* note 5.

[845] U.K., The Shipman Inquiry, *Death Disguised* (London: HMSO, 2002) [Shipman Inquiry, *Death Disguised*], online at: The Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/>.
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the extent of scandals across different subsectors or locations of care, the greater the perception that risk attaches to systemic failures in the way in which that sector is regulated. I identified seventeen scandals within the NHS between 1980 and 2005, the details of which are set out in Table 1. Table 1 graphically illustrates the sheer volume of scandals during this period and their nature.

Table 1 Scandals in the National Health Service 1980 – 2005

This table describes where the event occurred, a brief description of the event, whether or not there was an inquiry, and if so the mechanism(s) through which those inquiries were constituted. Many of the events listed in the table were also examined as part of a coronial process.

Year	Events	Event Description	Inquiry
1979–80	Rampton Special Hospital[846]	Allegations of large-scale ill-treatment and brutality against patients in a forensic psychiatric facility	(1980) Independent inquiry convened by the Secretary of State for Social Services
Mid–late 1980s	Contaminated blood[847]	Thousands were infected with HIV and hepatitis C because of contaminated blood supplies.	(1995) Discussed in the House of Commons and the House of Lords (2002) Internal review (2007–2009) Public inquiry (convened and funded by private interests)
1991	Ashworth Special Hospital[848]	Allegations that patients in a forensic psychiatric hospital were mistreated, including that a patient died after a beating, and other patients were sexually or physically assaulted	(1992) Independent inquiry convened by the Secretary of State for Health
1991	Beverly Allitt[849]	A nurse, Beverly Allitt, was convicted of murdering four children, attempting to murder three others, and the grievous bodily harm of six others in the children's ward at Grantham and Kesteven Hospital.	(1994) Independent inquiry convened by the Secretary of State for Health under section 2 of the *National Health Service Act 1977* [*NHS Act*] (held in private)
1992	Christopher Clunis[850]	Christopher Clunis, a mental health patient, killed a member of the public, Jonathan Zito, in a chance encounter in London.	(1994) Private inquiry commissioned by the North East Thames and South East Thames Regional Health Authority

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[846] U.K., Committee of Inquiry, *Report of the Review of Rampton Hospital,* (London: HMSO, 1980) [Rampton Inquiry].

[847] The Archer Inquiry, *Independent Public Inquiry Report on NHS Supplied Contaminated Blood and Blood Products* online: The Archer Inquiry <http://www.archercbbp.com/report.php> [Archer Inquiry].

[848] U.K. Committee of Inquiry, *Report of the Committee of Inquiry into Complaints about Ashworth Hospital,* (London: HMSO, 1992) [Ashworth Inquiry, 1992].

[849] U.K., Department of Health, *The Allitt Inquiry: Independent Inquiry Relating to Deaths and Injuries on the Children's Ward at Grantham and Kesteven General Hospital,* (London: HMSO, 1994) [Allitt Inquiry].

[850] U.K., J. Ritchie, *Report of the Inquiry into the Care and Treatment of Christopher Clunis,* (London: HMSO, 1994) [Ritchie Inquiry].

Year	Events	Event Description	Inquiry
1993	Richard Neale[851]	Dr Neale, gynaecologist, was struck off the medical register in Ontario, Canada, after a patient died, but gained registration in Britain and continued to practise. There were allegations that he was incompetent.	1) (1993–1994) internal NHS inquiry 2) (2004) Report of a modified statutory inquiry called by the Secretary of State for Health (held in private).
1996	Kent and Canterbury Hospitals Trust[852]	Allegations that cervical screening practices were inadequate which resulted in 90,000 cervical smears being re-examined.	(1997) Report of an independent inquiry
1996	Rodney Ledward[853]	Allegations that Dr Ledward, obstetrician/gynaecologist, provided inadequate treatment over a 16-year period.	1) (1996) NHS internal disciplinary inquiry 2) (2000) Report of a modified public inquiry convened by the Secretary of State for Health (held in private).
1996	Bristol Royal Infirmary[854]	Allegations that the treatment provided to children undergoing paediatric cardiac surgery at the Bristol Royal Infirmary between 1984 and 1995 was inadequate.	(2001) Report of an independent public inquiry established pursuant to the *NHS Act*.
1997	Ashworth Special Hospital[855]	Allegations that patients misused drugs and alcohol, had access to pornography, and one patient was an active paedophile within the Personality Disorder Unit.	(1997) Report of inquiry convened under section 84 of the *NHS Act*.
1997	Royal Devon and Exeter Hospital[856]	Allegations that breast cancer screening practices were inadequate	(1997) Internal inquiry by the Royal Devon and Exeter Hospital Trust. (1997) Independent inquiry by the Chief Medical Officer convened by the Secretary of State for Health
1998	Dr Peter Green[857]	Dr Green, GP, was convicted of nine counts of indecent assault against patients.	(2001) Commission for Health Improvement inquiry.
1998	Dr Clifford Ayling[858]	Dr Ayling, GP, was convicted of 12 charges of indecent assault relating to ten patients.	(2004) Report of a modified statutory inquiry called by the Secretary of State for Health (held in private).

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[851] U.K., Committee of Inquiry, *Committee of Inquiry to Investigate How the NHS Handled Allegations about the Performance and Conduct of Richard Neale* (London: HMSO 2004) [Neale Inquiry].

[852] W. Wells, *Review of Cervical Screening Services at Kent and Canterbury Hospitals NHS Trust* (London: NHS Executive, 1997) [Wells Inquiry].

[853] U.K., Committee of Inquiry, *An Inquiry into Quality & Practice Within the National Health Service Arising from the Actions of Rodney Ledward* (London: Department of Health, 2000) [Ledward Inquiry].

[854] BRI Inquiry, "Learning From Bristol", *supra* note 287.

[855] U.K., Committee of Inquiry, *Ashworth Special Hospital: Report of the Committee of Inquiry,* (London: HMSO 1999) [Ashworth Inquiry, 1999].

[856] U.K., K. Calman & Department of Health, *Breast Cancer Services in Exeter and Quality Assurance for Breast Screening: Report to the Secretary of State* (London: HMSO, 1997) [Royal Devon Inquiry].

[857] U.K., Commission for Health Improvement, *Investigation into Issues Arising from the case of Loughborough GP Peter Green*, (London: Stationery Office, 2001) [Green Inquiry].

[858] U.K., Committee of Inquiry, *Committee of Inquiry to Investigate how the NHS Handled Allegations about the Performance and Conduct of Clifford Ayling* (London: HMSO, 2004) [Ayling Inquiry].

Year	Events	Event Description	Inquiry
1998	Dr Harold Shipman[859]	Dr Shipman, GP, was convicted of the murder of 15 patients. The public inquiry concluded he murdered a total of 200 patients and suspected he murdered a minimum of 45 others.	(2005) A public inquiry commenced in 2000 under the *Tribunals of Inquiry (Evidence) Act 1921*.
1999	Royal Liverpool Children's Inquiry[860]	Allegations that organs from deceased children were retained without the knowledge or consent of their families	(2001) Report of an independent confidential inquiry called by the Secretary of State for Health under the provisions of section 2 *NHS Act*.
1999	Drs Kerr and Haslam[861]	Dr Kerr, psychiatrist, was convicted of indecent assault of a female patient, and Dr Haslam, psychiatrist, was convicted of indecent assault on four female patients.	1) (1997–1998) NHS internal investigation 2) (2005) Report of a modified private statutory inquiry called by the Secretary of State for Health under sections 2 and 84 of the *NHS Act*.
2005	Stoke Mandeville Hospital[862]	Over 30 patients died in two separate outbreaks of the bacterium *Clostridium difficile* in Stoke Mandeville Hospital in 2003–2004 and 2004–2005.	(2005–2006) Healthcare Commission inquiry under section 52 (1) of the *Health and Social Care (Community Health and Standards) Act 2003* on the request of the Secretary of State for Health

Figure 2 (below) illustrates how many of the scandals set out in Table 1 clustered within a five to ten year time period, thus amplifying the effect of the aggregation of scandals. Specifically, the figure highlights that the period 1995–2000 saw the emergence of eleven scandals: three in 1996; two in 1997; three in 1998; and two in 1999. This resulted in a fairly constant barrage of negative publicity about the health system. However, the effect of these scandals was not limited to this time period. While the period 1995–2000 saw the emergence of eleven scandals, the period 2000–2005 saw the completion of nine public inquiries, ensuring that the scandals were kept in the public spotlight and embedded in public consciousness. These inquiries often lasted for months, if not years. For example, the Shipman Inquiry commenced in 2000 and was completed in 2005. Scandals that resulted in

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[859] U.K., The Shipman Inquiry, online at: The Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/> [Shipman Inquiry].

[860] U.K., The Royal Liverpool Children's Inquiry, *Report of the Royal Liverpool Children's Inquiry,* (London: Stationery Office, 2001) [RLCH Inquiry].

[861] U.K., Committee of Inquiry, *The Kerr/Haslam Inquiry: Final Report* (London: HMSO, 2005) [Kerr/Haslam Inquiry].

[862] U.K., Healthcare Commission, *Investigation into Outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust* (London: Commission for Healthcare Audit and Inspection, 2006) <http://www.cqc.org.uk/_db/_documents/Stoke_Mandeville.pdf> [Stoke Mandeville Inquiry].

public inquiry processes and that were held in public were prime tabloid and news fodder in which the faces and voices of patients, or their families if the patients had died, could be heard. Even for those inquiries held in private, witnesses could choose to speak with the media, and ultimately their stories were told when the inquiry reports were publicly released.

Figure 2 Incidence of Scandals within the NHS 1980-2005
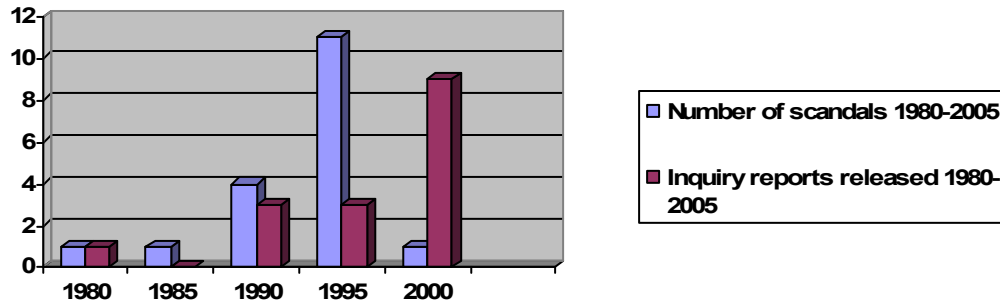
Note that one scandal, contaminated blood, did not result in a public inquiry during the period of this review.[863]

In Canada, the picture is very different. During the period 1980–2005, I identified five scandals relating to patient safety in the health system, and these scandals are described in Table 2. These scandals were few in number and dispersed in time (with intervals of six, three, four, and nine years between scandals). The relative infrequency of these events suggests that any aggregate effect to create a perception of a risk that there were broad systemic fissures within safety regulation in the health system requiring reform was likely to be minor at the very best, but, more likely, I suggest there was no aggregate effect.

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[863] A privately funded and commissioned public inquiry into the contaminated blood scandal commenced in 2007 after continued government refusals to commission an inquiry.

Table 2 Scandals in Canadian Health Systems 1980 – 2005

This table describes where the event occurred, its date, a brief description of the event, whether or not there was an inquiry, and if so the mechanism(s) through which those inquiries were constituted.

Years	Events	Event Description	Inquiry/Mechanism for Inquiry
1981	Hospital for Sick Children (HSC), Ontario[864]	35 babies/children die at the HSC from suspected digoxin poisoning. A nurse is arrested but discharged for lack of evidence at a preliminary hearing	1) Independent inquiry pursuant to the *Public Hospitals Act* (Ont.) (1983). 2) Centre for Disease Control review commissioned by the Department of Health. 3) Commission of Inquiry under the *Public Inquiries Act* (Ont.) (1984).
Mid-1987	Blood contamination[865]	Approximately 2,000 people are infected with HIV/AIDS and others with hepatitis C because of contaminated blood supplies.	1) Report of the sub-committee on Health Issues of the Parliamentary Standing Committee on Health and Welfare, Social Affairs, Seniors and the Status of Women (1993) 2) Commission of Inquiry under Part 1 of the *Inquiries Act* (commenced 1993; completed 1997). 3) Criminal charges filed against key institutions and individuals in 2005.[866]
1990	Sexual abuse[867]	Allegations of inadequate complaint-handling by the College of Physicians and Surgeons of Ontario (CPSO) in respect of allegations of sexual abuse by physicians	1) Taskforce on Sexual Abuse by Physicians (1991) (Ont. CPSO)
1994	Manitoba paediatric cardiac surgery[868]	12 children die during or after paediatric cardiac surgery at the Winnipeg Health Sciences Centre (WHSC), Manitoba	(2000) Coronial inquest

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[864] Ontario, Hospital for Sick Children Review Committee, *Report of the Hospital for Sick Children Review Committee,* by Justice C. Dubin (Toronto: The Committee, 1983) [Dubin Inquiry]; Ontario, Royal Commission of Inquiry, *Report of the Royal Commission of Inquiry Into Certain Deaths at the Hospital for Sick Children and Related Matters* (Toronto: Ministry of the Attorney General, 1984)[Grange Inquiry].

[865] Canada, Commission of Inquiry on the Blood System in Canada, *Final Report*, (Ottawa: Public Works and Government Services Canada, 1997) [Krever Inquiry].

[866] The Canadian Red Cross subsequently pled guilty to distributing contaminated blood supplies and a charge of criminal negligence was dropped. Several doctors involved in the management of blood supplies and a pharmaceutical company also faced various criminal charges, including most seriously charges of criminal negligence. In 2008, a judge found the defendants not guilty, concluding that the defendants had acted responsibly and appropriately in carrying out their responsibilities. *R v Armour Pharmaceutical Company* [2007] O.J. 3733 (Ont. S.C.) [*Armour*].

[867] Taskforce on the Sexual Abuse of Patients, *The Final Report of the Taskforce of the Sexual Abuse of Patients*, (Toronto: College of Physicians and Surgeons of Ontario, 1991) [TSAPP].

[868] Manitoba, Winnipeg Provincial Court, *The Report of the Manitoba Paediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994,* by Associate Chief Judge Murray Sinclair (Winnipeg: Provincial Court of Manitoba, 1998) online: Paediatric Cardiac Inquest <http://www.paediatriccardicinquest.mb.ca> [Sinclair Inquest].

Years	Events	Event Description	Inquiry/Mechanism for Inquiry
2003	SARS[869]	An outbreak of severe acute respiratory syndrome (SARS) in Toronto kills 44 people in 2003.	1) (2003) National Advisory Committee on SARS and Public Health (federal government) (Naylor Report) 2) (2003) Standing Senate Committee on Social Affairs, Science and Technology 3) (2003–2004) Expert Panel on SARS and Infectious Disease Control (Ontario) (Walker Report) 4) (2003–2007) Commission of Inquiry under section 78 of the Health Protection and Promotion Act (Ontario) (Campbell Commission)

Scale of the Scandal

The numbers of victims, and therefore the scale of the event, generally result in a greater impact upon the public because the risks to the public as patients are brought to life, both in terms of their perception of risk and the need for any reform. Although the unnecessary death of one person affects that person's family and friends and the health professionals involved, it is rare that a single death makes an impact upon public perceptions of the risks associated with the provision of health services – at least to the point of widely expressed public outrage. One life lost unnecessarily is bad, but the loss of multiple lives through malice or negligence illustrates risk and enhances risk perception. All but one of the scandals in Canada and Britain involved multiple patients.

In Canada, the scale of the scandals varied. The impact of the transmission of HIV/AIDS and hepatitis C through blood supplies resulted in approximately 2,000 recorded HIV infections.[870] SARS also touched hundreds of patients and health professionals within Ontario, although only some of the 40 or so deaths were thought to have been associated

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[869] Canada, National Advisory Committee on SARS and Public Health, *Learning from SARS: Renewal of Public Health in Canada,* (Ottawa: Health Canada, 2003) [National Advisory Committee, *SARS*; Canada, Standing Senate Committee on Social Affairs, Science and Technology, *Reforming Health Protection and Promotion in Canada: Time to Act: Report of the Standing Senate Committee on Social Affairs, Science and Technology,* by M. Kirby & M. LeBreton Proceedings of the Standing Senate Committee on Social Affairs, Science and Technology, 37:26 (Ottawa: The Senate, 2003) [Senate, *Reforming Health Protection*]; Ontario, Expert Panel on SARS and Infectious Disease Control, *For the Public's Health: A Plan of Action. Final Report of the Ontario Expert Panel on SARS and Infectious Disease Control,* (Toronto: Ministry of Health and Long-Term Care; 2004) [Expert Panel of SARS]; Ontario, The SARS Commission, *The SARS Commission - Spring of Fear: Final Report,* (Toronto: Ministry of Health and Long-Term Care, 2006) [Campbell Commission, *Final*].
[870] Krever Inquiry, *supra* note 865.

with mismanagement.[871] The two hospital cases from Canada (HSC and WHSC) involved less than fifteen patients at each location.[872] The allegations that the CPSO had ineffectively dealt with sexual abuse complaints involved multiple patients. The Taskforce on Sexual Abuse of Patients by Physicians (TSAPP) heard 303 detailed reports of sexual abuse of patients by doctors and other health professionals.[873] Although these events were all significant in terms of the numbers of victims, the intervals between these cases probably limited their aggregate effect on risk perception.

Many of the scandals in Britain had far-reaching impacts upon patient populations. The blood-contamination scandal saw 1,500 HIV infections recorded.[874] Ninety thousand cervical-screening tests were reread at Kent and Canterbury, affecting many thousands of patients.[875] Dr Harold Shipman is suspected of killing around 245 of his patients.[876] Hundreds (possibly many hundreds) of children and families were affected by a decade of paediatric heart surgery procedures, with morbidity and mortality rates for some procedures outside the norm,[877] and the many thousands of families across Britain discovered that some health professionals and hospitals had retained organs or tissue from the bodies of deceased children and adults without the knowledge or consent of families (an audit disclosed 54,000 retained organs across the NHS[878]). Eight hundred allegations of brutality exposed at Rampton Hospital were said to have involved 100 nurses.[879] An epidemic of *Clostridium difficile*, a hospital-acquired infection (HAI), at Stoke Mandeville Hospital killed, or was the probable cause of death, of 90 patients across three hospitals, and had infected more than 1,170 patients in the course of an eighteeen-month outbreak.[880] Thirteen children were murdered or harmed at Grantham and Kesteven Hospital by Nurse Beverly Allitt.[881]

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[871] National Advisory Committee, *SARS*, *supra* note 869; Expert Panel, *SARS, supra* note 869; Campbell Commission, *Final, supra* note 869.

[872] Dubin Inquiry, *supra* note 864; Sinclair Inquest, *supra* note 868.

[873] C. Robinson, "Sexual Misconduct: The Canadian Experience" in J. Bloom, C. Nadelson & M. Nottman, eds., *Physician Sexual Misconduct* (London and Washington D.C.: American Psychiatric Publications, 1999) [Robinson].

[874] Archer Inquiry, *supra* note 847.

[875] Wells Inquiry, *supra* note 852.

[876] Shipman Inquiry, *Death Disguised, supra* note 845.

[877] BRI Inquiry, "Learning from Bristol", *supra* note 287.

[878] U.K., Department of Health, *Report of a Census of Organs and Tissues Retained by Pathology Services in England* (London: Stationary Office 2000) [CMO Census]; RLCH Inquiry *supra* note 860.

[879] Rampton Inquiry, *supra* note 846.

[880] Stoke Mandeville Inquiry, *supra* note 862.

[881] Allitt Inquiry*, supra* note 849.

Upwards of 40 patients were thought to have been affected by the actions of Dr Ayling[882] – and the list goes on. Scale reinforces risk perception – the more victims, the greater the perception that there are risks to everyone who receives health services and that those risks must be managed.

Again, aggregation plays a role in amplifying the perceived risks.   While it might be expected to find greater numbers of those affected by these scandals in Britain, especially given the population differences between Britain and Canada, the numbers were exponentially higher in Britain than in Canada on aggregate – potentially creating a perception that the risks to patients were more widespread in Britain. In 2005, the British population was estimated to be 60,209,500,[883] and the Canadian population was estimated to be 32,299,500.[884]

Locations of Scandals
The locations of the scandals (geographically and sectorally) may also contribute to risk perception. The geographic location of events may suggest that scandals are localized in effect or that there are profound systemic failings across a country. The sectoral location may suggest that one facet of the health system is failing – for example, public health. Of the five Canadian scandals, one focused for the most part on the handling of complaints about sexual abuse by a regulatory agency in Ontario; two occurred in children's hospitals in Ontario and Manitoba; and two were essentially public-health-related issues around the safe provision of blood services (national) and responding to the emergence of a new infectious disease (Ontario and national).

Geography may be particularly important in Canada.   In Chapter 4, I noted that constitutional structures may be an important variant of regulatory directionality within Canada. It has been suggested that Canada's constitutional structure may have contributed to scandals having highly localized impacts.[885] With thirteen health systems within Canada,

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882 Ayling Inquiry, *supra* note 858.
883 U.K., Office of National Statistics, *Key Population and Vital Statistics,* (London: HMSO, 2005) [UK, Statistics].
884 Canada, Statistics Canada, "Canada's Population: The Daily: 27 September 2006" online: Statistics Canada <http://www.statcan.gc.ca/daily-quotidien/060927/dq060927a-eng.htm> [Canada, Statistics].
885 J. Davies, "Painful Inquiries: Lessons from Winnipeg" (2001) 65:11 CMAJ 1503 [Davies, "Painful Inquiries"]; A. Gillies, *What Makes a Good Healthcare System? Comparisons, Values, Drivers* (Abingdon: Radcliffe Medical Press, 2003) at 180 [Gillies].

each governed by different regulatory frameworks, it is easy to see how events occurring in one jurisdiction can be discounted by others as being a problem peculiar to that health system and that regulatory framework. For example, looking at the WHSC scandal, it is possible that the small size (one surgeon) of Manitoba's paediatric cardiac program, compared to other, larger programs in other provinces, may have been a distinguishing factor in the eyes of policy-makers and regulators in other provinces.[886] The Canadian centres of political gravity are the eastern provinces of Ontario and Québec, and, increasingly, include the western provinces of Alberta and British Columbia. Events in 'have-not' provinces, including Manitoba, may cause a ripple in public and political consciousness, but not a tidal wave. One commentator noted in respect of the WHSC scandal: "If it had happened in Toronto then it would have had a much bigger impact, but people outside of Manitoba just said 'well that's Winnipeg for you'."[887]

Notably, three of the four Canadian scandals had their loci in Ontario, the supposed centre of Canadian political gravity. But these scandals, too, could be localized. For example, the HSC murder allegations were regarded within and outside Ontario as the work of a bad apple – a once-in-a-lifetime event that was unlikely to occur again and which did not require a fundamental reappraisal of regulatory frameworks.[888] Even the results of the Dubin Inquiry into the operations of the HSC were highly localized in impact to the HSC, as the inquiry concluded there were major problems within the systems of the HSC, not more generally.[889] Interestingly, while the HSC was required to revise its processes in light of the inquiry's recommendations, no other hospital in Ontario was required to take similar steps, although many of the recommendations were generally applicable to other hospitals.[890] The Dubin Inquiry was, after all, commissioned to improve public confidence in the HSC, not in the health system more generally.[891]

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[886] Sinclair Inquest, *supra* note 868.

[887] Cited in Gillies, *supra* note 885.

[888] Dubin Inquiry, *supra* note 864.

[889] *Ibid.*

[890] S. Stead, "McMurty Says Report Attained Public Accountability Goal" *The Globe and Mail* (4 January 1985) M05 [Stead].

[891] Anonymous, "Judge Appointed to Probe Practices at the Hospital for Sick Children" *The Globe and Mail* (26 May 1982) A1 [Anonymous, "Judge Appointed"].

Conversely, the concerns about the operations of the CPSO, and especially the recommendations made by the TSAPP, which one would have thought to be highly localized, in fact had a national impact.[892] The work of the TSAPP and associated publicity associated with its operations and findings spread across the country with other provinces, such as British Columbia, Alberta, Québec, Prince Edward Island, Saskatchewan, and New Brunswick, establishing committees to review the issue.[893] In these, and other Canadian provinces and territories, changes to the legal framework in that province resulted, or policy statements or guidelines were developed on that issue. In Canada, blood was a national issue as the blood system involved cooperation between federal, provincial, territorial, and non-governmental actors. SARS was somewhat localized in that its direct impact was limited to British Columbia (which had the second-highest number of cases) and Ontario. The subsequent inquiries were national in scope as they focused on systems to ensure effective collaboration between federal, provincial/territorial and local government actors.

Not surprisingly then in Canada it was the public-health-related cases, blood and SARS, that seem to have raised the greatest public perception of risk. These cases raised issues about the adequacy of federal, provincial, and territorial cooperation, the allocations of resources (fiscal and human) to this traditionally under-funded sector, and decision-making at the policy level, rather than any reflections upon the quality of clinical care. The blood-system scandal graphically highlighted risks and was a catalyst for change in how that sector of the health system was managed, but the Krever Inquiry's scope was limited to that sector.[894] While the Canadian Supreme Court in its comments about "restoring public confidence in our *system* of health care"[895] made a conceptual leap from blood system to health system, this was not a leap made by many others. Although the implications of the blood scandal, and the Krever Inquiry, were to elevate safety as the core principle to drive decision-making within the blood system, its impact was not felt in the health system more generally. Two of the other cases, HSC and WHSC, were centred in paediatric services in hospitals. However, the effect of the HSC case was limited by an effective counter-narrative that raised

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[892] Robinson, *supra* note 873.
[893] *Ibid.*
[894] Krever Inquiry, *supra* note 865.
[895] *Canada (Attorney-General) v Canada (Commission of Inquiry on the Blood System)* [1997] 3 S.C.R. 440 [*Canada v. Blood System*].

uncertainty as to whether any wrongdoing had actually occurred, and the limitation of the inquiry's relevance to the HSC.[896] So what we see on reviewing the Canadian cases is limited geographic dispersal, as well as sectoral limitations, diluting any aggregate effect.

The picture is different in Britain. There, one scandal concerned public-health-related services (blood); three involved general practitioners (family medicine); five involved the provision of mental health services, all but one within hospitals; and the remaining eight scandals involved hospitals. In contrast to Canada, the preponderance of British scandals were associated with the provision of primary and acute health services within the NHS. Although the scandals were geographically dispersed, the dispersal occurred in a much smaller country, with a more compact population, a national health service, and within a unitary political state, thus mitigating the impact of geography. The majority of the British scandals – and notably all but one of the many scandals that occurred at the high point in incidence from 1997 to 2005 – were located where the vast majority of the population would expect to receive health services themselves: hospitals and general practices (the outlier involved a forensic psychiatric hospital). This could have brought risk to life for the public, as these are ordinary sites of care accessed by millions each year. Therefore risks were more likely to be regarded as not isolated or not restricted to one 'bad' hospital or 'bad' doctor, but universal and inherent in the system.

The Narrative of Scandals

Considering the narratives of scandal is vital as narratives raise perceptions of the level and degree of risks faced by the public. In Canada, although the deaths of children at the HSC began as murder, they ended in continuing uncertainty as to whether the children had indeed been murdered, had died as the results of errors or accidents, or had sustained a natural death. The issue around the events at the HSC became more one of a miscarriage of justice in the context of concerns about the performance of police and prosecution services.[897] The impact of the Grange Inquiry was to divert attention from systemic issues within the HSC, the Ontario health system, and Canadian health systems more generally, as the inquiry focused attention on the miscarriage of justice that occurred when Ms Nelles, a nurse, faced

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[896] Grange Inquiry, *supra* note 864.
[897] *Ibid.*

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murder charges after a manifestly rushed and, according to the Grange Inquiry, inadequate investigation.[898]   As discussed above, although the Dubin Inquiry found that there were significant problems within the HSC, particularly in respect of drug errors, patient safety, and communication between staff and patients, the impact of that inquiry was restricted as there was no acknowledgement in the inquiry or by the Minister of Health that similar problems could affect other Ontario hospitals.[899]

In 1990, public attention in Ontario focused on the perceived failures of the CPSO to adequately address complaints of sexual abuse and to impose appropriate penalties on doctors who acted in a sexually inappropriate manner towards their patients.[900] The concerns about the CPSO were in the context of its role to receive, investigate, and address complaints about doctors. The TSAPP concluded that the CPSO had done a poor job of investigating and hearing complaints of sexual misconduct and that often penalties were viewed as being too lenient, reflecting an over-identification with the physician.[901]   The risks highlighted by this case were twofold: that patients might be at risk of sexual abuse by physicians, and that the regulatory body responsible for managing complaints might be ineffectual as it did not create the conditions for prospective and retrospective accountabilities and therefore did not act in the public interest.

The SARS scandal raised concerns about the adequacy of the readiness and ability of systems and systems managers to respond to pandemics, and ineffective coordination between agencies, but it did not raise concerns about clinical care and treatment per se. One inquiry noted, "[t]he problems of SARS were systemic problems, not people problems"[902] and "hospitals did their best within the limits of their lack of preparation, their generally inadequate infection control systems and their inadequate worker safety systems. Inevitably they made mistakes in the fog of war against an invisible enemy."[903]   As Wilson put it:

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[898] *Ibid.*

[899] Dubin Inquiry, *supra* note 864.

[900] TSAPP, *supra* note 867.

[901] S. Rogers, "Zero Tolerance Some of the Time: Doctors, Discipline and Sexual Abuse in Ontario" (2007) 15 Health L.J. 335 [Rogers].

[902] Ontario, The SARS Commission, *The SARS Commission: Interim Report: SARS and Public Health in Ontario,* by Hon. A. Campbell (Toronto: The SARS Commission, 2004) at 4 [Campbell Commission, *Interim*].

[S]everal reports, including that of a national advisory committee, described critical problems with the structure and functioning of the public health system. These problems were identified as playing an important role in the extent of and the harm caused by the SARS outbreak.[904]

In other words, deficiencies in the management of the public health system in Ontario were said to have led to harms to patients and to the health professionals working with those patients.[905] Specifically, the Campbell Inquiry noted:

SARS showed Ontario's central public health system to be unprepared, fragmented, poorly led, uncoordinated, inadequately resourced, professionally impoverished, and generally incapable of discharging its mandate. The SARS crisis exposed deep fault lines in the structure and capacity of Ontario's public health system.[906]

These findings were not altogether surprising given other public-health-related scandals that had occurred within Canada in areas outside of the healthcare system (for example, the contamination of the water system in Walkerton, Ontario), and the earlier Krever Inquiry into the blood system. The Krever Inquiry into the blood system in Canada reached four broad conclusions that: 1) the multiplicity of organizations involved in the blood system resulted in poor coordination; 2) the response to emerging scientific evidence that viruses may be transmitted through blood lacked urgency; 3) the eight-month delay between the approval of a HIV test in the US and its approval in Canada resulted in 97 Canadian recipients receiving blood or blood products infected with HIV/AIDS; and 4) doctors and the general public had received insufficient information about risks associated with HIV/AIDS and hepatitis.[907] As a consequence of the blood scandal in Canada, there was a significant regulatory shift in the regulatory frameworks that supported the Canadian blood systems from private to public provision, with the explicit priorities being safety and

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[903] Campbell Commission, *Final, supra* note 869 at 13.

[904] K. Wilson, "Structural Reform in the Canadian Blood System" in C. Beach *et al.*, *Health Services Restructuring in Canada: New Evidence and New Directions* (Kingston: John Deutsch Institute for Public Policy, 2005) 345 at 345. [Wilson, "Structural Reform"].

[905] Three health professionals died and 100 became ill.

[906] Campbell Commission, *Interim, supra* note 902 at 1.

[907] Krever Inquiry, *supra* note 865.

accountability. Both cases placed a spotlight on and elevated risk perceptions about the governance of the public health sector, but neither the blood scandal nor the SARS scandal raised concerns about clinical care per se or about the governance of the health system more generally.

It was really only the WHSC case that raised risk perceptions about clinical care and the governance of the health system in the Canadian context. Contemporaneous to the public discovery of the problems with the paediatric cardiac surgery program in Bristol, at the WHSC twelve children died and other children experienced serious complications during or after undergoing paediatric cardiac heart surgery in 1994.[908] Overall, Justice Sinclair found the evidence suggested that "the Pediatric Cardiac Surgery Program at the Health Sciences Centre did not provide the standard of health care that it was mandated to provide."[909] Given the context – a newly appointed and inexperienced surgeon performing delicate, highly specialized surgery – it was possible to characterize the scandal as a one-off failure of effective governance by the WHSC and thus localize public perception of any risks.

Seven of the British scandals raised allegations that nurses and doctors had committed serious criminal offences involving numbers of their patients: everything from physical abuse and mistreatment, to sexual abuse and assaults, and serial murder. Through the processes of criminal prosecution and a commission of inquiry, it was established that Dr Harold Shipman was one of the world's worst serial killers, suspected of killing approximately 245 of his patients via lethal injection during his 27-year career as a GP. The scope and scale of his criminal offending against patients was and is unprecedented. Nurse Beverly Allitt was convicted of the murders of four of her child patients, the attempted murders of three others, and six instances of causing grievous bodily harm via lethal injection or smothering, all within a fifteen-day period. Justice Burnton, after hearing Allitt's appeal against her sentence, commented "[b]y her actions, what should have been a place of safety for its patients became not just a place of danger, but if not a killing field something close to it."[910]

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[908] The inquest concluded that one child died from natural causes, the deaths of three children were unexplained, three children died after undergoing surgical procedures that should not have been attempted, and the deaths of five children involved some form of mismanagement, surgical error, or misadventure and were possibly preventable.

[909] Sinclair Inquiest, *supra* note 868 at 465.

[910] Allitt Inquiry*, supra* note 849 at para 44.

Dr Ayling, GP, was convicted of twelve counts of indecent assault against ten patients, was acquitted of nine charges, and a further fourteen were ordered to lie on the file. Other complainants subsequently emerged. The allegations made against Dr Ayling involved what one complainant described as "brutal and sadistic"[911] internal examinations, chaotic practice, overuse of forceps, sexualized and inappropriate comments, voyeurism, excessive and prolonged breast and vaginal examination, often using bare hands, and inappropriate touching during examinations in his 27-year career as a GP. Dr Kerr, psychiatrist, was convicted of one count of indecent assault against a patient and found not guilty of four other counts of indecent assault and two of rape; twelve charges were left on the record because the jury could not reach a decision.[912] Sixty-seven patients gave evidence to the public Kerr/Haslam Inquiry alleging Dr Kerr would expose himself and ask patients to perform sexual acts upon him or have intercourse, sometimes suggesting it was part of their treatment,[913] during the 23 years he was in practice at York. Dr Haslam, a psychiatrist who worked with Dr Kerr, was convicted of four counts of indecent assault; a rape conviction was overturned on appeal. Several other complainants came forward during the Kerr/Haslam Inquiry. The Manzoor Inquiry (internal NHS inquiry) suggested that Dr Haslam used grooming techniques on his patients and concluded that he "had taken advantage of his position as a doctor to sexually exploit the complainants who were vulnerable patients."[914] Dr Green, GP, was found guilty of nine counts of indecent assault against five patients, including one teenage patient. He was found not guilty on a further nine counts of indecent assault against four male patients and their female partners who claimed that he had asked them to have intercourse or arouse each other while he watched. It subsequently emerged that there were 21 other allegations of indecent assault by Dr Green, sometimes involving the administration of drugs, but a further trial was not pursued.[915] The patients had performed sex acts in front of the doctor, thinking that they

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[911] Ayling Inquiry, *supra* note 858.

[912] He was convicted after a trial of the facts that occurred in his absence. He was unable to appear because of his physical and mental impairments.

[913] Kerr/Haslam Inquiry, *supra* note 861.

[914] *Ibid* at 387.

[915] D. Graves, "Eight Years for 'Deviant Doctor who Assaulted Patients' " *Telegraph* (19 June 2001) [Graves], online: Telegraph <http://www.telegraph.co.uk/news/uknews/1347891/Eight-years-for-deviant-doctor-who-assaulted-patients.html>.

were involved in fertility research.[916] There were also two scandals where endemic abuse of patients by staff was alleged inside forensic psychiatric facilities.[917] In aggregate, these scandals create a highly troubling picture of rampant and serial criminal conduct by health professionals against patients on a level hitherto unimagined, and raise risk perceptions.

Most of the other scandals in Britain involved substantiated allegations of inadequate clinical performance and/or conduct. For example, concerns were raised and substantiated about surgical procedures performed by two paediatric cardiac surgeons, Mr Wishart and Mr Dhasmana, who had unacceptably high mortality and/or morbidity rates over a ten-year period.[918] Dr Richard Neale, an obstetrician and gynaecologist, faced allegations in relation to his conduct and competence.[919] He had been removed from the medical register in Canada before commencing practice in Britain. While working for the NHS, he received a police caution over an incident in a public toilet involving voyeurism. Generally, the allegations against Dr Neale involved what the Neale inquiry termed:

> high-risk activity coupled with a lack of sound judgement and reliability; a willingness to obscure and disguise certain negative aspects of conduct and performance and a general reluctance to address areas of difficulty and problematic behaviour.[920]

Dr Neale's patients were generally not provided with important information about failure rates and complications, and his attitude was found to be arrogant. However, the inquiry also concluded that allegations that Dr Neale was a butcher and a consistently incompetent surgeon were unfounded. Dr Ledward was another obstetrician and gynaecologist who faced allegations that he had provided consistently inadequate treatment over a 16-year period, allegations later substantiated by the Ledward inquiry.[921]

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[916] Anonymous, "GP Indecently Assaulted Male Patients" *BBC News* (10 July 2000), [Anonymous, "GP Indecent Assault"], online: BBC News <http://news.bbc.co.uk/2/hi/health/827421.stm>.
[917] Rampton Inquiry, *supra* note 846; Ashowrth Inquiry, 1992, *supra* note 848.
[918] BRI Inquiry, "Learning from Bristol", *supra* note 287.
[919] Neale Inquiry, *supra* note 851.
[920] *Ibid* at 17.
[921] Ledward Inquiry, *supra* note 853.

There were also narratives of misread slides and scans at hospitals across Britain resulting in the potential misdiagnosis of hundreds and perhaps thousands of women.[922] The Royal Liverpool Inquiry determined that the Royal Liverpool Children's Hospital (RLCH) had retained 2,080 children's hearts, other organs from more than 800 children, and 400 foetuses, some of which were used for research, but most of which were simply stored, all without the knowledge and consent of parents.[923] It also emerged that some children had been "systematically stripped of their organs" through the malpractice of one pathologist, Dr van Velzen.[924] The aggregate effect of these British scandals was to suggest again that many doctors had conduct and/or competence issues and posed a risk to patients. These scandals raised perceptions of risk.

However, analysis of scandals associated with hospital-acquired infections raise some questions. By the end of the 1990s, the incidence of hospital-acquired infections (HAIs) was to cause concern in both jurisdictions. The incidence of, for example, methicillin-resistant *Staphylococcus aureus* bacterium (MRSA) in NHS hospitals rose from three per cent in 1991 to 37 per cent in 1999 – "epidemic levels".[925] In one hospital in Québec, the incidence of *Clostridium difficile* bacterium (another form of HAI) reached 13.8 per cent in 2003, up from 4.7 per cent in 1991–92.[926]

Yet only in Britain did HAIs cause a scandal. In 2004–2005, an outbreak of *Clostridium difficile* killed, or was the probable cause of death of 90 patients across three hospitals in the Maidstone and Tunbridge Wells NHS Trust where it had infected more than 1,170 patients over the course of eighteen months.[927] Also, an outbreak of the same bacterium at Royal Devon and Exeter NHS Trust in early 2005 infected 265 patients and caused 23 deaths. Public inquiries were convened and highlighted organizational factors that contributed to the spread of HAIs – for example: high bed occupancy rates; increasing movement of patients within and between hospitals and other healthcare facilities; high nurse-to-patient ratios; the

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[922] Royal Devon Inquiry, *supra* note 856.
[923] RLCH Inquiry, *supra* note 860.
[924] *Ibid.*
[925] S. Mayor, "England sets standards to Reduce Hospital Acquired Infection" (1999) 319 BMJ 1392 [Mayor].
[926] L. Eggerston, "*C. difficile* hits Sherbrooke, Que., hospital: 100 deaths" (2004) 171:5 CMAJ 436 [Eggerston, "Sherbrooke"].
[927] Stoke Mandeville Inquiry, *supra* note 862.

increasing use of health technologies;[928] and, more controversially, government policies. The inquiries also highlighted flaws in existing regulatory systems, particularly when one set of policy priorities (waiting list management) conflicted with another (infection control to ensure patient safety), and where the unintended consequences of adherence to one desired policy outcome caused a deleterious effect on the other.[929] Governments assigned responsibility to the policies of previous governments, whose commitment to the free market saw cleaning of hospitals and other health facilities contracted out to the most competitive private-sector operator, operators who often did not train their employees about the requirements for hospitals.[930] Government did not deny that waiting lists policy may have contributed to the infection, but noted that NHS Trusts should be able to meet quality *and* safety targets.[931] The scandals placed the role of government as a policy-maker squarely in the spotlight and highlighted the difficulties faced by the management of NHS Trusts in reconciling conflicting policy objectives.[932]

Contrast this with events in Canada, where a similar outbreak of HAIs resulted in the deaths of thousands of Canadians but did not raise the question of scandal. Doctors at just one hospital in Sherbrooke, Québec, lost 100 patients from HAIs in an eighteen-month period.[933] The Québec Health Ministry stated that 1,270 people died from *Clostridium difficile* between April 2003 and March 2004.[934] Researchers estimated that 2,000 deaths may have occurred during this outbreak, although this figure was strongly contested by the Québec government.[935] An infection-control specialist from Québec stated that it was "the worst epidemic of hospital-acquired infections that we've had."[936] The Canadian events also demonstrated failures in infection-control capacity, attributed by some to a lack of

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[928] See for example, Parliamentary Office of Science and Technology, "Infection Control in Healthcare Settings" Postnote July 2005 No 247 at 1 online:
<www.parliament.uk/parliamentary_offices/post/pubs2005.cfm>
[929] Stoke Mandeville Inquiry, *supra* note 862. Also see, for example, Anonymous, "NHS Targets to 'Blame for MRSA'" *BBC News* (15 January 2005) [Anonymous, "Blame for MRSA"], online: BBC News
<http://news.bbc.co.uk/2/hi/health/4177395.stm>.
[930] Anonymous, "Blame for MRSA" *ibid.*
[931] J. Laurence, "Hewitt Orders Inquiry into the Hospital's Lethal Bug" 12 June 2005 Independent [Laurence].
[932] L. Eggerston, "*C. difficile* may have killed 2000 in Québec: Study" (2005) 173:9 CMAJ 1021 [Eggerston, "*C. difficile* may have killed 2000"].
[933] Eggerston, "Sherbrooke", *supra* note 926.
[934] L. Eggerston, "*C. difficile*: By the Numbers" (2004) 171:11 CMAJ 1331 [Eggerston, "By the Numbers"].
[935] Eggerston, "*C. difficile* may have killed 2000", *supra* note 932.
[936] Eggerston, "Sherbrooke", *supra* note 926.

investment in hospitals, meaning that facilities were old and difficult to clean, and patients shared rooms and bathrooms – encouraging the spread of disease.[937] At least one critic attributed the lack of government action to the fact that most of the deaths were elderly patients,[938] a factor that may have also contributed to a relative lack of public interest in the issue. There was no inquiry, and limited public discussion.

The scope of the scandal does not seem to be a relevant distinguishing feature, as it appears more patients died in one hospital in Québec than in the three hospitals that were the focus of scandal in Britain combined. Perhaps the explanation as to why HAIs became a scandal in one jurisdiction and not another is as simple as risk perception. By 2005, when HAI became an issue of grave public concern, the British public expected problems within the NHS, and such events were almost automatically categorized as scandals. Perhaps also the British government was so conditioned by the multiplicity of scandals within the NHS that it had to be seen to be directly responding. In so doing it reinforced that the HAI outbreak was a scandal and contributed to risk perception.

Victims of the Scandal
The identity of the victims may also be relevant; the more vulnerable the victims are perceived to be, the greater the scandal[939] and the greater the impetus for policy change. I also suggest that the more similar the victims are to the public at large, the greater the empathy felt by the public, thus creating a heightened risk perception. To some extent, in healthcare all patients are vulnerable. There is seldom a balance in knowledge and expertise between health-provider and patient. For example, the Ayling inquiry noted:

> With limited or no previous information of similar situations, it was hard for patients to know whether what they had experienced was normal or justified – "I was young and inexperienced and I had nothing to compare this treatment to." "I did not make a complaint, because although I found these examinations unpleasant, I did not

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[937] Eggerston, "*C. difficile* may have killed 2000", *supra* note 932.
[938] Eggerston, "Sherbrooke", *supra* note 926.
[939] Stanley & Manthorpe, *supra* note 818 at 1.

realise that they were unnecessary. Ayling was the only doctor I had visited for contraceptive advice."[940]

Nor can a patient necessarily control what is done to their body or the quality of the medications, products, and devices that form part of their treatment. The patient must place complete trust in the provider of health services and in the safety of health-related products. To trust is to place oneself at risk – in the health context, the risk of incompetence and the risk of malice. The narratives that emerged from some scandals graphically illustrated this. The most shocking was the actions of Dr Harold Shipman, who murdered many of his mainly elderly patients through the administration of a lethal injection in their homes or in his surgery. The Shipman Inquiry believes that patients consented to the administration of what they thought was an innocuous injection, perhaps of a vitamin, and instead received a lethal dose.[941] They trusted their doctor and in doing so were placed at fatal risk.

In many scandals in Britain, vulnerability was evident in terms of the nature of the relationship between patient and doctor. Historically, this relationship was characterized by its hierarchical nature, with many members of the medical profession adopting a paternalistic attitude towards many or all of their patients. Patients were generally expected to unquestioningly follow their doctor's instructions. The nature of this relationship has evolved and changed over the course of the later part of the 20th century, with law playing a role in changing medical norms. The development of the doctrine of informed consent has been an important factor in changing the nature of the relationship moving towards a partnership between doctors and patients, as has the rise of consumerism.

But legal change may precede cultural change – some patients remain deferential, and informational and/or hierarchical asymmetries remain. Some patients in Britain, especially in the 1970s and 1980s, held the view that they could not or should not challenge a professional as to his or her conduct or competence. As the Ayling inquiry put it, "there was a general reluctance amongst patients to challenge a professional. Doctors, as skilled professionals,

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[940] Ayling Inquiry, *supra* note 858 at 109-110.
[941] Shipman Inquiry, *Death Disguised, supra* note 845.

were widely thought to 'know best'."[942] Many patients also feared that their complaints or concerns about a doctor, a highly respected member of society, would not be taken seriously. The Ayling inquiry noted: "The fear that patients had, that their word would not be believed, was not unjustified."[943] The Green inquiry noted that "even in the inappropriate circumstances occurring in consultations between Peter Green and some of his patients, it is difficult for patients to question their GP – particularly so when people involved are young."[944]

Thousands of people in Britain and Canada were infected with HIV/AIDS and/or hepatitis C through receiving blood or blood products, or because of their relationship with people who had become infected from blood.[945] Those who received blood or blood products were vulnerable. They may have received them because their life depended upon it – those, for example, who received blood after a traumatic accident, after difficult childbirth, or who had severe haemophilia – and had no real choice if they wanted to live. Others received blood because it improved their wellbeing, notably those with mild to moderate haemophilia. Some did not know that they had received blood at all and therefore could not make a choice. Even if there was prior knowledge, patients were generally not told about the possible risks of viral transmission and so did not have information to make a choice to refrain from using blood products.[946]

Those who interacted with infected persons were also vulnerable – they had no idea that a blood-borne virus could be transmitted to them via shared bodily fluids. The true scale of the tragedy and the perception of the risks were highlighted by those cases where a virus was transmitted between spouses or from mother to newborn child.[947] Although haemophiliacs as a group sustained perhaps the most harm from blood-borne viruses, all of those who were

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[942] Ayling Inquiry, *supra* note 858 at 109.
[943] *Ibid* at 113.
[944] Green Inquiry, *supra* note 857 at 47.
[945] Krever Inquiry, *supra* note 865; Archer Inquiry, *supra* note 847.
[946] Justice Burton concluded there were no warnings or publicity by the regulators of the possibility, and the medical profession seldom shared that information with patients. *A & Ors v. National Blood Authority & Ors* [2001] E.W.H.C. 446, (2001) 65 B.M.L.R. 1 (Q.B.) at para. 80 [*A v. National Blood Authority*].
[947] For example, Janet Connors, a Nova Scotian blood activist who contracted AIDS from her deceased husband, Randy, who was a haemophiliac who received blood or blood products contaminated with the AIDS virus. T. Marmor, P. Dillon & S. Scher, "Conclusion: The Comparative Politics of Contaminated Blood: From

unlucky enough to have a major accident, give birth, or undergo major surgery during this period were potentially exposed to the associated risks of receiving blood. Risks to the population as a whole were vividly brought to life by these events, as was the perception of the vulnerability of the population as a whole when receiving health services.

However, victim identification may also have a converse affect. Although cases involving children often invoke greater public outrage, other factors may also play a role. The child patients at the WHSC were, for the most part, members of visible minorities, particularly from First Nations communities, or from lower-income families.[948] Many families lived in remote communities. One of the whistleblowing nurses noted that she had said to another colleague:

> one of these days this is not going to be an aboriginal child, this is not going to be a child from up north, it is going to be an upper middle class white family that has the ins into the medical system and is going to know that this shouldn't have happened …[949]

Justice Sinclair noted, at least in respect of the first three deaths:

> the victims of these tragic events were from families of the least powerful in society. None of the families of the children who had died to this point were in a position to be able to influence large institutions … it seems clear that if any of the deaths involved a family that had more social-economic standing … events might have proceeded differently.[950]

This contention is perhaps overstated, as some of the families of patients in Bristol certainly had more socio-economic standing than those in Winnipeg; and in Bristol the problems continued for ten years. It seems likely then that the socio-economic status of the patients

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Hesitation to Scandal" in E. Feldman & R. Bayer, eds., *Blood Feuds: AIDS, Blood and the Politics of Medical Disaster* (New York & Oxford: Oxford University Press, 1999) 350 [Marmor, Dillon & Scher].

[948] Sinclair Inquest, *supra* note 868 at 205; S. Armstrong, "The Crying Shame" *Chatelaine* (March 2001) 86 at 88 [Armstrong].

[949] Sinclair Inquest, *ibid* at 204.

[950] *Ibid* at 205.

and their families had little impact upon internal processes, but socio-economic standing, age (some parents were very young), and ethnicity may have had an impact upon how the scandal was transmitted to the public and thus influenced risk perceptions.

The sense that those who sustained harm in these scandals were ordinary people facing situations and circumstances that they might also face and who may not be able to shield themselves from intentional or unintentional harm may have amplified perceptions of risk. Again, the aggregate effect of these scandals may mean the victim identification was experienced more strongly in Britain than in Canada.

Scandal Communication

How scandals are communicated to the public is an important factor in elevating an event to a scandal, according to Best, who writes of three layers of communicators: victims/families/interest groups; the media; and the public.[951] But communication is also an important factor in illustrating and amplifying risk perception. I suggest that some differences can be seen between the jurisdictions on this front. In the five Canadian scandals, only one, the contaminated blood scandal, saw patients and families playing an active role, in conjunction with interest groups like the Haemophilia Society and the media, to communicate the scale and nature of the risk to the public at large. These groups and individuals began by battling for compensation, but their role evolved into a broader one – they ultimately sought to hold individuals and systems accountable for harm and to achieve real changes in the systems that had failed them.[952] It is noticeable that this was one of the two scandals in Canada which resulted in wide-ranging reforms across jurisdictions.

Although, in Canada and Britain, individuals and interest groups, notably the respective haemophilia organisations, were involved in raising the public profile of this issue and could be characterized as blood activists,[953] it appears that in Canada individuals played a more salient role in engaging public attention on this issue. These individuals were characterized by their high visibility in the media, their vulnerability (many were cross-infected by their

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[951] Best, *supra* note 828.

[952] M. Orsini, "The Politics of Naming, Blaming and Claiming: HIV, Hepatitis C and the Emergence of Blood Activism in Canada" (2002) 35:3 Canadian J. of Political Science 475 [Orsini].

[953] *Ibid.*

spouses with the result that a whole family could be infected), and their eloquence and openness about the consequences of their infection.[954] They provided human faces to the tragedy. Activists also stressed that they just happened to be the ones in hospital receiving blood, and in doing so emphasised the random nature of the events and of the vulnerability of *all* patients.[955]

Groups granted official standing in the inquiry were also accorded greater standing and credibility by the media and by the public.[956] Particularly prominent was the Canadian Haemophilia Society which, although initially supportive of the Canadian Red Cross (CRC), increasingly became more critical of the CRC and of the conduct of politicians and government regulators.[957] A branch of this organization called for a public inquiry as early as 1985.[958]

In some respects, the fractured blood system in Canada may have been politically advantageous for activist groups, as some argue that the opportunities for social movements to influence policy and regulation increases with the dispersal of political decisions.[959] In the Canadian blood system, decisions were dispersed across the federal and provincial/territorial tiers of government and between government and non-governmental actors. Some activists worked solely within their provinces; others worked nationally and provincially. Success in a province or federal arena could create cracks in federal/provincial solidarity enabling greater access, as did the tensions and rivalries between and among the two tiers of government.[960] In contrast, in the unitary political system in Britain, if government wanted to limit or exclude the involvement of social movements in policy-making, it could – and in Britain it did – by offering humanitarian assistance to the afflicted, while denying that the systems had been mismanaged so as to cause patient harm. It appears that while unitary governments can be quick to institute reforms they can be equally as quick and effective in stalling them.

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[954] For example, Janet Connors, a Nova Scotian blood activist who contracted AIDS from her deceased husband, Randy, a haemophiliac who received blood or blood products contaminated with the AIDS virus. Marmor, Dillon & Scher, *supra* note 947.

[955] Orsini, *supra* note 952.

[956] *Ibid.*

[957] See, *ibid.* for example.

[958] *Ibid.*

[959] *Ibid.*

[960] *Ibid.*

Likewise, running counter to the arguments advanced in Chapter 4 that change in federalist states is generally can be slow with provinces taking the opportunity to learn from each other, this example indicates that in areas of shared jurisdiction reforms can occur rapidly if activist groups exploit the vulnerabilities in the system.

The SARS scandal demonstrated that it is not necessarily victims, families, and interest groups working with the media that can raise risk perception and therefore create impetus for regulatory change. Increased risk perception occurred on two fronts in the SARS pandemic. On the first front, SARS raised risk perceptions about pandemics. Secondly, the pandemic raised concerns that the public might be at greater risk because of perceptions that the governance responses were inadequate. Because of the nature of that event – i.e. the necessity for quarantine – patients and families played a limited role in public advocacy. Advocacy in respect of this scandal occurred more from health professional groups and pubic health workers and associations. However, in this case, the more potent force raising risk perceptions and ultimately impelling regulatory change was arguably international embarrassment. The World Health Organization's travel ban, justified or not, was imposed because of publicly expressed concerns that Canadian authorities were not doing enough to combat the transmission of SARS.[961] It sent a signal to the world, and to the Canadian public, that governance arrangements for emergent pandemics in at least one Canadian province (the province most greatly affected by SARS) were inadequate and coordination with federal authorities was generally ineffective.[962]

In other Canadian cases also, there was a lesser involvement of patients and families in communicating their concerns than was evident with the blood systems scandal. In Winnipeg, parents played a fairly traditional role – some called for a public inquiry and/or appeared before the inquest, and their lawyers made public comments on the inquest report and review and implementation reports. Some also commenced litigation proceedings. Their faces and voices may have been heard in Manitoba, but they did not have a national presence, and did not challenge the structures of the health system in such an overtly political way with the avowed intention of compelling significant and substantive changes, as did the

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[961] Campbell Commission, *Final Report, supra* note 869.
[962] *Ibid.*

parent pressure groups that arose from the events in Bristol. The nurses involved in raising concerns in Winnipeg did form a quasi-interest group, with some visibility in national media.[963] However, their focus was the very real problem of nurses' subordination and silencing within a hierarchical health system.[964] Their story illustrated problems with the culture of healthcare, particularly its sexism, but their advocacy of systemic change was directed at changing institutional and professional cultures, rather than reforms to regulatory frameworks.

In Britain, patients and families, in conjunction with the media and newly formed interest groups, effectively mobilized public opinion in respect of many of the scandals; particularly notable are the cases involving children. In Bristol, some of the parents of children who underwent paediatric cardiac surgery adopted an advocacy role with the specific intention of challenging institutional and systemic norms to promote real change in the health system. They formed pressure groups – for example, the Bristol Heart Children's Action Group and, during the end stages of the inquiry, the Constructive Dialogue for Clinical Accountability – these groups were highly visible and influential. What characterized these groups was the presence of individuals who were educated and articulate and highly motivated to influence policy and to protest against the injurious experiences they or their loved ones had been through.[965] They effectively used the media to make their claims, illustrate the risks, and to sustain public pressure on the government. For example, television networks showed images of parents laying tiny coffins outside the GMC's headquarters in London.[966] Their status as 'victims' was a powerful emblematic force. However, parents were not united. A parental group, the Bristol Surgeon's Support Group, was also formed, providing a counter-narrative that the surgeons were scapegoats for the wider failures of the NHS. However, this counter-narrative was less visible and had a lesser impact in the media, particularly given that the surgeons were being disciplined by the GMC for negligent acts.

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[963] For example, they appeared in a feature article in *Chatelaine*, a national women's magazine. Armstrong, *supra* note 948.

[964] C. Youngson, "Winnipeg's Pediatric Cardiac Inquest – A Nursing Perspective" (1999) 17:4 Can. Oper. Room Nurs. J. 7 [Youngson].

[965] J. Allsop, K. Jones & R. Baggott, "Health Consumer Groups in the UK: A New Social Movement?" (2004) 26:6 Sociol. Health Illn. 737 [Allsop, Jones & Baggott].

[966] G. Scally, "Deaths in Bristol have Changed the Face of British Medicine" (2001) 165:5 CMAJ 628 [Scally].

The revelations of organ retention at the Royal Liverpool Children's Hospital saw the emergence of more advocacy groups. These were comprised family members of the deceased, and played an important advocacy role in the context of the inquiry but also in respect of subsequent events, especially the Summit on Organ Retention and on the workings of the Retained Organs Commission.[967] The families of the Shipman victims played an equally effective advocacy role, as did the women affected by the breast and cervical screening programs scandals.

The blood contamination scandal was really the only event in Britain where a different pattern could be detected. An analysis of this event demonstrates that primary (interest groups such as the Haemophilia Society and victims), secondary (media), and tertiary claims-makers (particularly members of the House of Lords) actively engaged the public, raising a highly salient issue involving the deaths and injury of thousands of people. Yet, a powerful counter-narrative was raised by successive governments so that governments remained resolute in refusing to convene a public inquiry. Perhaps the most significant difference between this event and other events within the NHS in this period was that successive governments steadfastly asserted that those who ran the blood system did everything that was reasonable in the face of an uncertain emergent risk. Governments refused to admit, or even acknowledge, the possibility that these events were anything other than inevitable, although regrettable – a conclusion supported by an internal review. In contrast with Canada, the continued refusal by the British government to countenance a public inquiry somewhat limited the opportunities for victims and activist groups to bring the issue to the fore. It also limited their impact, as their role was not sanctioned or affirmed by a public inquiry process, and the existence of a scandal was not affirmed by the performance of a public inquiry. An analysis of these scandals generally confirms that communication strategies contribute to risk perception.

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[967] CMO Census, *supra* note 878; U.K. Retained Organs Commission, online: Department of Health <http://collections.europarchive.org/tna/20060802143339/nhs.uk/retainedorgans/> [Retained Organs Commission].

Responses to Scandal

Some suggest that "*responses* to the risk event actually *define* the risk itself" where the risk is previously unknown.[968] The actions taken by authoritative social actors, such as government, are, as MacGregor phrases it, "in a sense, regenerative and len[d] additional credence and validity to concerns already being expressed in the media."[969] Externally, the law and legal instruments play a peculiar role in risk perception. The highly public interaction between the risk(s) and legal processes that result from the manifestation of that risk may heighten public perceptions of the risk and its seriousness.[970] Put another way, if a specific event results in a death or deaths, the choice of the mechanism(s) used to address the acts or omissions that contributed to that death sends a message to the public about how they should perceive the seriousness and significance of the act and what the level of risk associated with that act is.

The criminal law is the penultimate symbol of societal condemnation of an act or practice, as it generally comprises offences that are *mala in se* ('evil in itself') and which therefore incorporates moral denunciation of the act and punishment of the offender. It speaks volumes if criminal charges are laid, as it can increase public perceptions of the seriousness of the risk. That so many British cases saw a police investigation and/or successful criminal prosecution sent a message to the public about how they should perceive risk.

Counter signals can also be sent, and this was seen in the two of the scandals in Canada that attracted criminal charges (Nurse Susan Nelles was charged with murder after the events at HSC; and the CRC, doctors who worked for the CRC, the regulator, and the manufacturers, Armour Pharmaceuticals, were charged with criminal negligence after the blood scandal). While the laying of charges indicated the societal abhorrence of the alleged acts or omissions, in general, these charges were not sustained. The charges against Ms Nelles were dismissed at a preliminary hearing due to insufficient evidence, amid concerns that there had been a

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[968] M. Poumadère & C. Mays, "The Dynamics of Risk Amplification and Attenuation in Context: A French Case Study" in N. Pidgeon, R. Kasperson & P. Slovic, eds., *The Social Amplification of Risk* (Cambridge: Cambridge University Press, 2003) 209 at 209 [Poumadère].

[969] D. MacGregor, "Public Response to Y2K: Social Amplification and Risk Adaptation: Or 'How I Learned to Stop Worrying and Love Y2K' " in N. Pidgeon, R. Kasperson & P. Slovic, eds., *The Social Amplification of Risk* (Cambridge: Cambridge University Press, 2003) 243 at 261 [MacGregor].

[970] Wells, *Negotiating Tragedy*, supra note 817.

miscarriage of justice.[971] After a long trial, the doctors and the pharmaceutical company associated with the blood scandal were found not guilty on all charges. Madam Justice Benotto of the Supreme Court of Ontario concluded that:

> … the conduct examined in detail for over one and a half years confirms reasonable, responsible and professional actions and responses during a difficult time. The allegations of criminal conduct on the part of these men and this corporation were not only unsupported by the evidence, they were disproved.[972]

Only in relation to the CRC were criminal charges successful, and then only in part. In 2005, the CRC pled guilty to distributing contaminated blood; in return, charges of criminal negligence were dropped. The CRC made a public apology, was fined $5,000, and donated 1.5 million Canadian dollars to a scholarship and research fund for those affected by the blood scandal.

In respect of the HSC case, the impact of unsuccessful criminal proceedings – coupled with continued uncertainty raised by a counter-narrative which questioned whether murders had actually occurred (despite the Dubin Inquiry's findings to the contrary) – somewhat transformed the public's risk perception. The perception of the risk went from children being murdered by a health professional to the risk of what the Grange Inquiry deemed inadequate police investigations and prosecution proceedings, in short, of a miscarriage of justice.[973] The blood charges had a more equivocal effect on risk perception, as the charges and subsequent trial occurred so long after the events in question that it did not really contribute to risk perception.

Legal responses, such as the coronial inquest seen in Winnipeg, are different again, and their symbolic effect is more muted. An inquest is, after all, a relatively routine inquiry into the cause of a particular individual(s) death and any factors that contributed to that death. On the other hand, the establishment of an independent inquiry, seen in all but one of the

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[971] Ms Nelles subsequently sued the police and the Attorney-General for malicious prosecution. Grange Inquiry, *supra* note 864.

[972] *Armour, supra* note 866 at para. 305.

[973] Grange Inquiry, *supra* note 864.

scandals in Britain, and in three out of the five scandals in Canada, confirms that an event is out of the ordinary and of sufficient importance that ordinary mechanisms of inquiry/investigation, such as inquests, are not sufficient to address all the issues.[974] In general, an independent inquiry is commissioned because, justified or not, there is a perception that there has been some failure to act or there were deficiencies in the actions that were taken. Thus, to commission a public inquiry, whether to occur in public or in private, sends a signal that the public should perceive there was an unusual risk of harm.

Characterizing many of the scandals examined within this chapter is the multiplicity of official responses to their emergence. In all but one of the scandals, there was some form of external inquiry or review process, but these were accompanied by other mechanisms which also played a role in constituting the risk as discussed throughout this section of the chapter. For example, Dr Shipman's conduct saw a police investigation, GMC processes, and a public inquiry. The conduct of Drs Neale, Haslam and Kerr resulted in internal NHS inquiries, GMC processes, police investigations, and public inquiries. In Ontario, the SARS pandemic saw a number of reviews or inquiries from a federal-government-commissioned National Advisory Committee on SARS and Public Health, a review by the Standing Senate Committee on Social Affairs, Science and Technology Review, an Expert Panel on SARS and Infectious Disease Control (Ontario government), and a Commission of Inquiry under section 78 of the *Health Protection and Promotion Act* (Ontario). A multiplicity of internal and external inquiry processes may further reinforce the sense that there was a risk and the risk may continue and therefore need management.

The incidence, scale, scope, and nature of the risks apparent from the British scandals were different separately and in aggregate from the Canadian scandals. Taken together, the British scandals arguably illustrated a higher perception of the extent of the risk – risks associated with the provision of health services, but also in relation to the regulation of those services and that system. Conversely, in Canada, the incidence, scale, scope and nature of the risks were less evident in aggregate and separately, with the exception of public health related scandals.

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[974] Butler & Drakeford, *supra* note 817.

<u>Trust</u>

Trust is, and has always been, a cornerstone of the relationships within the health system and between patients and health-providers, institutional and individual.[975] In the health system, actors that provide health services, or that are representatives of those who do – for example, the health professions – have moral, ethical, and legal obligations through the common law, and at times legislation, to provide services to those who use health services with reasonable care and skill. These obligations form the basis of the public trust in those actors. At the macro-systems level, in both Britain and Canada, health services are a public good, substantially funded and/or provided, managed, and regulated by the state, or by policy actors to whom that state has delegated authority. Public institutions, government or otherwise, generally have a duty to act in the public interest. Public trust, or distrust, of the effectiveness of these institutions in protecting the public from harm is a significant factor in determining the acceptability of current regulatory arrangements to manage risks. When governments delegate authority to other actors at the macro and meso levels, they generally do so trusting that actor to act in the public interest towards the public good. At the micro level, patients put their future wellbeing, and sometimes their lives, in the hands of health professionals and health-providers trusting that those professionals will provide services with reasonable care and skill and will ultimately act in such a way that maximizes their wellbeing. These micro-level trust relationships may influence macro-level trust, and vice versa, although such interactions are complex.[976]

Reflecting the normative status of a social value like trust, there are differing views about what constitutes 'trust' or 'distrust'. In a recent review of the literature, Kramer and Tyler noted at least sixteen definitions of trust.[977] I adopt the sociological approach that considers that trust relates to expectations and beliefs we have as social actors about the future or contingent actions of other actors.[978] Accordingly, trust emerges from social relationships and the obligations that flow from these relationships,[979] but is not limited to relationships

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[975] Calnan, *supra* note 69; Sharpe, *supra* note 70; McLeod, *supra* note 70 at 186.

[976] See, for example, Misztal, *supra* note 71; Calnan, *supra* note 69 at 353-354.

[977] R. Kramer & T. Tyler, *Trust in Organizations: Frontiers of Theory and Research* (Thousand Oaks: Sage, 1996) [Kramer]; Misztal, *supra* note 71; B. Barber, *The Logic and Limits of Trust* (New Jersey: Rutgers University Press, 1983) [Barber].

[978] Misztal, *ibid*; Rowe, *supra* note 62; Barber, *ibid*; N. Luhmann, *Trust and Power* (Chichester: Wiley, 1979).

[979] Misztal, *ibid*. at 21.

between individuals. Individuals and societies can have trust relationships with systems, government, and institutions.[980] As Barber puts it: "[t]o talk about the nature and meaning of social phenomena such as trust is to define their functions and dysfunctions in terms of social relationships and social systems."[981]

Braithwaite describes the established typologies of trust expectations as falling within three recurring themes.[982] She describes the first as inferring trustworthiness from one's emotions or values; the second as a matter of rational assessment; and the third is the notion of trust as performance. It is the latter that arguably has the most resonance in health systems. Barber focuses his analysis of trust in health systems on performance considered through the lens of professionalism. Claims to professionalism from health-providers, systems, institutions, professions, and individuals are the basis of their legitimacy. Barber states that in this context, trust is created and maintained by the expectations we have of the conduct and performance of professionals, noting:

> The most general is expectation of the persistence and fulfilment of the natural and the moral social order. Second is expectation of technically competent role performance from those involved with us in social relationships and systems. And third is expectation that partners in interaction will carry out their fiduciary obligations and responsibilities, that is, their duties in certain situations to place others' interests before their own.[983]

Barber's formulation has attracted some criticism; notably, Misztal argues that Barber's distinction leaves unspecified the social mechanisms that generate trust and that it is:

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[980] See, for example, V. Braithwaite & M. Levi, eds., *Trust and Governance,* (New York: Russell Sage Foundation, 1998) [Braithwaite & Levi].

[981] Barber, *supra* note 977 at 19.

[982] V. Braithwaite, "Communal and Exchange Trust Norms: Their Value Base and Relevance to Institutional Trust" in V. Braithwaite & M. Levi, eds., *Trust and Governance* (New York: Russell Sage Foundation, 1998) 46-74 at 49 [Braithwaite, "Communal and Exchange Trust Norms"].

[983] Barber, *supra* note 977 at 9.

too normative and optimistic in its assumption that people internalize a 'collectivity-orientation', which leads them to be more concerned with others' interests than with their own.[984]

What Misztal overlooks is that society holds all professionals, and indeed all providers of health services, to higher normative standards. This is due to the serious consequences of improper role performance, and to external factors that require professionals, and health-providers, to internalize an orientation that has at its heart requirements to place the interests of others above one's own interests. These external factors include rigorous codes of ethics for health professions, where obligations of non-maleficent and beneficent conduct are critically important, legal doctrines creating, in Canada, fiduciary obligations and duties, and other obligations and duties that require professionals to place others' interests above their own.

This does not mean to say that Barber's taxonomy should be accepted uncritically.[985] Because of the context in which it was formulated, the third component of Barber's expectations – fiduciary obligations and duties – is necessarily specific to the professions. Its narrow ambit, in that fiduciary obligations only arise in the context of the interactions between a health professional and his or her patient, and the fiduciary relationship is not accepted in all common-law jurisdictions,[986] is too limiting. It is especially limiting when the focus of analysis goes beyond health professionals and the health professions to include a variety of other systemic actors who cannot be characterized as having fiduciary relationships. What these actors have in common is that they generally have legal, ethical, and moral obligations to act in the public interest and to prevent, or at least minimize, the possibility of harm. Barber's taxonomy can be reframed[987] to state that, within health systems, the public's trust rests upon the belief that all actors will perform their roles with

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[984] Misztal, *supra* note 71 at 23.

[985] Rowe, *supra* note 62 at 377.

[986] See discussion in P. Milchalik, "Doctors' Fiduciary Duties" (1998) 6 J. L. Med. 168; P. Bartlett, "Doctors as Fiduciaries" [1997] Med. L. Rev. 193. That doctors are in a fiduciary relationship with their patients is accepted in Canadian law; see *Stamos v. Davies* (1985) 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 [*Stamos*]; G. Robertson, "When Things go Wrong: The Duty to Disclose Medical Error" (2002) 28 Queen's L.J. 355 [Robertson, "When Things Go Wrong"]. In Britain, such a doctrine is not accepted; see *Sidaway v. Bethlem Royal Hospital Governors* [1985] AC 871 at 884 per Lord Scarman [*Sidaway*].

[987] See also Rowe, *supra* note 62 at 377.

competence, and will carry out their obligations, responsibilities, and duties (fiduciary or otherwise) to place others' interests before their own or to act in the public interest by preventing or minimizing risks of harm. Thus an individual's, or indeed a society's, motivation to trust is based on expectations and beliefs and the context within which the decision to trust or distrust is made.[988] Accordingly, this section reviews trust in this broader context examining role performance and whether actors exercise their functions in the public interest, rather than in a self-interested manner.

Societal Attitudes

Some scholars identify a societal movement towards what they term 'post-trust' societies[989] – at least insofar as societies are increasingly expressing distrust, or suspicion, of traditional and established institutions of social order, such as governments, professions, religious institutions and other social edifices. Misztal is one of many to describe "the emergence of a widespread consciousness that existing bases for social cooperation, solidarity and consensus have been eroded."[990] Societies, they argue, are moving from unconditional trust in the actions of important social and policy actors to conditional trust or moderated distrust.[991] According to scholars such as Mechanic, this trend can be seen in some health systems, claims that are to some extent backed by empirical data.[992] A generalized mistrust of certain actors may be reinforced by specific scandals that create a perception that certain actors either can or cannot be trusted.

Duration of the Scandal

Duration may be an important factor in reinforcing trust or creating mistrust in governance systems. Retrospective examinations of scandals that have unfolded over a long time period often raise many questions. How could the conduct have continued for so long? Why did no-one intervene earlier? Why did systems not identify problems?[993] Why did systems and/or individuals not respond effectively to problems? Was there a cover-up?

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[988] See, for example, R. Hardin, *Trust and Trustworthiness* (New York: Russell Sage Foundation, 2002).
[989] See, for example, Lofstedt, *supra* note 61.
[990] Misztal, *supra* note 71 at 3.
[991] Quick, *supra* note 589.
[992] See, for example, Mechanic, *supra* note 72.
[993] Stanley & Manthorpe, *supra* note 818 at 5.

An analysis of scandals that occur over a long duration generally expose a series of missed opportunities, where systems and individuals could have intervened but, for whatever reason, did not, or where interventions were unsuccessful.[994] Generally, it seems, then, that the longer the duration of the event and the more missed opportunities to intervene that are exposed, the greater the perception that actors and systems failed, creating conditions for mistrust. The argument goes that if the regulatory system(s) had been working effectively, problems ought to have been identified and dealt with in a more timely way. The argument might continue that the actors did not act as they put institutional, professional, or self-interest ahead of the welfare of patients and the public interest, and thus are not worthy of the trust vested in them.

The Canadian scandals were of a relatively limited duration before some form of definitive intervention occurred, with no event lasting for more than five years, and three out of the five lasting less than one year (see Figure 3). Many of the scandals in Britain, especially the more prominent scandals, were subsequently discovered to have been of long duration, and subsequent investigations determine missed opportunities to intervene. Figure 3 illustrates that a majority of the British events that became scandals were subsequently determined to have been occurring for over five years before definitive action was taken.

Figure 3 Comparative Duration of Scandals

Note that the duration of some events is estimated. The Kerr/Haslam Inquiry is considered as one scandal.
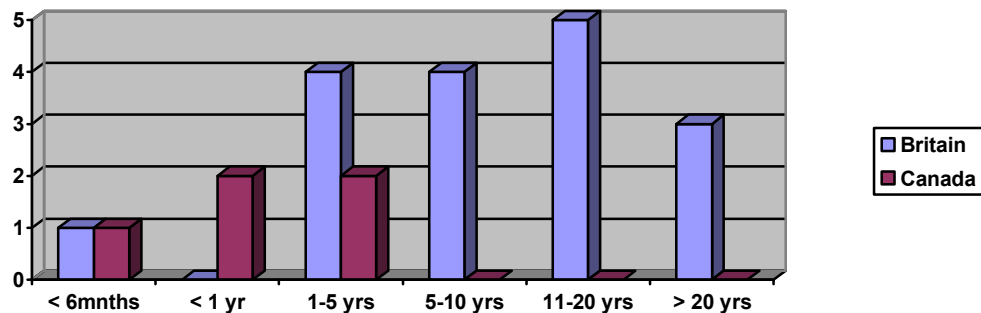
At the extreme, public inquiries in Britain established that Dr Shipman had been murdering his patients for a 27-year period; and Drs Ayling, Kerr, Haslam, and Green had been

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[994] *Ibid.*

involved in sexualised conduct with patients, including sexual assaults, for respectively 27, 24, 23, and thirteen years.[995] Higher than normal rates of surgical complications from paediatric cardiac surgery in Bristol occurred for approximately eleven years, whereas only eleven months was to pass at WHSC before high complication rates in its paediatric cardiac surgery program were such that surgery was suspended. The relatively short duration of most Canadian scandals may illustrate more effective governance systems – systems worthy, then, of the trust reposed in them by the public. Duration can be one factor, especially in aggregate, that can contribute to the mistrust of certain regulatory and other actors. That so many events could go on for so long in Britain indicates, among many other things, a failure in regulatory systems such that trust in those systems can be undermined.

The Narrative of Scandal

As discussed in the context of risk perception, the narratives of scandals are important, as they can graphically illustrate reasons why the public should mistrust certain actors in the health system. In Britain, the narrative of scandals, separately and in aggregate, was sufficient to create a rationale for the public to mistrust key actors, in particular members of the medical profession and regulatory bodies. In Canada, two scandals resulted in the conditions for mistrust of public-health-related systems and actors, but in general trust in other actors remained at the traditional (or pre-scandal) levels. In this section of the chapter, the impact of scandals is examined in some detail to determine what the narrative of a scandal may tell the public about the level of trust they should accord health professionals, health-providers, and the health professions and regulatory bodies, especially those associated with self-regulation.

<u>*Health Professionals*</u>

The relationship between health professional and patient is based on trust. The patient trusts health professionals to act in the patient's best interest. The scandals that occurred in Britain, singly and in aggregate, illustrated instances where health professionals did not act in the best interests of patients and betrayed that trust. In aggregate, the British scandals demonstrate reasons for the public to mistrust health professionals.

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[995]Shipman Inquiry, *Death Disguised, supra* note 845; Ayling Inquiry, *supra* note 858; Green Inquiry, *supra* note 857; Kerr/Haslam Inquiry, *supra* note 861.

Deceit and Deception

Although using the terms 'deceit' and 'deception' to describe the conduct of health professionals may attract criticism, the actions of some health professionals in actively withholding information has been characterized as such by some patients and families.[996] Withholding information has been a particular issue in a number of the British scandals, but plays a lesser role in Canadian cases.

In Britain, that health professionals were perceived to have withheld information was a focus of concern in respect of organ retention investigated in both the Bristol and RLCH inquiries. Some characterized the failure by the health professionals concerned to provide information to parents as a form of deceit.[997] The day the RLCH Inquiry report was to be issued, the *Guardian* reported that "The medical profession is bracing itself for a wave of revulsion and distrust from the public."[998]

Other scandals, too, raised concerns about information disclosure by health professionals. In the Bristol case, at least one of the doctors concerned, Dr Dhasmana, admitted that he had difficulties with certain types of procedures and had sought retraining. The families of prospective patients were not told of his difficulties.[999] The Neale Inquiry concluded that Dr Neale's patients were generally not provided with important information about failure rates and complications.[1000]

In Winnipeg, too, parents were denied certain key information so they could make truly informed decisions about their child's care. The inquest noted that parents lacked information about the experience of the surgeon and the team, information about surgical risk that was program-specific, and, for those whose children underwent surgery after 14 May 1994, the withdrawal of services by anaesthetists.[1001] The inquest concluded that they

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[996] RLCH Inquiry, *supra* note 860.

[997] *Ibid.*

[998] S. Boseley, "Organ Horror Report Outcry" *The Guardian* (30 January 2001)[Boseley], online: The Guardian <http://www.guardian.co.uk/society/jan/30/health.alderhey>.

[999] BRI Inquiry, "Learning From Bristol", *supra* note 287.

[1000] Neale Inquiry, *supra* note 851.

[1001] Sinclair Inquest, *supra* note 868.

ought to have been told this information. Not only were parents not told of the lack of experience of the surgeon, and of the team in working with the surgeon, but the inquest suggested parents were, in effect, misled by comments implying that their children could not be in better hands because of the surgeon's credentials and the strength of the program.[1002] What might be termed misleading and deceptive conduct, coupled with failure to provide information to the parents about concerns about the program's performance, is not a combination calculated to inspire trust in health professionals and health-providers.

Some of the public-health-related cases also illustrate issues with information disclosure. In both jurisdictions, the contaminated-blood scandals illustrated failures in information sharing. Although it was known in regulatory and medical circles that transfusions carried with them risks – not just of transfusion-related side effects but also of the communication of infectious diseases – this information was not effectively communicated to the public.[1003] While in some immediately life-threatening cases patients would have had no choice but to receive blood, for at least some haemophiliacs blood was provided only to enhance their wellbeing, their conditions not being life-threatening. If these patients had information about likely or even possible harms, they may have chosen to avoid blood. Equally, those who received blood in an emergency situation, if told of the risks after receipt of blood, may have chosen to protect their partners from any person-to-person transmission In both jurisdictions, then, the blood system events contributed to what has been described as a "common sense of violation of deeply held social beliefs about responsible medical practice."[1004] A perception that health professionals have been deceitful undercuts the basis of the social contract between medicine and the state, and between patients and health professionals – relationships based upon trust.

Incompetence
Many of the British cases illustrated concerns about the professional competence of health professionals, whereas only one Canadian case, WHSC, really raised issues of professional

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[1002] *Ibid.*

[1003] Justice Burton concluded that the public at large was entitled to expect that blood would be free from infectious agents. There were no warnings or publicity by the regulators of the possibility, and the medical profession seldom shared that information with patients. *A v. National Blood Authority, supra* note 964 at para. 80.

[1004] Marmor, Dillon & Scher, *supra* note 947 at 353.

competence of health professionals in a clinical context. It is recognized – and, I suggest, on the whole accepted – that doctors and other health professionals will make mistakes from time to time. What the competence-related scandals illustrated was that for some doctors lack of competence was endemic, posing greater risks to patients and raising issues of trust. After all, if a heath professional has ethical, legal, and moral obligations to act in the interests of patients, it would seem obvious that an incompetent health professional should not provide treatment that places patients at risk. Doing so violates the trust patients place in that health professional.

In both the key screening cases from Britain, and in the other cases where allegations of screening errors arose, allegations were made that doctors lacked competence – allegations confirmed by subsequent inquiries. For example, the Royal Devon and Exeter inquiry found there were "serious faults" in screening and that the radiologists concerned failed to "provide the standard expected of consultants involved in mammographic screening."[1005] The scandal at Bristol is widely felt to have been a turning point in Britain in terms of the public's trust in health professionals. Commentators variously noted: "Bristol is different. It is different because the scandal marked the moment when many people's trust in doctors first wavered significantly";[1006] "[t]he deaths in Bristol have changed the face of British Medicine";[1007] "[t]he disaster at Bristol Royal Infirmary is a defining moment for health and social care";[1008] and the editor of the British Medical Journal wrote, "All changed, changed utterly."[1009] Alan Jones, a member of the Bristol Children's Heart Action Group, stated, "this is the end of the age of the doctor is right. We have to now question and get correct answers on doctors' ability and performance."[1010]

The scandal at Bristol was followed by other scandals raising concerns about the competence of doctors – Drs Ledward and Neale also faced allegations that they lacked competence in

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[1005] Anonymous, "Dobson Orders Breast Screening Review" *BBC News* (3 Nov 1997) [Anonymous, "Breast Screening Review"], online: BBC News <http://news.bbc.co.uk/2/hi/uk_news/21241.stm>.

[1006] D. Sandford, "Why Bristol is so Important" *BBC News* (18 July 2001), online: BBC News <http://news.bbc.co.uk/2/hi/health/1443081.stm>.

[1007] Scally, *supra* note 966.

[1008] A. Alaszewski, "The Impact of the Bristol Royal Infirmary Disaster and Inquiry on Public Services in the UK" (2002) 16:4 J. Interprof. Care 371 at 371.

[1009] R. Smith, "All Changed, Changed Utterly" (1998) 316 BMJ 1917.

their professional practice. Although the Neale inquiry concluded that Dr Neale was in fact a generally competent surgeon, it also noted that Dr Neale's career showed:

> high-risk activity coupled with a lack of sound judgement and reliability; a willingness to obscure and disguise certain negative aspects of conduct and performance and a general reluctance to address areas of difficulty and problematic behaviour.[1011]

Generally, the British scandals provided a narrative of endemic incompetence on the part of several doctors. In the one Canadian case that related to allegations of a lack of clinical competence, WHSC, the focus was on the competence of Dr Jonah Odim, a paediatric cardiac surgeon who had been working in Winnipeg for eleven months. The position at Winnipeg was Dr Odim's first role as a consultant paediatric cardiac surgeon. The inquiry concluded that the appropriate standard was not met, primarily because of some over-confidence about skills, expertise, and experience. This scandal can be distinguished from the narratives of incompetence seen in Britain. Dr Odim was relatively new to surgical practice, as opposed to being an experienced doctor. The events occurred during an eleven-month period as opposed to decades. In addition, the inquiry determined there were significant failures on the part of the WHSC to induct, train, and adequately support Dr Odim. One swallow does not make a summer, and in Canada one scandal in relation to one doctor does not indicate a broader problem.

Abuse of Position
The issue of a health professional abusing his or her position was front and centre in many of the British scandals. In the RLCH scandal, Dr van Velzen, a pathologist, was said to have 'stripped' the bodies of many dead children of their organs for research purposes – without the knowledge or consent of parents and in excess of his capacity to actually conduct any research on them.[1012] The pain experienced by parents who believed that they had buried their child – but who were forced to rebury their child's remains, sometimes several times over, as the haphazard system kept discovering more retained organs – cannot be imagined.

[1010] Anonymous, "Bristol: Parents Reaction" *BBC News* (18 July 2001) [Anonymous, "Bristol: Parents Reaction"], online: BBC News <http://news.bbc.co.uk/2/hi/health/1444830.stm>.
[1011] Neale Inquiry, *supra* note 851 at 17.

The chair of the GMC's disciplinary panel hearing concluded, "He [Dr van Velzen] has undermined the trust placed in medical practitioners to such an extent it has damaged the medical profession as a whole."[1013]

All three of the forensic mental health scandals related to allegations that staff, either through violence, abuse, or peculation, abused their position.[1014] These gross types of abuse of position were also seen in many of other scandals, especially in regard to the sexual exploitation or abuse of patients by Drs Kerr, Haslam, Green, and Ayling. All of these cases illustrated that a profound breach of trust had occurred. To cite but a few examples of the discourse around trust that these scandals provoked, the Kerr/Haslam inquiry concluded, "In most if not all cases, the effect upon the women of the breach of trust that occurred has been devastating."[1015] In respect of Dr Green, the judge at his criminal trial stated that his "behaviour was a 'wicked betrayal' of the trust placed in him by patients."[1016] The Ayling Inquiry noted that his conduct "…broke the boundaries of the trust and integrity patients have the right to expect from their doctor."[1017]

The Canadian sexual abuse scandal highlighted the preponderance of sexual abuse by medical professionals against patients, but primarily focused on the CPSO's response to complaints.[1018] The rapid response of the CPSO refocused the debate onto the positive steps being taken by the profession.

The cases where health professionals are alleged to have murdered their patients, of course, create conditions for mistrust. Three scandals, two British and one Canadian, related to suspected mass murders of patients. In Britain, nurse Beverly Allitt murdered child patients in her care – a case described as "an example of one of the most flagrant instances of

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[1012] U.K., The Royal Liverpool Children's Inquiry, *Report of the Royal Liverpool Children's Inquiry,* (London: Stationery Office, 2001).

[1013] H. Carter, "Former Alder Hey Pathologist Struck Off" *The Guardian* (21 June 2005), online: The Guardian <http://www.guardian.co.uk/uk/2005/jun/21/alderhey.helencarter>.

[1014] Ashworth Inquiry, 1992, *supra* note 848; Rampton Inquiry, *supra* note 846.

[1015] Kerr/Haslam Inquiry, *supra* note 861 at 4.

[1016] Anonymous, "Reform Calls After GP Abuse Scandal" *BBC News* (30 August 2001), online: BBC News <http://news.bbc.co.uk/2/hi/health/1516667.stm>.

[1017] Ayling Inquiry, *supra* note 858 at 21.

[1018] TSAPP, *supra* note 867.

professional abuse of power by a very disturbed and evil minded health care worker."[1019] In Canada, allegations that children had been murdered in the ward of a Toronto hospital saw murder charges laid against a nurse. Although several reviews concluded that the children had been murdered, many doctors and administrators from HSC advocated that there had been no murders, and this counter-narrative created uncertainty for the public. Couple this uncertainty with a focus on the miscarriage of justice that had occurred, and one can see that any focus of mistrust was in the direction of police and prosecution services.

It is fair to say that the case of Dr Shipman shook Britain and shook the world. While in the past there had been instances where doctors had been involved in the deaths of multiple patients and research subjects[1020] – for example, the Nazi doctors – Dr Shipman's murders of his patients make him one of the worst serial killers in history. By being willing to make house calls, by offering to pick up medications for patients, he created the illusion that he was a caring, trustworthy doctor – the reality was profoundly different.   The Shipman Inquiry noted:

> As a general practitioner, Shipman was trusted implicitly by his patients and their families. He betrayed their trust in a way and to an extent that I believe is unparalleled in history.[1021]

Pringle argues that the Shipman scandal, and other similar scandals:

> fundamentally challenge the core values of the doctor-patient relationship.   If a patient cannot trust their GP not to deliberately harm them then how can they trust their doctor not to avoid accidental harm?[1022]

Ultimately, serial killers, and serial abusers of patients are extremely rare. The relationship between GPs and their patients is often very personal, and so trust in one's individual doctor

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[1019] G. Brykczyńska, "Implications of the Clothier Report: The Beverly Allitt Case" (1994) 1:3 Nurs. Ethics 179.
[1020] I use this term advisedly, as Jews and others experimented on by the Nazis were decidedly the subjects of what the Nazis considered to be 'research', which was generally thinly disguised torture.
[1021] Shipman Inquiry, *Death Disguised, supra* note 845 at para. 14.21.
[1022] M. Pringle, "The Shipman Inquiry: Implications for the Public's Trust in Doctors" (2000) Br. J. GP 355.

is likely to rebound. However, the fact that a doctor and indeed other health professionals can intentionally murder is now branded into public consciousness in Britain. The doctor as a serial killer narrative is one that is extensively discussed by the media and other forums.

It is not always the case that a narrative of a scandal could create the conditions for mistrust. The SARS scandal did not shatter preconceptions about health professionals. Indeed, if anything, the scandal reinforced the narrative that health professionals act beneficently and in service of the public good. Some health professionals died or became seriously ill because they chose to continue to provide care for patients despite the risks to themselves. All of the inquiry reports focused on the narrative of heroic health workers who succeeded in spite of the system, not because of it, and at great personal cost. For example, the National Advisory Committee wrote:

> The SARS story as it unfolded in Canada had both tragic and heroic elements. Although the toll of the epidemic was substantial, thousands in the health field rose to the occasion and ultimately contained the SARS outbreak in this country, notwithstanding systems and resources that were manifestly suboptimal".[1023]

In this scandal, health professionals providing care for patients were seen to have more than held up their end of the social contract with the public.

Overwhelmingly, the narratives about the conduct of health professionals from Britain emphasized the many breaches of the trust relationships between patients and health professionals. The narratives coming from the Canadian scandals were fewer in number, limiting the aggregation effect. Generally, some form of counter-narrative or other concern limited the perception that competence or conduct were significant issues.

<u>Hospitals, Other Health-Providers and Health Systems</u>
Health professionals are not the sole actors in the health system. Many of these scandals also illustrate reasons why the public might come to distrust other actors, including hospitals, non-governmental actors, general practices, and departments of health. Many of the

scandals illustrated that actors had failed to do their duty, creating the conditions for mistrust of those actors and/or those systems.

As discussed earlier, the Dubin Inquiry's findings about the HSC found that there were problems with the HSC's systems, particularly in respect of drug errors, patient safety, and communication between staff and patients.[1024]   However, the impact of these findings was overshadowed by the continued focus on the forthcoming criminal proceedings and a public fight over the government's refusal to release the Centres for Disease Control Review and the later Grange Inquiry.[1025]   The counter-narrative that there had in fact not been any murders further diverted attention from the hospital. The combined effect was to divert attention from systemic issues within HSC and to counteract the creation of conditions for the mistrust of the system more generally.

The inquest into events at the WHSC concluded "the Pediatric Cardiac Surgery Program at the Health Sciences Centre did not provide the standard of health care that it was mandated to provide."[1026]   The inquest noted specifically that systemic problems "related to the structure of the HSC, in particular to hospital policies and procedures … Weaknesses in all these areas led to problems in the procedures and outcomes of the program."[1027]   The inquest also concluded that there has been evidence in front of regulators to suggest that Manitoba lacked the population to sustain a high-quality, full-service paediatric cardiac surgery program and that this meant a greater risk of adverse outcomes, particularly in respect of more complicated procedures.[1028]   Although the inquest acknowledged that there were benefits to patients being treated within the province, it found that policy-makers had to weigh these against the increased risk of adverse outcomes. It seems then that the continuation of the surgical program, in the face of expressed doubts about its viability and the province's/WHSC's level of commitment to the program, smacked of hubris on the part of the province and the WHSC. The hubris lay in the desire to provide the most advanced services within the province, while overlooking the true costs and consequences of such a

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[1023] National Advisory Committee, *SARS*, *supra* note 869 at 12.
[1024] Dubin Inquiry, *supra* note 864.
[1025] Grange Inquiry, *supra* note 864.
[1026] Sinclair Inquest, *supra* note 868 at 465.
[1027] *Ibid.*
[1028] *Ibid.*

decision. Such decision-making sends a signal that decision-makers are not necessarily making decisions to fund, and therefore provide a service, based solely on safety – other considerations, more political in nature, may be important determinants of a decision. The thought that the safety of patients may be traded for political or institutional self-interest is not calculated to imbue the public with trust in decision-makers.

However, the Manitoba government's response was swift and comprehensive. It established a Review and Implementation Committee to consider the recommendations flowing from the inquest. The committee made 53 recommendations which sought to "identify institutional arrangements and procedures that would provide Manitobans with a stronger guarantee of competent, safe and ethical healthcare in the future."[1029] The committee emphasised that it was concerned with "restoring trust and confidence in institutions which played a central role in those events."[1030] The committee noted that as a consequence of the inquest "there are growing demands for greater transparency, greater public input, greater responsiveness and strengthened accountability at all levels within Manitoba's complex and dispersed health care system."[1031] This type of response may restore trust although, as can be seen in Britain, such a response may also create conditions for further mistrust. Possibly the difference is in the mechanisms employed. In Britain, regulators and policy-makers imposed prescriptive monitoring and audit requirements, whereas the Manitoban reforms were designed to foster co-regulation.

In Ontario, there was a perception that poor management of the first outbreak of SARS created an opportunity for the virus to re-emerge to infect more patients and staff. Dr Richard Schabas, Chief of Staff at York Central Hospital in Toronto, was quoted as saying, "SARS I [first wave of SARS in Canada, 13–25 March 2003] was not avoidable. We were struck by lightning. Everything after that was."[1032] There was a further perception key systemic actors focused on restoring Toronto's international image to remedy the damage resulting from the World Health Organization's travel advisory (recommending against travel

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[1029] Manitoba, Review and Implementation Committee, *Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest* (Winnipeg: Manitoba Health, 2001) [Review and Implementation Committee].

[1030] *Ibid* at 125.

[1031] *Ibid* at 126.

[1032] Quoted in National Advisory Committee, *SARS*, *supra* note 869 at 40.

to Toronto) rather than on maintaining precautions: "health care workers have complained that authorities dropped their vigilance in May in a rush to proclaim Toronto safe after the initial outbreak of SARS."[1033] The primary focus of the inquiries were on systemic failures at the provincial and federal levels. Although the performance and actions of hospitals attracted some scrutiny, the Campbell Commission concluded hospitals were not to blame, being themselves victims of the system.[1034] The commission noted:

> hospitals did their best within the limits of their lack of preparation, their generally inadequate infection control systems and their inadequate worker safety systems. Inevitably they made mistakes in the fog of war against an invisible enemy.[1035]

Generally, the effect of this was to suggest that hospitals were let down by governments and reinforced systemic mistrust about the governance of the *public* health system at the provincial and federal levels.

Events in the blood systems in each jurisdiction in the mid to late 1980s identified systemic failings that raised concerns about the trust vested in certain actors. At that time, blood systems in Canada were operated by a non-governmental humanitarian charitable organisation, the CRC, with limited involvement by provincial and federal regulators. In Britain, the blood system was part of the NHS and services were provided, managed, and funded by the NHS on a regional basis. In both jurisdictions, the actions and omissions of various systemic actors, providers, and regulators were scrutinized, resulting in a largely unflattering picture emerging of the conduct of providers and regulators of blood systems.

Although both the NHS and the CRC had legal, ethical, and moral obligations to act in the public interest and to safeguard the interests of those who were the ultimate consumers of blood and blood products, in some respects it appears that the sense of betrayal experienced by Canadians was greater than that in Britain. The CRC had a sterling reputation among Canadians, providing programs and services that benefited the most vulnerable Canadians, and had a proud record of service during World War II. It was a member of the

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[1033] Associated Press, "12 Patients Show Signs of SARS at Toronto Hospital" *Baltimore Sun* (June 11 2003).
[1034] Campbell Commission, *Final, supra* note 869 at 8.

International Red Cross – one of the world's most respected humanitarian agencies assisting people caught up in conflict or disaster. Many Canadians had donated money or blood to the agency, had volunteered their services, and some had received assistance from the CRC at times of peace or war. The CRC was supposed to be above the fray, in terms of politics, resources, costs, and profits. Because of the CRC's status, it is possible that the expectations of and for the CRC appeared greater than those in respect of the NHS, and the consequences for public trust more profound. Gilmore and Sommerville noted:

> Public attention given to the Krever Commission reflected and contributed to a widespread sense of dismay regarding the blood system. The sense of trust and pride it had evoked was shattered by revelations of incompetence and apparent indifference on the part of those responsible for its operation.[1036]

The CRC, which before the blood scandal, "was, by many accounts, one of the country's most venerated institutions"[1037] or, more narrowly, one of Canada's "most revered institutions in the healthcare field",[1038] bore the brunt of this mistrust. When a group or institution associated with altruism is seen by the public to have failed and to have failed in such a manner that members of the public suffered serious harm, the sense of betrayal might be magnified.[1039] Bayer and Feldman note:

> In the course of conflicts over blood, long-established convictions about the moral and political status of the institutions responsible for the blood supply were shattered. Symbols of altruism and national solidarity, such as Red Cross societies, became targets of escalating criticism.[1040]

[1035] *Ibid* at 13.
[1036] N. Gilmore & M. Sommerville, "From Trust to Tragedy: HIV/AIDS and the Canadian Blood System" in E. Feldman & R. Bayer, eds., *Blood Feuds: AIDS, Blood and the Politics of Medical Disaster* (New York & Oxford: Oxford University Press, 1999) 128 at 128 [Gilmore].
[1037] Orsini, *supra* note 952.
[1038] A. Picard, *The Gift of Death: Confronting Canada's Tainted Blood Tragedy,* (Toronto: Harper Collins, 1995) at 17 [Picard, "*Gift*"].
[1039] Orsini, *supra* note 952.
[1040] R. Bayer & E. Feldman, "Introduction: Understanding Blood Feuds" in E. Feldman & R. Bayer, eds., *Blood Feuds: AIDS, Blood and the Politics of Medical Disaster* (New York & Oxford: Oxford University Press, 1999) 2 at 4 [Bayer].

This loss of trust may particularly arise when the institution seems unresponsive to emerging issues. The CRC did not take steps to limit at-risk groups and individuals from donating blood and was, according to some, slow to introduce testing procedures. Also, the public may lose faith when a trusted actor, suspected of causing harm, vehemently opposes calls for an independent public inquiry and resists any admission that they might have been at fault. Post-event emergence, the CRC and other actors continued to publicly downplay the scandal.[1041] Even when the Krever Inquiry was underway, governments and later the CRC, as Justice Gomery put it, "vigorously opposed" how the inquiry was conducted – actions not calculated to imbue the public with great trust in those institutions.[1042] A further sense of betrayal may set in when an institution like the CRC makes public statements that infection rate was negligible and the deaths inevitable.[1043] Victims, interest groups, and members of the public were further irked that the CRC, a respected humanitarian organization, refused to apologize for its actions until 2005 when it did so as part of a plea bargain in the context of criminal proceedings. Picard also suggests that another factor that caused the public to lose trust in the CRC was its failure to institute a call-back system to identify those who had received blood to limit re-transmission to family members.[1044]

So great in fact was the criticism and the mistrust that it was not tenable for the CRC to retain its role in the blood system even before the Krever Inquiry reported back. As the Krever Inquiry progressed, there developed a sense, especially among politicians and bureaucrats, that the Canadian blood system had been so deeply tainted by the scandal, and that trust in institutional actors had been so badly diminished, that there was really no other option than to completely redesign the blood system. Accordingly, a new cross-provincial/territorial (excluding Québec) quasi-independent body to manage the blood system was created with oversight (at least in the short term) by an independent body.[1045] The system's new operating principles were very clearly designed to restore and retain public trust and confidence in the system – safety was and is the first priority, and accountability the second.

[1041] M. Trebilcock, R. Howse & R. Daniels, "Do Institutions Matter? A Comparative Pathology of the HIV-Infected Blood Tragedy" (1996) 82 Va. L. Rev. 1407 [Trebilcock]; Picard, "Gift", *supra* note 1038.

[1042] Justice J. Gomery, "The Pros and Cons of Commissions of Inquiry" (2006) 51 McGill L.J. 783 at 791.

[1043] Picard, "*Gift*", *supra* note 1038.

[1044] *Ibid.*

[1045] Krever Inquiry, *supra* note 865.

The British blood system at the time of its blood scandal had been regionalized and faced similar problems. A lack of coordination mechanisms between regions resulted in decision-making in those systems being subject to regional priorities. Canada at least had one provider of blood in the CRC, with relatively consistent direction from a national directorate, albeit with some room for provincial innovation. In both countries, the management of blood systems was subject to the priorities of government, which at that time were very much focused on cost-cutting or at least maintaining health budgets at current levels.[1046] It would be overstating matters considerably to suggest that regional NHS blood centres were 'venerated'. Lacking the same reputational status as the CRC, any failings by regional NHS centres would likely not elicit, to the same degree, the levels of mistrust directed at the CRC. In refusing to convene an inquiry, in repeatedly assuring the public that the NHS had done no wrong and that the infections were an unfortunate unavoidable consequence of progress, in showing compassion by providing public assistance and by taking swift action to centralise the blood system, government was seemingly able to contain or withstand any mistrust that the problems may have caused.

In the British screening cases, it was clear that management systems in the affected facilities were ineffective in that they could neither identify nor respond appropriately to concerns about the quality of the outcomes of the screening process, particularly as related to individual performance, even over a long period of time. The inquiries identified opportunities to develop systems for effective quality assurance and to intervene earlier in respect of individuals whose competence was in question. The many events that occurred within screening programs were considered to have had a significant impact on public trust. Some commentators noted that "some serious clinical failures – for example, in breast and cervical cancer screening programmes – have been widely publicised and helped to make clinical quality a public confidence issue."[1047] In 1998, the National Screening Committee noted:

[1046] *Ibid.*

[1047] G. Scally & L. Donaldson, "Looking Forward: Clinical Governance and the Drive for Quality Improvement in the New NHS in England" (1998) 137 BMJ 61 [Scally & Donaldson].

Events in recent months in the breast and cervical screening programmes have rightly highlighted the high expectations we have of our national screening programmes and how public confidence can be quickly undermined when questions are raised about quality, effectiveness and reliability."[1048]

Chiam noted that screening programs assisted in reducing cancer death rates but that scandals "must inevitably undermine women's confidence in cervical screening programmes, if not in the NHS as a whole."[1049]

In Britain, scandals highlighted ineffective internal management within the NHS. Particularly relevant in respect of the maintenance of trust was the apparent inability of the NHS as an institution to have in place mechanisms to identify and respond to performance or conduct issues. The Wells Inquiry, for example, noted the failure of management to respond to signs of poor-quality work because of confused lines of accountability for quality assurance.[1050] The Royal Liverpool Inquiry identified flagrant violations of the *Human Tissue Act 1961* and failure by the Trust and the University of Liverpool to undertake adequate oversight of services and employees and to respond appropriately to complaints and audits.[1051] In regard to the retained organs scandal, the Health Secretary was quoted as saying:

The days have gone where the NHS could act as a secret society. It cannot operate behind closed doors. It cannot keep patients in the dark. It has to actively earn the trust of patients in life and it has to actively seek the consent of relatives in death.[1052]

The Bristol Inquiry, too, concluded that the systems in place in Bristol were fundamentally flawed. It noted:

It is an account of a time when there was no agreed means of assessing the quality of care. There were no standards for evaluating performance. There was confusion

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[1048] U.K., National Screening Committee, *First Report of the National Screening Committee,* (London: Department of Health, 1998) at 3.

[1049] M. Chiam, "Cervical Smear Scandal: Women Deserve Better" (1997) 6:20 Brit. J. Nurs. 1153.

[1050] Wells Inquiry, *supra* note 852.

[1051] RLCH Inquiry, *supra* note 860.

[1052] Alan Milburn quoted in Boseley, *supra* note 998.

throughout the NHS as to who was responsible for monitoring the quality of care. It is an account of a hospital where there was a 'club culture'; an imbalance of power, with too much control in the hands of a few individuals … And it is an account of a system of hospital care which was poorly organised. It was beset with uncertainty as to how to get things done, such that when concerns were raised, it took years for them to be taken seriously.[1053]

The Bristol Inquiry was one of the first inquiries to lay bare the inability of the NHS to deal with performance or conduct related issues. In that case, concerns had been formally raised with the chief executive officer (CEO) in 1990 about excessive mortality in the paediatric cardiac surgery program. From that point, there was a series of meetings, much correspondence, the presentation of audit findings, communications from the Department of Health, and so on. Events came to a head after the 1995 death of Joshua Loveday when the issue of excessive death rates reached the media. Hence it took five further years for hospital management to address concerns about excessive death rates, not assisted by the fact that one of the surgeons was medical director of the hospital, and the club-culture endemic in that institution protected him. The CEO intimated to the inquiry that in his view it was inappropriate for management to intervene in surgical practices.[1054] The GMC had earlier found the CEO, who was also a registered doctor, to have committed professional misconduct for his failure to take action and deregistered him. The disciplinary committee noted:

> Your own evidence demonstrates that you chose, over a long period, to ignore the concerns which were being brought to your attention, preferring to leave these matters to the consultants concerned. Yet, faced with information suggesting that children were being placed at unnecessary risk, you took no adequate steps to establish the truth.[1055]

In Bristol, as in Winnipeg, the continuation of the paediatric cardiac surgery program was a matter of considerable prestige – or hubris in both cases. In Bristol, as was the case in

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[1053] BRI Inquiry, "Learning from Bristol", *supra* note 287.
[1054] *Ibid.*

Winnipeg, the patient base served by the program was insufficient to maintain the skills of the surgeons. Also, again with parallels to Winnipeg, there had been concerns expressed about the viability of the service, but these concerns were trumped, as in Winnipeg, by political considerations. Although the surgeons in Bristol were senior and experienced at adult cardiology, they too had limited experience with paediatric cardiology, a fact known to decision-makers and other regulators. As in Winnipeg, the Department of Health did not escape criticism for a decision to fund the service at Bristol despite potential safety issues, and for failing to effectively monitor and evaluate the services, especially once they had been advised of the empirical evidence that supported claims of excessive deaths. Not surprisingly, the Bristol families emphasized the need for a fundamental reappraisal of the health system. Maria Shortis, chair of Constructive Dialogue for Clinical Accountability, stated, "The report certainly demonstrates the need for a radical transformation due to the systemic failure of the NHS, that allowed Bristol to develop into an avoidable tragedy."[1056]

The inquiry into Dr Neale similarly indicated significant failings within the NHS, especially given that he was employed in 1985 despite being deregistered in Canada after the death of a patient. Dr Neale had falsified his CV, although he was registered to practise in Britain. In 1988, the Yorkshire Regional Health Authority (YRHA) was advised by police of the Canadian deregistration and commenced a limited internal review. At this time, the YRHA believed that Dr Neale had been treated unduly harshly by the Canadian authorities, were satisfied with his clinical competence, and took no action.[1057] The Neale Inquiry concluded that this review "did not show sufficient regard to the protection of his UK patients."[1058] Subsequently, in 1991, Dr Neale received a police caution after an incident in a public toilet, during which he provided the police with false information. He was given a formal written warning by the YRHA.[1059] In 1993, Dr Neale's Canadian deregistration, and the public toilet incident, became public knowledge and some clinical complaints were received. Dr Neale was provided with what the inquiry termed "pastoral support" for a period. Complaints

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[1055] *Roylance, supra* note 645.
[1056] Anonymous, "Bristol: Parents Reaction", *supra* note 1010.
[1057] He has been deregistered for negligence, which at the time in Britain did not constitute grounds for discipline.
[1058] Neale Inquiry, *supra* note 851 at 67.
[1059] He was caught by police allegedly for observing a sex act occurring two between males in an adjacent toilet cubicle. He claimed he was in the public toilet eating his lunch(!), had heard a noise, and took a look.

about Dr Neale's conduct, especially collegiality and professionalism, increased and a severance agreement was negotiated, including the provision of a reference. The Neale Inquiry concluded:

> It is my judgement that between 1985 and 1997 there were systems failures within the employment and complaints procedures within the NHS, and very importantly, failures within other professional bodies upon whom the NHS was dependent."[1060]

While internal NHS mechanisms were ineffectual, at least in the Neale case formal review processes were, eventually, convened – such was not always the case in some of the other scandals.

The Ledward Inquiry also noted failures in NHS systems relating to employment, complaints, audit, appraisal, and review.[1061] The Allitt Inquiry concluded there had been lax hiring processes and less than rigorous internal reporting mechanisms.[1062] The Kerr/Haslam Inquiry noted a lack of rigour in recruitment and appointment processes, poorly developed disciplinary processes, an over-reliance on defensive legal advice, and a management style that was consensus based, which meant that managers were less likely to be proactive in terms of performance review and oversight.[1063] It concluded:

> administrators felt powerless, and devised mechanisms to protect themselves, rather than the patients or those who raised concerns … sadly some of the failure arose because it was easier, perhaps professionally safer, to do little or nothing at all.[1064]

Similar problems were also noted in inquiries relating to general practitioners. The Green Inquiry concluded: "Peter Green's patients were failed not only by him but by a system that allowed a credible person to do incredible things to patients to whom he owed a duty of care." [1065] The Green Inquiry noted, "We found a culture that simply did not listen to

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[1060] Neale Inquiry, *supra* note 851 at 13.
[1061] Ledward Inquiry, *supra* note 853.
[1062] Allitt Inquiry*, supra* note 849.
[1063] Kerr/Haslam Inquiry, *supra* note 861.
[1064] *Ibid* at 13.
[1065] Anonymous, "Reform Calls", *supra* note 1016.

patients, and fudged accountability" [1066] and stated that "at the heart of the matter lay an NHS culture that did not listen to, or treat complaints inquisitively." [1067]

The Ayling Inquiry concluded "there were persistent concerns about Ayling's practice throughout his career – and on very few occasions were those concerns fully investigated or properly followed through." [1068] Nurses reported making complaints to management and being told nothing could be done. Serious concerns about sexualized conduct were not followed up, and his other employers were not advised of the incidents or the reasons for the non-renewal of his contracts. In addition, some key actors within the NHS, such as the Local Medical Committee, the Family Health Services Authority, and the Poorly Performing Doctors Committee, chose to provide counselling rather than to take any definitive action. There were concerns within the NHS about Dr Ayling's professional proficiency, in particular around his delivery practices, but also about his penchant for conducting internal examinations without gloves or chaperones. But despite this concern, there was no audit of his practice and no systematic supervision. There were also concerns among the consultants that Dr Ayling's full-time general practice, two clinical assistantships, after-hours cover, and family planning sessions were affecting his ability to carry out his professional responsibilities; but these concerns were never raised with him. The Ayling inquiry further noted a lack of coordination between various health organizations. [1069] The consistent themes running through the majority of the inquiries in Britain were that systems within the NHS were consistently ineffectual and ineffective. This was not a recipe calculated to inspire trust in the NHS; rather, the opposite.

That distrust may have been further fostered by the conduct of some NHS Trusts who, rather than take action against a doctor with performance and/or conduct issues, chose to 'export' the problem. 'Exporting' a problem was a solution with certainty of outcome:

> 'Exporting' a problem ensured that a doctor causing concern no longer worked
> within one's own organisation, but did not address wider issues of protecting future

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[1066] *Ibid.*

[1067] Green Inquiry, *supra* note 857 at 22.

[1068] Ayling Inquiry, *supra* note 858 at 31.

[1069] *Ibid* at 90.

patients; and it encouraged an attitude to 'work around' a problem rather than tackling it vigorously.[1070]

The Ayling Inquiry noted that within the NHS "the expedient use of a rolling contract became a mechanism to disguise the lack of action in addressing the real problems that they had found."[1071] Expedience topped public protection.

In Dr Ayling's case, his contract as a clinical assistant in obstetrics and gynaecology at Thanet and Kent & Canterbury Hospitals was not renewed after a serious untoward incident in 1987, and also because of general concerns about his delivery techniques. He was, however, given a clinical assistant position in colposcopy in that same hospital for a further year until that contract was terminated after a complaint of sexually inappropriate conduct. In 1993, after a serious complaint relating to an incident for which Dr Ayling was subsequently convicted of indecent assault, the William Harvey Hospital did not renew Dr Ayling's contract. After a serious complaint was made in the context of Dr Ayling's work in family planning clinics, the Director of Public Health at East Kent Health Authority took what she described as "the easy way out" and took Dr Ayling's name off the list of locums and said he was not to cover family planning clinics again.[1072]

But Dr Ayling was not the only problem doctor to be exported. In the face of a number of concerns about Dr Haslam's conduct, the NHS essentially adopted a similar approach to that taken with Dr Ayling – they let the conduct be someone else's problem. Dr Haslam was encouraged to resign from the NHS and move to private practice – where he allegedly sexually abused at least one other patient. The Kerr/Haslam Inquiry noted if the NHS believed in 1988–89 that Dr Haslam was a danger to women:

> we do not believe that the NHS should simply have washed their hands, and said nothing or done nothing … Whatever the legal position the NHS had a moral duty to ensure that such patients [existing NHS patients who could be referred to Dr Haslam for private treatment] were not exposed to a possible risk of harm that the NHS

[1070] *Ibid* at 120-121.
[1071] *Ibid* at 80.

managers had already foreseen. It would be disgraceful if the NHS was merely allowed to wash its hands of a suspect doctor, without at least taking some steps to protect existing and future patients.[1073]

A similar pattern can be seen in respect of Dr Kerr. The allegations were old, the investigation was taking a long time, and he was due to retire. It was easier just to let Dr Kerr retire with a letter of thanks for his "valuable contribution" to the NHS,[1074] rather than pursue investigations.

Dr Neale, too, was 'exported' after the negotiation of a severance agreement. In his case, the Trust felt that there were no grounds for a successful lawful dismissal, and they had no indications that there was significant concern about clinical competence – to the contrary, his clinical competence had been attested to by a range of colleagues. The inquiry concluded in respect of this decision:

> We consider that the Trust was in an impossible position in the circumstances …. In deciding to negotiate Richard Neale's departure from the Trust, it took the pragmatic course. We find that it was the choice of the lesser of two evils. It was the system within which the Trust was operating which made it difficult to deal effectively with problem doctors without damage to the viability of the hospital service. … the unfortunate consequence of the Trust's decision was that it looked after the interests of its own patients to the detriment of the protection of the wider public.[1075]

In these scandals, weak NHS systems to address concerns about conduct or performance led to NHS Trusts abrogating their responsibilities to act in the public interest – a recipe for mistrust.

So what the narrative of the scandals tells us about the respective health systems in each jurisdiction is markedly different. In Britain, there is a uniformity in the narrative, such that

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[1072] *Ibid* at 86.
[1073] Kerr/Haslam Inquiry, *supra* note 861 at 369.
[1074] *Ibid.*
[1075] Neale Inquiry, *supra* note 851.

it suggests an NHS in every area and every context is worthy of mistrust because it has demonstrated an inability to safeguard the public interest. In contrast, the lesser number of Canadian scandals have been limited through sectoral, institutional, or geographic boundaries and thus the level of distrust was not sufficient to challenge the regulatory consensus.

Professional Self-*Regulation*

The next narrative to be considered is what the scandals illustrated about professional self-regulation. Self-regulation, whether based on professionalism or government sanctioned through legislation, depends upon the self in question being "responsible political actors", as Kagan and Scholz put it, or "virtuous' actors", as Braithwaite describes it.[1076] If the prevailing regulatory culture is neither "responsible" nor "virtuous", the social contract between profession and the state/public will have been breached, creating conditions for mistrust. On this front, too, a significant divergence may be seen between the two jurisdictions. In Britain, the many scandals illustrated a deficit in the practices and mechanisms of professional self-regulation both in respect of what Paul terms "the internal morality of the profession"[1077] and the profession's legislative responsibilities. In Canada, the scandals illustrated professions that, on the whole, responded and acted appropriately and were generally responsive to public concerns. Self-regulatory activity in Canadian jurisdictions was more robust than in Britain and arguably maintained the public trust.

A key facet of the internal morality of the professions, especially in terms of the social contract, is the will to act as self-regulatory actors. In the context of patient safety, this means that all individual members of the profession must be active in ensuring that their profession and their members act to protect the public. The narratives of scandal illustrate much about how members of professions internalize their responsibilities and whether they maintain the trust of the public in their capacity to self-regulate.

In Britain, as noted above, many of the events leading to scandal were of a long duration. When the inquiries came to examine whether there had been opportunities along the way to intervene, they discovered that there had indeed been many missed opportunities. Some of

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[1076] Kagan, *supra* note 434 at 67; Braithwaite, *supra* note 433.

these were due to the systemic issues within the NHS systems, discussed above, and some with the processes of regulatory actors, specifically the GMC, discussed below; but often it was because health professionals failed to recognize concerns, failed to act upon those concerns, or failed to act effectively.

Conversely, in Canada, there were few illustrations of lapses in the internal morality of the profession, and those that did occur were markedly different from scandals in Britain. At the HSC, the Dubin Inquiry identified some problems with the systems at HSC that contributed to a delay in identification of the murders, but the internal morality of the professions was not put seriously in question. In Ontario, the TSAPP commissioned research that found that many professional colleagues did not report to the regulatory body suspected sexual abuse of patients by colleagues.[1078] At the WHSC, from the beginning of Dr Odim's (the new surgeon) tenure nurses and anaesthetists expressed concern about the practices of the surgeon and the high death rates within the program. Ultimately, the anaesthetists withdrew their services from the program, citing high death rates. These actors continued to raise concerns until the program was shut down, although the inquest noted that many were reluctant to explicitly specify that they believed the surgeon was not competent.[1079] As Dr Odim was a junior surgeon restarting a highly specialized program, there was some professional tolerance and acceptance by other surgeons of a learning curve to explain away problems with surgical outcomes.[1080] In addition, the problems were also attributed to interpersonal difficulties between medical specialities. Despite this, an inter-profession and inter-speciality review committee (including the surgeon) was struck to review cases and practices. The collegiality of the review process was judged by the inquest to be somewhat problematic as it precluded full and frank discussions in the interests of being seen to be collegial. Although the inquest criticized the timeliness and effectiveness of the WHSC's response, it took only eleven months after Dr Odim had commenced practice for paediatric cardiac surgery to be halted. Contrast this with the Bristol case, where it took eleven years

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[1077] C. Paul, "The Internal and External Morality of Medicine: Lessons from New Zealand" (2000) 320 BMJ 499.

[1078] Robinson, *supra* note 873.

[1079] Sinclair Inquest, *supra* note 868.

[1080] *Ibid.*

for action to be taken to shut down the surgery program. Professional self-regulation at WHSC was perhaps not optimal, but it certainly did not wholly fail either.

It was otherwise in the majority of the British scandals. In the British screening scandals, misreading of slides or scans had occurred over relatively long periods of time, in some cases as much as five years. There were indications that other health professionals had suspicions or had known that the individuals in question had problems, and either protected them or failed to raise their concerns with colleagues or management.[1081]

The retained organs scandals in Britain also illustrated problems with the internal morality of medicine. Inquiries established that organ retention after autopsy was a standard professional practice, often occurring without the knowledge or consent of families.[1082] This illustrated a disjunction in perspectives about retaining organs for medical research between parents and the public and the medical profession. Or, as Campbell and Willis put it, "the inquiries [Bristol (the interim report) and Royal Liverpool] revealed unbridgeable differences in understanding between the professionals and the bereaved families."[1083] For many medical professionals, the retention of body parts and tissues after autopsy "formed an essential part of medical education and research."[1084] Thus, medical professionals saw the bodies of deceased patients as serving a functional purpose[1085] in the public interest – the public interest being continuing scientific and medical progress. Organs were retained as tools to be employed for the greater good.[1086] The big picture of scientific progress meant that less, if any, attention was paid to the fact that for families the body remained the embodiment of the deceased person[1087] and ought to be treated with the dignity and respect that the person should have been accorded in life.

[1081] Royal Devon Inquiry, *supra* note 856.

[1082] CMO Census, *supra* note 878; RLCH Inquiry, *supra* note 860; U.K., The Bristol Royal Infirmary Inquiry, *The Inquiry into the Management of Care of Children Receiving Complex Heart Surgery at The Bristol Royal Infirmary - Interim Report: Removal and Retention of Human Material*, (Norwich: The Stationery Office Limited, 2000) [BRI Inquiry, *Interim*].

[1083] A. Campbell & M. Willis, "They Stole My Baby's Soul: Narratives of Embodiment and Loss" (2005) 31 Med. Humanit. 101 at 101 [Campbell & Willis].

[1084] U.K., Department of Health, "Royal College of Physicians Ref 222" in *Chief Medical Officer's Summit on Organ Retention: Evidence Documentation,* (London: Department of Health, 2001).

[1085] Campbell & Willis, *supra* note 1083 at 101.

[1086] BRI Inquiry, *Interim*, *supra* note 1082.

Doctors noted that families were not informed in detail about post-mortem and organ retention practices out of a "simple and understandable wish to spare them further anguish and distress at the time of bereavement."[1088] This paternalistic position, at odds with the development of informed consent, was adversely commented upon in both the RLCH Inquiry and the interim report of the Bristol Inquiry. These inquiries suggested that the profession's position on organ retention was characterized by arrogance and detachment as well as by a paternalism that may have masked a professional reluctance to undertake the informed consent process.[1089] Discussions with bereaved persons, and perhaps particularly parents of deceased children, about autopsies and the retention of organs for teaching and/or research are difficult. But that these discussions are difficult is no reason not have them.[1090]

In contrast, parents used such terms as "grave-robbing", "body-snatching", and "desecrated" to describe what had happened to the bodies of their children.[1091] Respecting the human body after death is, in most cultures, recognized as important for the wellbeing of the person in the afterlife, but also for the wellbeing of families and friends in this life.[1092] This yawning chasm between perspectives prompted calls for immediate law reform, given the profession had evidently proved incapable of self-regulating the practices of its members in accordance with public sentiment and robust medical ethics. A representative from the advocacy group Parents Who Interred their Child Twice was quoted as stating:

> Guidelines are not enough. It has been proven that they have been ignored. Self-regulation by the medical profession has been shown to be inadequate. We must have changes in the law.[1093]

[1087] *Ibid.*; Campbell & Willis, *supra* note 1083 at 101.

[1088] U.K., Department of Health, "Royal College of Pathologists Ref 101" *Chief Medical Officer's Summit on Organ Retention: Evidence Documentation,* (London: Department of Health, 2001).

[1089] BRI Inquiry, *Interim, supra* note 1082; RLCH Inquiry, *supra* note 860; S. Dewar & P. Boddington, "Returning to the Alder Hey Report and its Reporting: Addressing Confusions and Improving Inquiries" (2004) 30 J. Med. Ethics 463.

[1090] H. Bauchner & R. Vinci, "What Have We Learnt From the Alder Hey Affair?" (2001) 322 BMJ 309.

[1091] RLCH Inquiry, *supra* note 860.

[1092] D. Hall, "Reflecting on Redfern: What Can We Learn from the Alder Hey Story?" (2001) 81 Arch. Dis. Child 455.

[1093] U.K., Department of Health, Department of Education and Employment and the Home Office, *The Removal, Retention and Use of Human Organs and Tissue from Post-Mortem Examination: Advice from the Chief Medical Officer* (London: The Stationary Office, 2001) at 3.

This statement is significant in that it emphasises a marked distrust of the accepted regulatory paradigm of self-regulation. The implication is that the medical profession has not been a responsible regulator and thus more control mechanisms need to be implemented to require good practice from the profession.

The Green Inquiry illustrated that over the course of a thirteen-year period, 23 individuals or organizations had knowledge of concerns about Dr Green's sexualized conduct.[1094] Dr Green's practice partners were subsequently criticized by the inquiry for uncritically accepting his word that nothing had occurred, in the face of serious allegations of sexualized conduct; and an NHS committee referred them to the GMC for failing to report concerns about Dr Green. The Bristol Inquiry also illustrated that many health professionals, including senior medical administrators, were aware of concerns about high death rates in some procedures, and yet little action was taken for a number of years, despite the valiant efforts of a whistleblower.[1095]

The Shipman Inquiry determined that Dr Shipman had been murdering his patients with relative impunity since 1971, accelerating in numbers and incidence since 1992. As the court hearing the criminal proceedings noted, "the fact that deaths occurred over a long period without detection is suggestive of a breakdown in those checks and controls which should operate to prevent such a tragedy."[1096] One of the significant areas of concern identified in the Shipman Inquiry, in common with many of the other inquiries, was that professional colleagues either did not identify or did not respond to concerns that they may have had about a colleague's professional conduct or performance. While a colleague could always report concerns, many were reluctant to do so because the prevailing professional culture suggested that it was "improper to criticise or deprecate the conduct of a fellow professional. The culture was that it was 'not done'."[1097] The inquiry noted that by 1993, the GMC had made it clear that it was the duty of doctors to report to an appropriate authority any concern

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[1094] Green Inquiry, *supra* note 857.

[1095] BRI Inquiry, "Learning from Bristol", *supra* note 287.

[1096] *R v. Secretary of State for Health, ex parte Wagstaff and others* [*Wagstaff*]*; R v. Secretary of State for Health, ex parte Associated Newspapers Ltd and others* [2001] 1 WLR 292, 56 BMLR 199 [Q.B.] [*Associated Newspapers*].

[1097] U.K., The Shipman Inquiry, *Safeguarding Patients: Lessons from the Past - Proposals for the Future,* (London: HMSO, 2004) at 20 [Shipman Inquiry, *Safeguarding Patients*].

they might have about a colleague's treatment of a patient(s) if it gave rise to concerns about patient harm.[1098]   The Shipman Inquiry was told that, despite the GMC's direction, professional culture did not really change until after the events at Bristol when the GMC took disciplinary action against doctors who failed to act on information that death rates among paediatric cardiac patients were too high.

Although eventually (after 27 years) a doctor did report concerns about Dr Shipman to the coroner, the Shipman Inquiry noted a number of other instances where it believed there had been a failure by doctors and other health professions to report concerns. It highlighted particularly the case of Mrs Overton, who died after spending fourteen months in a persistent vegetative state. Dr Shipman had injected her with a large bolus dose (i.e. direct injection) of diamorphine, a drug that was contra-indicated for her as she had asthma. Doctors and nursing staff at the hospital believed Dr Shipman had made a mistake in giving Mrs Overton the drug and in giving her an excessive dose, administered incorrectly, yet no-one reported their concerns. One of the doctors proffered the excuse that he did not know how to report concerns about a GP within the NHS and did not report his concerns to the GMC as he thought it would not take action without more information. This doctor also suggested he had concerns about professional etiquette, i.e. he believed that it was unprofessional to disparage your colleagues in line with earlier professional practices. Last, the doctor believed the family should raise concerns as her son, a doctor, knew she had received morphine; however, the family were not told of the dosage or its means of administration.[1099]

The inquiry also focused on a period in 1993 when, on fourteen occasions, Dr Shipman prescribed 30 mg ampoules of morphine for patients – a dose too large to treat heart attack victims and too little to treat cancer patients, but a perfect dose to murder someone who had not developed a tolerance for morphine.[1100] A professional double-check on the prescribing practices of doctors was meant to be performed by pharmacists – a form of co-regulation where pharmacists work with doctors, and other prescribers, to protect patients.

[1098] *Ibid.*

[1099] *Ibid.*

[1100] U.K., The Shipman Inquiry, *Death Certification and the Investigation of Deaths by Coroners,* (London: HMSO, 2004) [Shipman Inquiry, *Death Certification*].

Pharmacists have legal and ethical obligations to patients to raise concerns about doctors' prescriptions or prescribing practices. In regard to Dr Shipman's unusual prescription of morphine in 1993, the pharmacist concerned did not identify, let alone raise, issues about Dr Shipman's prescribing practices then or at any other time. Nor did she question the fact that he inevitably picked up prescriptions of controlled drugs for his patients. The Shipman Inquiry concluded that the pharmacist's professional judgement had been compromised by her trust in Dr Shipman. A co-self-regulatory process reliant on the professionalism of doctors and pharmacists failed – and failed over a long period of time. It is suggested that "together with the Bristol children's heart surgery debacle, the Shipman case has shaken public confidence in the medical profession and is likely to lead to widespread reform."[1101]

Dr Ayling was another case that illustrated a multiplicity of failings by health professions to effectively self-regulate when professionals knew that Ayling's conduct was sexualized, yet took no action or took insufficient action. The Ayling inquiry noted that patients raised concerns with other health professionals seeking validation and reassurance.[1102] Instead, many of these health professionals in effect "recast what they heard into explanations which they could find acceptable and in so doing, deceived themselves and failed their patients."[1103] The reason for doing this was rooted in the internal morality of the profession. The Ayling Inquiry noted:

> A trust in the integrity, honesty and good faith of a doctor was, and remains, a fundamental element of the relationship between patient and doctor. It was a basic and deep belief, shared by doctors and patients alike, that doctors acted in the patient's best interests. Clear and convincing evidence could be needed, before this belief would be questioned – either by patients and other staff members who they might approach.[1104]

Speaking of procedures in the early 1980s, a witness before the Ayling Inquiry commented:

[1101] C. Dyer, "Tighter Control on GPs to Follow Doctors Murder Convictions" (2000) 320 BMJ 331 [Dyer].
[1102] Ayling Inquiry, *supra* note 858 at 22.
[1103] *Ibid* at 21.
[1104] *Ibid* at 109.

… I felt that the procedures were more heavily weighted in favour of the doctor rather than the patient. This was rooted in the predominant culture of the time of 'doctor knows best', the presumption of the effectiveness of self-regulation and an inherent professional defensiveness when challenged."[1105]

The Ayling inquiry established that Dr Ayling's unprofessional – and in some cases criminal – conduct probably occurred over 27 years during which time there existed many opportunities to prevent his actions.[1106] The inquiry established that the earliest ascertainable complaint about Dr Ayling dated from 1971 when a patient complained to a consultant that Dr Ayling had an erection during her post-natal examination and mismanaged the birth of her child. Serious concerns began to emerge from nursing and midwifery staff about Dr Ayling's behaviour towards female patients and his clinical management between 1975 and 1988, and these concerns were described by some witnesses as "widespread".[1107] To some, he was known as "Fingers Fred" or "Fingers Ayling".[1108]

The neighbouring general practice kept records of patient transfers from Dr Ayling's practice, including the patients' reasons for doing so. Between 1985 and 1998, there were 44 patients on their records whose reasons for transferring, in the opinion of the Ayling Inquiry, warranted further examination or investigation.[1109] One of the GPs gave evidence to the inquiry that he took no action about Dr Ayling because he was concerned about the possible repercussions. In response, the inquiry wrote:

> it seems to us that Dr Pickering's continued assertion that the possible damage to his reputation and the interests of his family outweighed any consideration of the harm that might come to patients' emotional wellbeing was at worst to verge on the culpable and at best to rely on a selective interpretation of GMC guidance.[1110]

[1105] *Ibid* at 114.
[1106] *Ibid* at 109.
[1107] *Ibid* at 37.
[1108] *Ibid* at 37.
[1109] *Ibid.*
[1110] *Ibid* at 71.

The inquiry concluded:

> that the failure of the practice as a whole to report the litany of complaints to any
> relevant bodies was a major factor in Ayling being able to continue practising over
> such a long period. In particular, it was the preference for informal approaches to
> colleagues rather than taking the step of reporting to a relevant body such as the
> FHSA or GMC that led to such a lack of action.[1111]

The Kerr/Haslam Inquiry also noted concerns about professional self-regulation. Dr Kerr
practised for 24 years before his retirement, and Dr Haslam for 23 years. The inquiry
concluded that, in respect to both Dr Kerr and Dr Haslam, "the overall picture is one of
failure, or missed opportunities, over a number of years."[1112] The Kerr/Haslam Inquiry
noted:

> The story that has emerged is not one of a deliberate conspiracy by healthcare
> professionals knowingly acting to conceal sexual misdemeanours (or worse) of two of
> their consultant colleagues … but for a complex of reasons … many nonetheless
> ignored warning bells or dismissed rumours and some chose to remain silent when
> they should have been raising their voices.[1113]

A journalist noted:

> The four cases [Kerr–Haslam, Ayling, Shipman, and Neale] are very different, but
> what they have in common is the devastation visited on patients and families, the
> profound deafness of medical professionals to complaints about colleagues and the
> repression of NHS whistleblowers. What shines through is the ease with which the
> deep trust placed in doctors was breached.[1114]

[1111] *Ibid* at 72-73.
[1112] Kerr/Haslam Inquiry, *supra* note 861 at 466.
[1113] *Ibid* at 5.
[1114] G. Hinsliff, "Betrayal: The Sex-Hungry Doctors Who Prey on Patients" *The Observer* (28 January 2007)
[Hinsliff], online: The Guardian <http://www.guardian.co.uk/society/2007/jan/28/health.socialcare>.

The British cases illustrated a medical profession that was reluctant to self-regulate even when the conduct or performance of colleagues placed patients at risk – behaviour that created mistrust of the profession's willingness to self-regulate without compulsion and oversight by other actors.

Legislative *Responsibilities* for Self-Regulation

Government-sanctioned self-regulation grants professions legal authority to self-regulate members of that profession pursuant to an implicit social contract, one term of which is that the profession will ensure its members act in the public interest. Part of the explicit grant of powers is the ability to determine professional standards related to competence and conduct, and the authority to discipline its members in furtherance of the safety of the public and the integrity of the profession.

In the Canadian scandals, the performance of the regulatory actors was an issue in two scandals, but paled into insignificance compared to what the British scandals illustrated about the GMC. In Winnipeg, the inquest report directed a mild rebuke towards the College of Physicians and Surgeons of Manitoba (CPSM). Despite the highly public nature of the concerns about the competence of Dr Odim, no investigation of his competence had been initiated by the CPSM as of 2000, about six years after the scandal became public. For a body that was supposed to act in the public interest to ensure physicians are publicly and professionally accountable for public safety, such an omission to act was curious indeed. No investigation occurred because the CPSM's rules required a complaint be laid before it before such an investigation could be commenced. Justice Sinclair recommended that the CPSM review its practices in this regard so that it could initiate an investigation without a complaint.[1115]

Significant disquiet was expressed in 1990 about the perceived failures of CPSO to impose appropriate penalties on doctors who acted in a sexually inappropriate manner towards their patients. In that year, the disciplinary committee of the CPSO exonerated a doctor of sexual

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[1115] In addition to Justice Sinclair's recommendation that the college review his report, six complaints were received by the college post-inquest and an investigation was commenced. The investigation was unsuccessfully challenged by the surgeon on the grounds of undue delay. *Odim v. College of Physicians and Surgeons of Manitoba* [2004] 2 W.W.R. 370; 174 Man. R. (2d) 312. No disciplinary action was taken.

abuse, a doctor who used a so-called psychotherapy technique called 'pelvic bonding' on a patient.[1116] At that time, the CPSO was still applying a variant of the common-law Bolam test in its disciplinary procedures. Thus, if what Justice McNair in Bolam termed "a responsible body of medical men skilled in that particular art"[1117] gave evidence that a particular practice was appropriate, even if it was a minority opinion, the doctor would not be found to have fallen below the expected standard of practice. The CPSO sought and deferred to the opinion of a few laypersons (because no doctors could be found to defend the use of this 'treatment') that the 'treatment' was reputable. The CPSO's decision, unsurprisingly, resulted in a "public uproar"[1118] as it appeared the CPSO had placed the interests of the profession and/or the individual doctor above the interest of the patient and the public interest.

Robinson attributes the CPSO's subsequent decision to convene the TSAPP to public embarrassment, as well as subsequent representations from action groups.[1119] The formation of the TSAPP was associational self-regulation in action – a self-regulatory body impelled by public pressure to recognize a possible problem and take action to both confirm it and devise solutions. The TSAPP concluded that the CPSO was doing a poor job of investigating and hearing complaints of sexual misconduct. For example, in 1990 the CPSO undertook 43 investigations into suspected sexual abuse. Fourteen cases proceeded to discipline, two were found to be professional misconduct, and in those two cases neither doctor lost his licence to practise.[1120] If a complaint did go to hearing, often penalties were seen as lenient, amounting to little more than a slap on the wrist, reflecting an over-identification with the doctor.[1121] When the disciplinary committee did impose a serious penalty, it was invariably overturned by the courts. [1122]

[1116] Where a patient is required to place their face in their therapist's genital area ostenisbly to remind the patient of the security experienced as a child while hugging his/her parent.

[1117] *Bolam, supra* note 185.

[1118] Robinson, *supra* note 873.

[1119] *Ibid* at 128.

[1120] *Ibid* at 127.

[1121] Rogers, *supra* note 901.

[1122] *Ibid.*

Subsequently, the CPSO sought and gained amendments to the *Regulated Health Professions Act* – the umbrella legislation that governs the regulation of health professions in Ontario.[1123] These changes instituted a zero-tolerance policy for sexual abuse, defined what the term means, instituted mandatory reporting of suspected sexual abuse by professional colleagues, and the withdrawal of a health professional's practising licence became the mandatory penalty for particularly serious cases. Consequently, in 1993 the CPSO conducted 127 investigations (more than double the number it investigated three years before) into complaints of sexual abuse. Fifty-nine cases involving sixteen doctors proceeded to discipline; nine doctors were found to have committed professional misconduct and seven had their licences revoked.[1124] However, in 2007 Rogers critiqued the long-term effect of the changes on practices within the CPSO. She noted "several locations of institutional resistance which interfere with the protection of the public and which undermine the intent of the zero tolerance legislation."[1125] These included an implicit requirement of independent corroboration, the criminalization of the process, reliance on psychological expertise to pathologize the complainant and exculpate the defendant, and a narrow technical interpretation of the provisions and guidelines.[1126] She noted that between 1994 and 2005, only 5.53 per cent of sexual abuse complaints proceeded to discipline.[1127] In addition, Rogers noted a tendency to reconceptualize complaints about sexual abuse as acts of clinical ineptitude (which essentially is what appears to have occurred in Britain in respect of Dr Ayling). Rogers' overall conclusion was that the:

> College of Physicians and Surgeons of Ontario and the Province of Ontario both showed early leadership in seriously responding to sexual abuse of patients by doctors. … it is deeply disturbing that that the momentum of this important initiative has been undermined in its implementation.[1128]

The work of TSAPP and associated publicity had an impact across the country, with other provinces, such as British Columbia, Alberta, Québec, Prince Edward Island, Saskatchewan,

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[1123] *Regulated Health Professions Act* S.O. 1991 c. 8 as amended by S.O. 1993 c. 37 [RHPA].
[1124] Robinson, *supra* note 873.
[1125] Rogers, *supra* note 901 at 357-58.
[1126] *Ibid* at 358.
[1127] *Ibid* at 358.
[1128] Rogers, *supra* note 901 at 398.

and New Brunswick, establishing committees to review the issue. In these and other Canadian jurisdictions, there resulted changes to the legal framework in that province or policy statements or guidelines on that issue. Regulatory bodies in Canada arguably retained public trust and respect by acting quickly, even if this was under pressure and in the face of scrutiny of the public. When self-regulatory actors act promptly on evidence of public disquiet, self-regulation is seen to work. By instituting these changes to the regulatory framework, along with education for the profession and the public, it can be argued that Canadian regulatory authorities created an environment where complaints were more likely to be made by patients, colleagues were more likely to express concerns, and the grey areas around sexual abuse were more likely to be clarified for health professionals. As a consequence sexual abuse was less likely to be overlooked. They also rebuilt trust in the self-regulatory process by affirming that the regulatory agencies were willing and able to make substantive changes to the legal framework within which they and their registrants operated and to place the public interest ahead of the interests of the profession. In short, Canadian regulatory bodies demonstrated that they were accountable to the public – that they were responsive, responsible, and virtuous regulators.[1129]

This may have been reflective of a change in professional culture where Canadian health professions were less dominated by a so-called 'old guard' and more attuned to changing societal norms. Contrast this with the position in Britain where professional bodies sent mixed messages about what conduct constituted sexual abuse and what did not, and there was therefore a lack of clarity surrounding the issue at least until the late 1990s. Dr Haslam (later convicted of four counts of indecent assault against patients) wrote an open letter on behalf of the Society of Clinical Psychiatrists to the British Medical Journal in 1992 arguing that sexual relations with a patient are not always harmful.[1130] The GMC and the health professions in Britain were aware of developments in Canada and elsewhere, but took no action to address the issue.

There was a perception that key actors within the GMC were resistant to changes to protect the public when those changes would be unpopular with the profession. The GMC was

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[1129] Some suggest that this effect was not to last; see, for example, Rogers, *supra* note 901.

considered to be dominated by an entrenched group of the 'old guard', whereas in Canada the medical profession was progressive, certainly in comparison. For example, the Canadian Medical Association set up a Gender Issues Committee in 1990, indicating awareness by and within the profession of the importance of gender issues.[1131] It also appears that attitudes of deference to doctors lingered in England until the late 1990s, whereas significant changes to the doctor–patient relationship were occurring in Canada from the late 1980s and early 1990s, as well as in the way in which the community regarded sexual abuse. Feminism was said to have played an important role in this cultural change.   By the late 1980s and early 1990s, sexual harassment and sexual abuse had become a significant issue in Canadian society.[1132] In the health context, in the 1990s female patients in Canada were increasingly showing a growing preference for treatment by female physicians.[1133] There was also increasing feminist criticism of male domination of psychotherapy and medicine in North America.[1134]

This arguably more-effective, regulatory self-governance may also be seen in respect of two episodes connected with two prominent British scandals. Dr van Velzen, the pathologist who attracted infamy in the RLCH Inquiry, moved to a position in a Canadian hospital in 1995. Dr van Velzen was fired from that position in 1998, not because of concerns about organ retention, but because of concerns about clinical competency.[1135] On 7 May 1999, Dr van Velzen formally consented to the issue of a written reprimand from the College of Physicians and Surgeons of Nova Scotia for falling below acceptable standards of clinical practice.[1136]

Similarly, Dr Richard Neale fell afoul of Canadian regulatory processes before he commenced his career in Britain. In 1977, Dr Neale performed a high-risk surgery on a

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[1130] Cited in P. Kennedy, "Kerr/Haslam Inquiry into Sexual Abuse of Patients by Psychiatrists" (2006) 30 Psychiatric Bulletin 204.

[1131] Anonymous, "Several Issues Dominate Agenda of Meeting of CMA's Gender Issues Committee" (1993) 148:1 CMAJ 69 [Anonymous, "Several Issues Dominate Agenda"].

[1132] D. Shaw, "Sexual Involvement Between Physicians and Patients: Regulations are not a Panacea" (1994) 150:9 CMAJ 1397.

[1133] S. Thorne, "Women Show Growing Preference for Treatment by Female Physicians" (1993) 150:9 CMAJ 1396.

[1134] *Ibid.*

[1135] RLCH Inquiry, *supra* note 860.

[1136] *Ibid.*

patient, against the advice of a senior colleague. The patient died, and Dr Neale lost his privileges at that hospital. A subsequent investigation by the College of Physicians and Surgeons of British Columbia said that Dr Neale should withdraw from practice or undergo further training. Dr Neale chose the latter option and completed further training in Ontario. In 1980, another patient died after receiving an elective induction of pregnancy from Dr Neale. Dr Neale was asked to withdraw his name from the roster at this hospital, and in 1982 the CPSO commenced an investigation into Dr Neale's management of this case. In late 1984, Dr Neale sought voluntary deregistration and returned to Britain. Despite this, the CPSO proceeded with its disciplinary proceedings in his absence and concluded that his lack of competence, and his subsequent alteration of medical records, to be serious professional misconduct. His name was erased from the medical register. The Canadian systems recognized that Dr Neale's conduct placed patients at risk, and disciplinary measures were instituted to ensure public safety.

The focus in Britain was on the GMC, whose many perceived failures resulted "… in calls for the GMC, a self-regulating body, to be scrapped."[1137] The scandals disclosed a raft of failures by the GMC, both prospective and reactive. Davies notes:

> in simple terms, the GMC … made no effort to look for it [misconduct]. They simply waited passively for complaints to be brought to them and … even then they were often unwilling to act.[1138]

In Britain, the Kerr/Haslam scandal was one of many which created conditions for the distrust of the GMC's commitment to policing the profession and acting in the public interest.[1139] From 1996, the GMC received multiple complaints from doctors, the York NHS Trust, and patients about Dr Haslam's conduct relating to sexual abuse of patients. Investigations into some of these complaints were commenced by the GMC. In 1997, the GMC wrote to the NHS inquiring whether recent newspaper articles about a police

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[1137] R. Syal, "GMC 'hit squad' to Speed Rulings on Misconduct" *Telegraph* (16 July 2000) [Syal], online: The Telegraph <http://www.telegraph.co.uk/health/1348739/GMC-hit-squad-to-speed-rulings-on-misconduct.html>
[1138] Davies, "*Self-Regulation*", *supra* note 19.
[1139] Kerr/Haslam Inquiry, *supra* note 861.

investigation into a psychiatrist related to Dr Haslam. In August 1997, the NHS advised the GMC that the police had concluded their investigation into Dr Haslam without laying charges and that the NHS had commenced an internal investigation. In January 1998, the GMC was informed of the NHS's heightened concerns about Dr Haslam. In March 1998, the GMC received the interim internal NHS review report and in June the final report, both of which suggested concerns about his sexually inappropriate conduct had been sustained. After receiving the NHS review, the GMC's lawyers said that the report alone could not form the basis of a disciplinary hearing because the standard of proof required for the GMC was the criminal standard of beyond reasonable doubt (as opposed to the civil standard of balance of probabilities). The GMC investigations into multiple complaints continued until February 1999, when Dr Haslam voluntarily withdrew his name from the register and the GMC's proceedings ceased. A doctor who raised concerns about Dr Haslam was quoted as saying:

> I have found the GMC to be opaque and uninterested … it is also worth saying that if Haslam has not sued the Sunday Times, he would have got away with it. None of these procedures actually did anything to stop what happened. … Nobody says anything about the human rights of patients. They really do not seem to be considered in this at all. … I am very well aware of the total failure to deal with medically qualified sociopaths … I would like to believe that in the future the GMC will take complaints seriously, as I do not believe they did so here.[1140]

The doctor continued, "I am still quite convinced that a highly intelligent and manipulative abuser would be able to get away with it again."[1141] The GMC, according to the NHS, "did nothing … the risk to patients could only be stopped if his [Dr Haslam's] registration was taken away … patient safety could only be guaranteed by the GMC."[1142] The Kerr/Haslam Inquiry concluded:

[1140] *Ibid* at 403.
[1141] *Ibid* at 408.
[1142] *Ibid* at 407.

when patients and the NHS are speaking with the same voice, it is to be hoped and expected that the GMC will heed criticisms and put their house in order. If not, their house must be put in order for them.[1143]

The Kerr/Haslam Inquiry's conclusions in relation to the GMC amount to a form of associational self-regulation – where a policy actor places pressure on another actor to encourage or compel it to meet its responsibilities, in this instance as a government-sanctioned self-regulator.[1144]

In another case, the GMC was unaware of any problems with Dr Ayling's practice until advised of two serious complaints by the East Kent Health Authority (EKHA) in March 1998. In June, the GMC requested further information from EKHA. In September, concerned about the apparent lack of action by the GMC, EKHA wrote to it urging expedited action. However, the GMC halted its investigation in November pending the criminal proceedings. In the meantime, Dr Ayling's bail conditions permitted him to continue to practise. The GMC did not act to suspend Dr Ayling from practice while on bail – and, as the Ayling Inquiry noted, it is difficult to argue that they should have second-guessed the High Court, which expressly permitted Dr Ayling to continue to practise. After his conviction in January 2001 on twelve counts of indecent assault, the Interim Orders Committee of the GMC suspended Dr Ayling's licence for eighteen months. It was not until June 2001, six months after Dr Ayling's conviction, that the GMC removed Dr Ayling's name from the medical register. A journalist noted, post the publication of the Ayling and Kerr/Haslam inquiries:

> The GMC has already moved to defuse criticism by publishing proposals for reform, including appointing an equal number of lay and medical members to investigative panels and a tougher code of conduct. That appears to be enough to avert threats to abolish the GMC.[1145]

[1143] *Ibid* at 407.
[1144] McDonald, "Working to Death" *supra* note 110.
[1145] Hinsliff, *supra* note 1114.

In yet another example, in 1993 the GMC received a complaint about a research project run by Dr Green which involved the use of a relaxant and sexual role-play; it is not clear whether the GMC took any action in response to that concern.[1146] In July 1997, the Leicestershire Health Authority forwarded to the GMC serious concerns about Dr Green's conduct, and at this time, again according to the inquiry report, the GMC was already investigating another complaint against Dr Green. Almost one year later, in June 1998, the GMC suspended Dr Green from the medical register. Because the GMC investigation "took some time to proceed", the trust made an application to the NHS tribunal to suspend Dr Green from the NHS medical list in November 1997.[1147] There was some betrayal of trust evident in that the GMC could not or would not act speedily in the public interest to prevent Dr Green from practising until charges were laid. A commentator noted: "As details emerged, many people were surprised both that he could continue to practise, and to continue to practise on his own."[1148]

After it was disclosed that Dr Neale had been deregistered in Canada in the 1980s, the question was asked: "How could Richard Neale have been allowed to practice at all, let alone for so long?"[1149] The inquiry determined that the GMC was advised by the Medical Council of Canada in 1985 or early 1986 that Dr Neale had been deregistered in Canada. A Canadian colleague of Dr Neale also advised the GMC of Dr Neale's deregistration in 1985–86 and was told that if a doctor was registered in good standing, then that doctor's standing in a foreign country was no concern of the GMC's.[1150] The GMC took no action to review Dr Neale's registration status in Britain and retained no records of these notifications. In 1988, the Yorkshire Regional Health Authority (YRHA) became aware that Dr Neale had been deregistered, and contacted the GMC to advise it of Dr Neale's history. They were told that such a matter was not within the GMC's jurisdiction. In 1988, the police also contacted the GMC about Dr Neale's deregistration. They were told that because Dr Neale had not committed any offence in Britain, the GMC would not take any further action.[1151] In 1991, the police advised the GMC that Dr Neale had received a police caution and explained the

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[1146] Green Inquiry, *supra* note 857.
[1147] *Ibid* at 1.
[1148] *Ibid* at 2.
[1149] Neale Inquiry, *supra* note 851 at 13.
[1150] *Ibid* at 36.
[1151] *Ibid* at 50.

circumstances in which it was made, including that Dr Neale had provided false information. A representative of the YRHA discussed the issue with the GMC and was advised that the GMC "could take no action on the basis of a Police caution."[1152] Although the GMC could have opened an investigation, no action was taken and the GMC had no record of the letter from the police or the discussion with YRHA. In March 1998, the regional director referred concerns about Dr Neale to the GMC and sent out an alert letter about Dr Neale within the NHS. It was not until 1999 that the GMC took action to suspend Dr Neale's registration. The inquiry noted:

> evidence was obtained that confirmed that not only had the General Medical Council been fully aware of his history in Canada, but had chosen deliberately not to act on this in 1986 and subsequently. … How such a situation can ever be acceptable or fair must now be considered with urgency …[1153]

The media concluded this "… again calls into question the ability of the GMC to police the medical profession effectively."[1154]

The Bristol Inquiry did not directly consider the role of the GMC, but it noted:

> All professional bodies charged with responsibility for disciplining their members must constantly keep in mind that they do so on behalf of the wider public. The trust granted to them is that they act in the public interest to preserve and maintain the safety and quality of healthcare provided to patients. To acquire the public's confidence and trust, these professional regulatory bodies must let the public in, to a degree not hitherto contemplated. … But the pace of change is not fast enough and the public's patience is running out. The professional bodies must be more flexible in their approach to what constitutes misconduct and practice that warrants disciplinary action; they must deal with cases as far as possible at a local level and they must have

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[1152] *Ibid* at 76.
[1153] *Ibid* at 13-14.
[1154] Anonymous, "Surgeon 'Mistreated Women' " *BBC News* (12 June 2000) [Anonymous, "Surgeon 'Mistreated Women' "], online: BBC News <http://news.bbc.co.uk/2/hi/health/787709.stm>.

available a range of actions to meet the problem before them which both serve the interests of the public and the needs of the professional.[1155]

The Shipman Inquiry also "disclosed a raft of flaws in professional governance."[1156] Dr Shipman is believed to have commenced his murderous course in 1971. In 1975, he first came to the attention of regulatory authorities when the Home Office Drugs Inspectorate and the West Yorkshire Police Drugs Squad noted that abnormally large quantities of pethidine were being obtained by the practice in which Dr Shipman worked. An inspector made a series of recommendations aimed at addressing deficiencies in the management of controlled drugs. In late September 1975, Dr Shipman's colleagues discovered he was addicted to pethidine, dismissed him from the practice, and reported his conduct to the requisite authorities. In 1976, Dr Shipman pled guilty to eight specimen criminal charges – three of obtaining a controlled drug (pethidine) by deception; three of unlawfully possessing a controlled drug; and two of forging a prescription – and was fined. The GMC noted the convictions and decided not to refer the matter for disciplinary action due to his addiction, for which he had received apparently successful treatment, and to good conduct reports obtained from his current employer.[1157] The Department of Health did not issue an order under section 12 of the *Misuse of Drugs Act* to restrict his access to controlled drugs. There were suggestions from some quarters that, had the GMC acted differently when it received notification of Dr Shipman's 1976 convictions, many of the murders may have been prevented. The inquiry determined that in 1976 the Penal Cases Committee and the Disciplinary Committee took the view that doctors who abused drugs should continue in practice until they were rehabilitated, and that acts of dishonesty associated with drug abuse were part and parcel of that person's addiction and did not point to general dishonesty.[1158]

The GMC received three other complaints about Dr Shipman's conduct after 1976, but no action was taken on them because none of the complaints suggested a "fundamental problem in the GP's practice."[1159] The inquiry concluded that even a full investigation by the

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[1155] BRI Inquiry, "Learning from Bristol", *supra* note 287, chap. 25 at 74.
[1156] T. Richards, "Chairman of Shipman Inquiry Protests at Lack of Action" (2006) 332 BMJ 1111.
[1157] Shipman Inquiry, *Safeguarding Patients*, *supra* note 1097.
[1158] *Ibid.*
[1159] Dyer, "Tighter Control" *supra* note 1101; see also Shipman Inquiry, *Safeguarding Patients, supra* note 1097.

GMC of each of these complaints would not have disclosed the extent of Dr Shipman's wrongdoing, and an investigation would likely have resulted in a low-level penalty, such as a reprimand.[1160] When Dr Shipman was arrested and charged with fifteen counts of murder, the GMC did not believe that it had the statutory authority to suspend a practitioner from practice until that practitioner had been convicted of a criminal offence, and did not impose a suspension (Dr Shipman was, of course, not in a position to practise as he was in custody – but perception is all).

Perhaps the key failing in all these cases, from a public interest perspective, was the GMC's reactive stance. The GMC did not actively monitor the competence and conduct of doctors; rather, it waited for complaints. Davies notes, "in simple terms, the GMC … made no effort to look for it [misconduct]. They simply waited passively for complaints to be brought to them and … even then they were often unwilling to act."[1161] In respect of Dr Shipman, while the inquiry noted that it was not reasonable for the GMC to foresee that personal drug abuse would lead to mass murder, it was reasonable to foresee that a history of personal drug abuse may lead to deficiencies in patient care. Accordingly, the inquiry concluded that the GMC's approach focused too much on the interest of the doctor and placed insufficient emphasis on the public interest in determining whether the doctor posed a threat to his or her patients during the course of his or her rehabilitation.[1162]

Indeed, the GMC admitted in evidence to the Shipman Inquiry that its procedures generally had "failed … to meet the reasonable expectations of patients and the public."[1163] Smith, in an editorial on the Shipman Inquiry, noted that:

> The General Medical Council (GMC) has been submitted to a highly detailed forensic examination and found severely wanting. It has broken its contract with the public – to protect patients in exchange for the privilege of self-regulation.[1164]

[1160] Shipman, *ibid*; Davies, "*Self-Regulation*", *supra* note 19.
[1161] Davies, "*Self-Regulation*", *ibid* at 237.
[1162] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.
[1163] *Ibid.*, also quoted in R. Smith, "The GMC: Expediency Before Principle" (2005) 330 BMJ 1 at 1 [Smith, "The GMC"].
[1164] Smith, *ibid.*

He further stated, "if it [the GMC] is to command public and parliamentary confidence then the council must put patients and the public first."[1165] The inquiry concluded that the GMC as regulator of the medical profession had not in the past been successful in its primary purpose of protecting patients, having at times acted in the interests of doctors at the expense of patients.[1166] The GMC's general defence was that at the relevant time it lacked appropriate statutory powers. Yet most of the issues of concern to the inquiry did not arise because of a lack of power but rather from the manner in which the GMC chose to exercise its powers. [1167]

The extent of the loss of trust in the GMC as a regulator was evident by some of the submissions received by the Shipman Inquiry that suggested that the GMC should no longer be permitted to regulate the profession.[1168] That lack of trust could not have been remedied by the inquiry's somewhat tepid endorsement of the GMC as a regulator. While the inquiry did not recommend that the GMC lose its regulatory powers to govern the profession, it reached some fairly damning conclusions about the GMC – that it had failed to act in the interests of patients, instead acting in the interests of doctors, and that this failure was due to the culture within the GMC, a culture that had not radically changed since the GMC was formed in the mid-1800s. It also concluded that, although the GMC may take action when the need to do so was pointed out to it, on the whole the GMC had not been able to identify and act upon its shortcomings.[1169]

The Shipman Inquiry suggested that the GMC's culture might change and public accountability enhanced if its members were appointed rather than elected by the profession, as persons who are appointed may see themselves, as the Shipman Inquiry put it, as "servants of the public interest."[1170] It also concluded that the GMC should be more directly accountable to Parliament for the manner in which it exercises the powers gifted to it by Parliament. Both steps would mean that while the statutory façade of self-regulation remains, professional autonomy is limited by greater government control and oversight. The

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[1165] *Ibid.*
[1166] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.
[1167] *Ibid.*
[1168] *Ibid* at 42.
[1169] *Ibid.*
[1170] *Ibid* at 46.

Shipman Inquiry highlighted a submission from the Tameside Families Support Group which was bewildered that, as phrased by the inquiry, "the State should apparently have abdicated its responsibility for monitoring GPs."[1171] According to the Shipman Inquiry, the explanation for the abdication, was that:

> there was a strong belief, apparently shared by Government, that the medical profession itself provided the best (indeed the only) means of imposing high standards of clinical care and professional conduct on doctors and of monitoring those standards. It believed that it would do so rigorously.[1172]

One Canadian commentator wrote in the aftermath of the Shipman case:

> The GMC, which has a disciplinary role similar to our Royal Colleges, now faces imposed reform or even the loss of its power to punish bad doctors. Meanwhile, a root and branch re-writing of the rules on physician monitoring will make British family doctors the most heavily scrutinized on earth.[1173]

Smith, then editor of the British Medical Journal, summed it up nicely when he wrote:

> It [the GMC] is reactive rather than proactive, prefers that doctors should be trusted rather than held accountable, places consensus before leadership, is driven by expediency and compromise, and in the last analysis will put fairness to doctors ahead of patient protection.[1174]

What the narratives of scandals illustrate about government-sanctioned self-regulation is that it in Britain it was profoundly inefficient, ineffective, ineffectual, and self-interested in Britain in terms of the internal morality of the profession and its performance of its regulatory powers. In short, professional self-regulation had well and truly earned its status as being

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[1171] *Ibid* at 9.
[1172] *Ibid.*
[1173] O. Dwyer, "Could a 'Dr Death' Work Undetected in Canada?" (2005) 2:3 Nat'l R. Med. [Dwyer], online at: NRM <http://www.nationalreviewofmedicine.com/issue/2005/02_15/2_pulse_03.html>.
[1174] Smith, "The GMC", *supra* note 1164 at 1.

worthy of mistrust. In Canada, the few scandals illustrated that professional self-regulation was not a perfect instrument but that many health professionals subscribed to a form of internal morality. It also demonstrated that regulators were sufficiently responsive to public concerns, in tune with public sentiment, and concerned about public safety and professional integrity that self-regulation remained a viable artefact. The actions of regulators had generally maintained public trust.

On the whole, the narratives of the British scandals created the conditions for the mistrust of health professionals, health professions, professional regulatory actors, and the management and structures within the NHS. The narratives of the Canadian scandals created the conditions for mistrust of the Canadian blood system, the Ontario public health system, and the federal role in public health, and, to a more limited extent, some facets of the management of the Manitoban health system. But, with the exception of the blood scandal and to some extent SARS, these events were sufficiently localised that any mistrust did not disturb the fundamental assumptions underlying the Canadian health systems. Even the mistrust of these actors was transient in the face of rapid and comprehensive responses to scandals.

Accountability

Accountability is another determinate of policy and regulatory acceptability, hence the need for control mechanisms. Mulgan notes that 'accountability' has emerged as a complex and chameleon-like term which performs all manner of analytical and rhetorical tasks.[1175] Rowe and Calnan note:

> changes in trust are driven by the dialectical relationship between trust, power, governance and accountability, so that each affects the other in a continuing iterative process.[1176]

At its core, accountability is associated with the process of being called to account by an interested or affected authority for one's actions or inaction.[1177] To frame it another way, it

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[1175] R. Mulgan, " 'Accountability': An Ever Expanding Concept?" (2000) 78:3 Pub. Admin. 555 [Mulgan].
[1176] Rowe, *supra* note 62 at 379.

is about actors who are responsible for a set of activities answering for their action or inaction.[1178] Accountability mechanisms are generally conceived as processes external to the body or person being held accountable. Accountability implies some form of hierarchy in that an actor has the authority or the right to hold a person or agency accountable.[1179] Not only can answers be demanded, but sanctions may be imposed.[1180] For many, sanctions are considered crucial as they give 'teeth' to accountability.[1181] Legal and regulatory sanctions offer the most 'teeth'; however, there are also other forms of sanction that may be as effective – for example, public exposure.[1182] But the mere existence of sanctions is insufficient without application – something that requires enforcement. A lack of enforcement, or selective enforcement, means that agencies or individuals are not in fact accountable.[1183] Sorrell argues that "it is not the *publication* of the standards but the *enforcement* of the standards that matters to whether trust is well placed."[1184]

Day and Klein note that the concept of accountability began with individual actors in a simple society, and its forms are currently challenged by institutions existing in complex societies.[1185] Traditionally, accountability mechanisms focused on holding individuals accountable based on the presumption of individual agency. Indeed, this presumption of individual agency furnishes the fabric of both law and medicine.[1186] Latterly, there have been suggestions that the individualized focus of accountability mechanisms should be revised, with greater attention paid to accountability at the systems level.[1187] Research into errors indicates that there is often a complex range of factors that contribute to errors over and above that of individual agency, and thus the simple model of causation that seeks out so-called 'bad apples' is inadequate in the face of increasingly complex causative factors that

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[1177] Mulgan, *supra* note 1175.

[1178] See, for example, Emanuel, *supra* note 73.

[1179] Mulgan, *supra* note 1175; Day & Klein, *supra* note 451.

[1180] Mulgan, *ibid.*

[1181] Brinkerhoff, *supra* note 75; Mulgan, *supra* note 1175.

[1182] Brinkerhoff, *supra* note 75.

[1183] *Ibid.*

[1184] T. Sorrell, "Safety, Accountability, and 'Choice' after the Bristol Inquiry" in S. Clarke and J. Oakley, eds., *Informed Consent and Clinician Accountability: The Ethics of Report Cards on Surgeon Performance* (Cambridge: Cambridge University Press, 2007) 52 at 55 [Sorrell].

[1185] Day & Klein, *supra* note 451.

[1186] Sharpe, *supra* note 70. See also McDonald, "Criminalisation", *supra* note 113.

[1187] Sharpe, *ibid.*; IOM "To Err", *supra* note 22; McDonald, *ibid.*

contribute to errors.[1188] There is also a perception that it is not just to hold an individual accountable where there is no moral blameworthiness on the part of that individual because of systemic faults.[1189]

Recently, some accountability mechanisms have been designed to focus on the acts or omissions of systems.[1190] This is not unproblematic. Some point to the possibility that locating accountability outside of individuals minimizes the role of individual agency and diminishes the prospective functions of accountability by creating a perverse incentive towards poor performance.[1191] Others suggest that notions of systemic failure may constitute a shield for human misfeasance.[1192] It is a transition that does not occur without straining some basic social understandings. At a cultural level, Douglas would suggest that, to quote Lupton, "in contemporary western cultures, every death, every accident and every misfortune is 'chargeable to someone's account' – someone must be found to be blamed."[1193] As individuals and as a society, we want a human face to hold accountable because, in the absence of that personal locus for blame, there may be no meaning, certainly if the push for accountability is driven by a desire for retribution for harm caused.[1194] There are, of course, circumstances in which sanctions can serve a dual purpose: retribution *and* remedy, a remedy which may restore trust in the fairness, compassion, and legitimacy of the actor(s) being held accountable.[1195] Conversely, accountability measures may, as O'Neill notes, further damage trust.[1196] Placing this in context, it might be said that whereas in the past accountability relationships in health were between the patient and the health professional, the "democratisation of social provision"[1197] of healthcare results in more complex accountability relationships between patients, health professionals, health-providers, and governments, but also with the public, who are both recipients of services and its funders.

[1188] Sharpe, *supra* note 70; J. Reason, *Human Error* (New York: Cambridge University Press, 1990) [Reason].

[1189] Sharpe, *ibid*; McDonald, "Criminalisation", *supra* note 113.

[1190] See, for example, the introduction of the concept of corporate manslaughter. See, for example, Almond, *supra* note 822.

[1191] Sharpe, *supra* note 70.

[1192] R. Gregory, "Political Responsibility for Bureaucratic Incompetence: Tragedy at Cave Creek" (1998) 76(3) Pub. Admin. 519 [Gregory]; McDonald, "Criminalisation", *supra* note 113.

[1193] Lupton, *supra* note 5 at 45.

[1194] Gregory, *supra* note 1192; Douglas, *supra* note 5.

[1195] Gregory, *ibid*; Douglas, *ibid*.

[1196] O'Neill, *supra* note 593.

Accountability may be retrospective or prospective in nature. Much of the focus of attention on accountability is often on mechanisms that retrospectively attempt to assign responsibility or, as Douglas would have it, blame after the fact.[1198] Holdsworth, for example, describes accountability as "the obligation to lay oneself open to criticism."[1199] However, accountability also has an important prospective role. Accountability processes may result in a normative guide to conduct.[1200] Mechanisms for accountability, by specifying the obligations of actors within that sphere, may orient everyone towards compliance and, optimally, towards a culture of improvement in practices and processes.[1201] However, these ends may be conflicting, as retrospective accountability with its focus on the loci of 'blame' may be at odds with prospective accountability, which emphasizes learning from mistakes and positive incentives to improve.[1202]

In the health context, Emanuel and Emanuel suggest that at times a single "key word" comes to dominate discussions within a particular sphere to both organize related ideas and as a shorthand expression for an entire perspective to the extent that any discussion seems incomplete without that term, and they suggest "accountability" has become such a word.[1203] Although the relationship between the state and the health professions appears, as Tuohy notes, hedged around with formal accountability mechanisms, at its essence it has traditionally been based on collegiality and trust.[1204] If retrospective accountability mechanisms are perceived to have been ineffective or unresponsive, then there are grounds to call for a review of the existing regulatory framework so as to make actors more accountable.

This section particularly examines the retrospective accountability mechanisms that responded to patient safety scandals experienced in Britain and Canada, as prospective

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[1197] Day & Klein, *supra* note 451.
[1198] Douglas, *supra* note 5.
[1199] D. Holdsworth, "Accountability and the Obligation to Lay Oneself Open to Criticism" in R. Chadwick, ed., *Ethics and the Professions* (Aldershot: Avebury, 1994) 42 at 42 [Holdsworth].
[1200] Emanuel, *supra* note 73.
[1201] Sharpe, *supra* note 70; Oakley, *supra* note 75.
[1202] Brinkerhoff, *supra* note 75; Sharpe, *supra* note 70.
[1203] Emanuel, *supra* note 73; see also Brinkerhoff, *supra* note 75.
[1204] Tuohy, "Agency", *supra* note 724.

accountability has been discussed in the context of trust in the previous section of this chapter. There are a variety of retrospective accountability mechanisms which perform different roles and send different messages to the public. In all inquiry processes related to healthcare, there is an element of moral judgement as to whether individuals, and often systems, have: 1) provided services of the expected standard; 2) acted in the interests of their patients and the public; and 3) acted in compliance with accepted standards of conduct.[1205]

The criminal law is the penultimate symbol of societal condemnation of an act or practice, as it generally comprises offences that are *mala in se* ('evil in itself') and which therefore incorporates moral denunciation of the act and punishment of the offender – as previously mentioned, the criminal law was used in respect of some of the scandals discussed in this chapter most notably in the conviction of Dr Shipman. Police investigations also occurred in respect of Drs Neale and van Velzen, although charges were not laid.[1206] In Canada, criminal charges were laid against four doctors, the CRC, and a pharmaceutical company in respect of the contaminated blood scandal.[1207] In laying these charges, Superintendent Rod Knecht stated:

> The Canadian public needs to have confidence in their public institutions … The Canadian public has the right to expect the safest blood and the safest blood products possible. This is fundamental to the health, safety and lives of everyone living in Canada.[1208]

In at least this instance, the criminal law was seen as a public accountability mechanism that might restore trust, but as discussed in Chapters 2 and 7, it can also be used to ensure accountability when other mechanisms are perceived to have failed.

Government-sanctioned self-regulatory actions are a form of *mala prohibita,* but prohibition by one's profession, not the state. In the Ontario sexual abuse scandal, concerns expressed

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[1205] Stanley & Manthorpe, *supra* note 818.
[1206] Neale Inquiry, *supra* note 851; RLCH Inquiry, *supra* note 860.
[1207] *Armour, supra* note 866; also see discussion in McDonald, "Criminalisation", *supra* note 113.
[1208] S. Warry, "Criminal Charges Laid in Tainted Blood Case" *eCMAJ* (21 November 2002) online: CMAJ <http://www.cmaj.ca/news/21_11_02.shtml>.

about the CPSO in respect of the manner in which it dealt with complaints of sexual abuse arose because the CPSO's ineffective policies and processes denied patients and the public accountability.[1209] In taking immediate steps to institute a review of its practices, CPSO showed that it perceived that it was, at least to some extent, accountable to the public for its actions. The measures taken by other medical regulators across Canada to institute changes to policies and practices also demonstrated an acceptance that they were accountable to the public.

In Britain, much of the concern expressed about the GMC was because its processes failed to ensure that patients could hold doctors accountable, and there was no real mechanism through which the public could in turn hold the GMC accountable for that failing. An example of failures to ensure accountability could be seen in the Kerr/Haslam scandal. In 1998, after an internal NHS inquiry found Dr Haslam to have sexually exploited some patients, and while he was under investigation by the GMC, he asked for voluntary erasure from the medical register.[1210] In 1999, the Preliminary Proceedings Committee (PPC) decided to charge Dr Haslam but to offer him the option of voluntary withdrawal from the register, irrespective that it was investigating other complaints about him.[1211] Once a doctor was removed from the register, the GMC's position was that no disciplinary proceedings could proceed.[1212] A voluntary removal from the register effectively preserved a doctor's reputation and denied affected patients an opportunity for accountability before that doctor's peers.[1213] The GMC permitted Dr Haslam to voluntarily withdraw from the register, and all proceedings and investigations against Dr Haslam immediately ceased.

In this instance, the GMC appeared to put the interests of Dr Haslam – and perhaps also its own convenience in regard to the investigations and disciplinary proceedings it would have otherwise had to undertake – ahead of the interests of complainants. Arguably, the GMC also sacrificed the public interest in failing to ensure that those given public privileges are also held accountable for any violations of public trust. Although it kept no records of its

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[1209] TSAPP, *supra* note 867.
[1210] Kerr/Haslam Inquiry, *supra* note at 387.
[1211] *Ibid.*
[1212] *Ibid.*
[1213] *Ibid.*

decision-making processes, the GMC explained its decision by suggesting that voluntary withdrawal was a speedy way to remove a doctor from practice – an action ultimately, in its view, in the public interest.[1214] While it may have been expedient, such action understandably undermined trust in the regulator entrusted to holding its registrants to account. A complainant was quoted by the inquiry as saying:

> Having regard to all that had gone before the GMC's conduct was little short of incredible. A show of support for patients which amounted to nothing less than a concerted and determined decision *not* to investigate what were by then universally well known accounts of Haslam's abuse; a steadfast refusal to respond to those who had made complaints in the past; complete disregard for the safety of patients. Those patients who thought that doctors would stick together and cover for one another could scarcely have guessed that if and when a doctor did take the complaint forward, then it would treated in such an off-hand manner by the very authority charged with regulation of the medical profession.[1215]

Another patient wrote:

> Whilst I appreciate that he [Dr Haslam] is no longer able to practice, he is still carrying out the posturing role of pillar of the community, social secretary of one of the University colleges and actively involved in the Schizophrenia Association. It would appear that the matter has been conveniently swept under the carpet and a man who used his position to systematically abuse vulnerable patients has once again got away scot-free and failed to have been called to public account. Even if this is not the case, I feel personally cheated of any justice and feel that once again there has been a cynical disregard for the suffering of the patient.[1216]

The GMC's decision attracted much condemnation from within the health system, too. Representatives of the NHS and the President of the Royal College of Psychiatrists wrote to

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[1214] *Ibid.*

[1215] *Ibid* at 407.

[1216] *Ibid* at 402.

express their concerns about the decision.[1217]   Dr Kerr was also allowed to voluntarily withdraw from the register, attracting similar condemnation. However, in that case approval was granted after receipt of medical advice that Dr Kerr's physical and mental condition meant he was unfit to plead. As noted by the inquiry, "fairness and natural justice left the GMC with no other option than to accept the application for voluntary erasure, thereby ensuring public safety."[1218]   On the whole, however, the GMC's practices appeared to undermine mechanisms to hold doctors accountable to individuals and to the public.

Further examples are legion. The Shipman Inquiry examined in detail the pre-Shipman mechanisms through which the GMC dealt with complaints about conduct.[1219] It found that complaints were first filtered by GMC staff, and those that were deemed appropriate were then screened by a medically qualified member of the GMC (after 1990, they were jointly considered by a medically qualified member and a layperson –the screeners).[1220]   The screeners forwarded appropriate cases for review by the PPC. The PPC in turn forwarded appropriate cases for consideration by the Professional Conduct Committee (PCC) (no more than five per cent of those initially received reached the PCC).[1221] The PCC would hold a public hearing, and if the doctor had been convicted of a criminal offence or if serious professional misconduct (SPM) was established, would consider whether action on registration was necessary.

The Shipman Inquiry identified a number of significant problems with this process. First, there was no generally agreed definition of what SPM was. Until 1985, the GMC's professional conduct guide said that SPM was not concerned with errors of diagnosis and treatment. From 1985, the GMC would only examine errors of diagnosis and treatment when there was such disregard or neglect of professional responsibilities that it amounted to SPM.[1222]   The inquiry determined that until the late 1980s–early 1990s, the GMC was primarily concerned with misconduct, i.e. dishonesty, drug abuse, indecency, improper relationships with patients, breach of confidence, and disregard of professional obligations

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[1217] *Ibid.*
[1218] *Ibid.* at 265.
[1219] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.
[1220] *Ibid.*
[1221] *Ibid.*
[1222] Davies, "*Self-Regulation*", *supra* at note 19.

(e.g. refusing to provide treatment).[1223] Allegations of incompetence or negligence (even serious negligence) were regarded by the GMC as matters for the civil courts.[1224] There was little consensus about what types of negligent conduct would amount to SPM, and thus little consistency in application.

The second problem was in the filtering, screening, and review processes.[1225] The initial filtering process was designed to weed out those cases that did amount to SPM – difficult when it was not defined – or where the complainant had not exhausted local complaints processes, unless the doctor was an evident danger to patients. About 65 per cent of complaints were closed at this point.[1226] Screeners were required to refer a matter on to the PPC unless they considered the matter "need not proceed further", and for many years there was no guidance as to what that meant. In practice, the inquiry heard, until the mid-1990s, cases would be closed unless there was a positive reason to proceed, which, as the inquiry noted, reversed the statutory test.[1227] A series of judicial review proceedings were successfully heard in the mid-1990s to reverse this.[1228] The inquiry noted that processes to standardize the application of the correct test had not been altogether successful, some screeners being remarkably resistant to changing their practices to comply with the law.[1229]

The PPC's statutory function was to consider whether a case "ought to be referred for inquiry" to the PCC or the Health Committee. As was the case with the screeners, the PPC exercised a wide discretion. Research commissioned by the GMC in the 1990s was highly critical of the PPC's processes, suggesting they lacked transparency, consistency, and fairness.[1230] Due to the fact that there was no definition of SPM, there were considerable disagreements within the PPC as to what SPM was. Often, the PPC would form an opinion and use that opinion to conclude whether a case ought to be referred. Two judicial review proceedings of the PPC's processes found that under the legislation the question of whether

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[1223] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.
[1224] *Ibid.*
[1225] *Ibid.*
[1226] In 2003, 65% were excluded by GMC staff. Shipman Inquiry, *ibid.*
[1227] *Ibid.*
[1228] *Ibid.*
[1229] *Ibid.*
[1230] *Ibid.*

conduct was SDM was for the PCC to determine, not the PPC or any other body.[1231] Thus, complaints processes privileged the interests of doctors over the interests of patients and the public interest.

The third problem, according to the inquiry, was a lack of investigation.[1232] No investigation of any sort occurred until the complaint was referred to the PCC. Some complaints were filtered or screened out because there was insufficient information to determine whether the allegation might amount to SPM – thus, many cases were closed due to a lack of evidence when the GMC had made no effort to gather any.[1233] The onus was placed on the complainant to prove the complaint, rather than a self-regulating profession acting to undertake a review of concerns raised about the conduct or performance of one of its members. The profession's social contract with the public/state was predicated on the belief that the profession would effectively police its members to ensure, at the very least, their retrospective accountability and to protect the public interest in ensuring, as much as is possible, the continuing safety of patients when receiving health services. Clearly, in respect of the GMC, the obverse was true and had been for some considerable time.

But it was not just government-sanctioned self-regulatory mechanisms that denied accountability; NHS processes and systems could be as bad. One of the criticisms of the GMC's Bristol disciplinary proceedings is that they focused only on three individual health professionals and a specified number of patients.[1234] Complainants had no real accountability mechanisms through which to examine the broader operations of the NHS, other than through instituting civil proceedings. Within NHS systems, there were accountability structures surrounding financial matters, but few effective accountability mechanisms in relation to conduct or competence of staff, and particular latitude was given to doctors. Such accountability mechanisms for doctors that did exist were mechanisms such as the 'three wise men',[1235] the Poorly Performing Doctors Committee, or the Local Medical Committees that were collegial peer-driven mechanisms. Complaints mechanisms

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[1231] *Ibid.*

[1232] *Ibid.*

[1233] *Ibid.*

[1234] BRI Inquiry, "Learning from Bristol", *supra* note 287.

[1235] This is a reference to a body set up in NHS Trusts to undertake peer review of clinical matters relating to the provision of medical services. Three senior doctors constituted the "wise" men.

were ineffectual, although recourse could be had to the Health Commissioner, who was not permitted to investigate clinical matters. Aside from pursing a negligence claim, until the Roylance case it was difficult to hold hospital management accountable for anything other than financial decisions.[1236] However, Roylance is only applicable to registered health professionals acting as administrators.[1237]

The scandals demonstrated that in Britain the public inquiry was the only mechanism through which affected parties could get retrospective accountability in terms of hearing the narrative of events, determining responsibility of actors, and seeking remedial action. The establishment of an independent commission of inquiry confirms that an event is indeed out of the ordinary and of sufficient importance that ordinary mechanisms of inquiry/investigation, such as inquests, are not sufficient to ensure accountability.[1238] Blom-Cooper (who managed more than a few British commissions of inquiry) suggests the "compelling reason" why independent inquiries are established is "the assuaging of public revulsion or repugnance that will not be satisfied by the traditional methods of remedial action."[1239] Others have suggested that public inquiries amount to "putting the state on trial" – a form of accountability.[1240] An independent inquiry is both a response to a scandal and, as discussed earlier, a confirmation of a scandal's wider importance.

The decision to convene a public inquiry is not made lightly – perhaps because of the signals it sends to the public, as well as the expense and potential embarrassment to the government. Only five of the scandals examined in this chapter were not subject to at least one public inquiry (with the Green and Stoke Mandeville scandals in Britain being subject to a public inquiry undertaken by a statutory investigation body rather than an ad hoc inquiry).

[1236] *Roylance, supra* note 1055.
[1237] *Ibid.*
[1238] Butler & Drakeford, *supra* note 817.
[1239] L. Blom-Cooper, "Some Reflections on Public Inquiries" in J. Peay, ed., *Inquiries After Homicide* (London: Gerald Duckworth & Co, 1996) 57 at 57.
[1240] L. Salter, "Two Contradictions in Public Inquiries" (1989) 12 D.L.J. 173.

In Canada, the scandal at the WHSC was the subject of an inquest, albeit an extraordinarily thorough one.[1241]   In controversially deciding to institute a coronial investigation, the Manitoban Minister of Health stated to the Legislature:

> the position I have taken in discussions with the families is that I feel that the inquest route, as ordered by the Chief Medical Examiner, is the route that is there. It is for this purpose.[1242]

In referring to the fatal inquiry process as a "route that is there", the minister made a number of implicit claims. Using an existent route, a standard mechanism, reassures the public that although an inquiry is warranted, standard mechanisms are sufficient to comprehensively address concerns. In some respects, it is a utilitarian appeal as well which sends the message: 'We have a mechanism. It is designed for this purpose; let it work'. The minister emphasized that the purpose of an inquest was " ... to get to the truth so that we can make decisions about how best to look after the children of this province in the future."[1243]   In the face of some doubts as to whether the inquest process could comprehensively address systemic issues, the minister asserted that an inquest process had "the capacity and scope and breadth" to examine all of the actors involved, whom he specified as including the hospital, the doctors, the Chief Medical Examiner's office, and the government.[1244]   Although the inquest fulfilled many accountability functions, in that individuals and systems were retrospectively held to account by having to publicly answer for their actions or omissions, some parents still perceived the process as inadequate.[1245]

In Britain, the decision not to hold a public inquiry into contaminated blood attracted much criticism. Lord Morris of Manchester stated in the House of Lords:

[1241] Sinclair Inquest, *supra* note 868.
[1242] Manitoba, Legislative Assembly, *Hansard*, 17A (13 March 1995) 1355 (Hon. James McCrae).
[1243] Manitoba, Legislative Assembly, *Hansard*, 15 (9 March 1995) 1335 (Hon. James McCrae).
[1244] *Ibid.*
[1245] B. Sibbald, "Twelve Deaths in Winnipeg: Judge Must Ponder 48,000 pages of Inquest Testimony" (1998) 159(10) CMAJ 1285.

That no public inquiry has yet been held into a medical disaster on this scale –
leaving 95 per cent of patients with the devastating complications of two life-
threatening viruses – is without precedent in the modern era."[1246]

Given the enormous number of inquiries into the NHS during this period, Lord Morris's
comment raised some important issues about why that event was not subject to a public
inquiry constituted by government. Government's response to that question was to say that:
"There has been no negligence; it is one of those tragedies. There is no need for a public
inquiry,"[1247] and that "The Government does not accept that any wrongful practices were
employed at the time and does not consider that a public inquiry is justified."[1248] Private
bodies subsequently commissioned a public, non-statutory inquiry some twenty years after
the events in question.[1249]

The importance of public inquiries as accountability mechanisms can be seen very strongly in
the British context, where in respect of the Allitt, Bristol, Shipman, Ayling, Kerr, and Haslam
scandals, family and patient groups lobbied both for the commissioning of public inquiries
and to influence their form, some going so far as to commence judicial review proceedings
when they deemed an inquiry to be held in private would deny them effective
accountability.[1250] Patient lobbying was also seen in the appointment and functioning of the
Canadian blood case because, as Gilmore and Sommerville noted:

[1246] U.K., H.L., *Parliamentary Debates,* vol. 625 no. 65, col. 66 (23 April 2001) (Lord Morris of Manchester).

[1247] U.K., H.L., *Parliamentary Debates,* (2005-2006) vol. 672, No. 9 col. 568 (26 May 2005) (Lord Warner).

[1248] Letter from Melanie Johnson MP, Parliamentary Under Secretary of State for Public Health, to Lord Morris
of Manchester, 29 October 2003, cited in Haemophilia Society, *Submission to the Archer Independent Public Inquiry
into the "circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the
haemophilia community and others afflicted; and further steps to address both their problems and needs and those of bereaved
families."* (2007) available online at:
<http://www.haemophilia.org.uk/UserFiles/Campaign%20briefings/Haemophilia%20Society%20Submission
%20to%20the%20Archer%20Inquiry.pdf>.

[1249] See U.K., House of Commons Library, *Investigatory Inquiries and the Inquiries Act 2005* (Standard Notes
SN/PC/02599) by Keith Parry & Parliament and Constitution Centre (London: House of Commons Library,
2008).

[1250] *R (on the application of Howard) v. Secretary of State* [2003] Q.B. 830 [*R. (Howard)*]; *Wagstaff, supra* note 1096*;
Associated Newspapers, supra* note 1096; *Crampton v. Secretary of State for Health* [1993] CA Transcript 824
[*Crampton*].

the blood system was governed by committee, consensus, and liaison between federal and provincial government departments and the CRCS [Canadian Red Cross Society]. … No mechanism existed to ensure public accountability.[1251]

No mechanism, except that is, for a public inquiry. After the commissioning of the Allitt Inquiry as a public inquiry to be held in private, parents unsuccessfully sought a judicial review of this decision.[1252] They suggested that, because of the inquiry's private nature, health service employees and the public could not be sure that "all the lessons that might have been learnt will be learnt."[1253] In their view, the inquiry as constituted was insufficient to assure public accountability. Ultimately, parents attacked the inquiry as being a "cover-up" in its focus on individual clinicians as opposed to hospital management.[1254] After the inquiry concluded, some parents challenged the inquiry as a violation of article 2 of the *European Convention on Human Rights* (the right to life, including the duty to investigate suspicious deaths), a challenge that was also unsuccessful.[1255]

In Britain in 2001, the Secretary of State for Health announced the formation of three independent statutory inquiries to be held in private, in respect of Dr Clifford Ayling, Dr Richard Neale, and Drs William Kerr and Michael Haslam. Patients and families were unhappy about the private nature of the inquiries and, after making representations to the Secretary of State commenced judicial review proceedings to achieve public inquiries into the allegations against Dr Ayling and Dr Neale.[1256] The Secretary of State made some concessions about the form of the inquiry, saying interested parties (i.e. patients or their representatives) would be permitted to attend the inquiries and could raise issues, but the media and the general public would continue to be excluded due to concerns about confidentiality, particularly given the subject matter of two of the inquiries. These judicial review proceedings were ultimately unsuccessful.

[1251] Gilmore, *supra* note 1036 at 131.
[1252] *Crampton, supra* note 1250.
[1253] W. Appleyard, "Murder in the NHS" (1994) 308 BMJ 287.
[1254] C. Dyer, "Inquiry into Serial Killer Criticises Hospital's Response" (1994) 308 BMJ 491.
[1255] *Taylor v. United Kingdom* (1994), [2004] ECHR 729, 18 E.H.R.R. CD 215.
[1256] *R. (Howard), supra* note 1250.

A group of relatives, friends, and media groups also applied for judicial review of the Secretary of State's decision to hold the public inquiry into Dr Harold Shipman in private.[1257] In reviewing the Secretary of State's decision, the court noted a number of factors that seemed to point towards the establishment of a full public inquiry. First, it is standard practice to hold a public inquiry after a major disaster. In the Shipman case, there had been a loss of public confidence, there was uncertainty about how many of his patients were murdered, checks and controls may have been insufficient or have failed, and therefore a public inquiry would be appropriate.[1258] Second, there were known advantages to undertaking inquiries in public. Third, the families wanted the inquiry to be public, and the Secretary of State's statement in the House of Commons about the nature of the inquiry could have given rise to a misunderstanding that it was to be held in public (a legitimate expectation argument). Fourth, there was what in the court's view amounted to a presumption that an inquiry should be held in public; and, lastly, a public proceeding commands greater public confidence, and in the circumstances of the Shipman case, "the restoration of confidence is a matter of high public importance."[1259] Accordingly, the court determined that the Secretary of State's decision to hold the Shipman Inquiry in private was irrational and the Secretary of State was required to reconsider his decision.[1260]

In both the commissioning and response to public inquiries, ministers frequently emphasised how these mechanisms served important roles in terms of accountability. For example, in response to the Grange Inquiry into the events at the HSC, the Attorney-General of Ontario observed: "The one and only goal of the Commission was to achieve the highest possible level of public accountability with respect of the deaths and the prosecution,"[1261] and that the inquiry's "deliberations and findings, … will underline the importance of the accountability of society's great institutions to the people whom they serve."[1262] And from Britain, when the Secretary of State announced the formation of the Shipman Inquiry, he acknowledged

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[1257] *Wagstaff*, *supra* note 1096; *Associated Newspapers*, *supra* note 1096.

[1258] *Ibid.*
[1259] *Ibid.*
[1260] *Ibid.*
[1261] Stead, *supra* note 890.
[1262] R. McMurty, "Statement of Inquiry into Baby Deaths" *The Globe and Mail* (23 April 1983) 5 [McMurty].

that systems of regulation and self-regulation would have to be strengthened.[1263]   He further stated:

> He [Shipman] preyed on some of the most vulnerable members of our society. He broke the trust of his patients in the most dreadful way imaginable. Having betrayed the trust of his own patients, Harold Shipman should not be allowed to break the trust that exists between family doctors and their patients. The action that I have outlined today is intended to strengthen that bond of trust.[1264]

Even when an inquiry was commissioned, some actors did not appear to embrace the concept that actors who received public funds should actually be held publicly accountable for their decisions. For example, the necessity for the Dubin and Grange Inquiries was questioned by the HSC.[1265]   The institutions that comprised the blood system in Canada continued to deny the need for an inquiry and contested the inquiry's processes.[1266] Accountability was a concept, however, that the Supreme Court of Canada (SCC) supported. Although ten years earlier the Ontario Court of Appeal prohibited the Grange Inquiry from naming names and making findings that could be the basis for civil or criminal proceedings,[1267] the SCC held that the Krever Inquiry was free to assign blame.[1268] The SCC distinguished the Grange Inquiry, noting that it was investigating specific events involving specific actors during a criminal investigation, whereas the Krever Inquiry was conducting a wider systemic review.[1269]   The SCC noted that there are different normative standards against which a failure may be measured, i.e. moral, political, and legal. While it was clear that a commission of inquiry may not reach conclusions in terms of civil or criminal liability, an inquiry was well within its mandate to conclude that there had been failures to comply with expected standards.[1270] The SCC viewed public inquiries as critical processes to ensure that government, and other public actors, are held to account.

[1263] U.K., H.C., *Parliamentary Debates,* vol. 343, col. 907-919 (1 February 2000) (Alan Milburn).

[1264] U.K., H.C., *Parliamentary Debates,* vol. 343, col. 907-919 at col. 909 (1 February 2000) (Alan Milburn).

[1265] Dubin Inquiry, *supra* note 864; Grange Inquiry*, supra* note 864.

[1266] Krever Inquiry, *supra* note 865.

[1267] *Re Nelles and Grange* (1984), 46 O.R. (2d) 210 (C.A.).

[1268] *Canada v. Blood System, supra* note 895.

[1269] *Ibid.*

An analysis of inquiry processes generally illustrates that in most cases a public inquiry was the only mechanism through which affected parties and the public could gain accountability. That the systems in place prior to the appointment of an inquiry were, on the whole, insufficient to assure accountability seemed to point to a need, again in most circumstances, to establish further mechanisms to ensure accountability.

Control

Increased perception of risks, accompanied by a mistrust of key institutional actors, and perceptions that current accountability mechanisms are ineffective, may result in increasing demands for greater control of actors and activities within a sector. Barber describes this phenomenon as "the increasing desire of the less powerful of all kinds to have a little more control over those whose greater power vitally affects them."[1271] This control is generally obtained through the employment of regulatory or quasi-regulatory instruments. Many assert that an increasing desire for control has been a characteristic of governance in Britain since the 1980s. Power's landmark research into the British governance system, for instance, highlights the increasing use of audit as a mechanism of control.[1272] Other studies from Britain highlight the growth of regulation within government during this period.[1273]

The combined effect of the events in Britain was to create public and political demands for greater control over key actors and over the system more generally. As is discussed in more detail in the next chapter, the 1990s and 2000s saw the implementation of various systems of oversight and control within the NHS, and more broadly within the health and welfare systems in Britain, bringing to mind Power's description of the Audit Society.[1274] The shift in regulatory emphasis is moved from a reliance on the health professions and the sector to self-regulate towards a greater use of direct and meta-regulatory mechanisms. This is demonstrated by legislative requirements that independent government agencies create standards, monitor, audit, and evaluate health professionals and health-providers. This shift also sees the increased use of meta-regulation through an increased use of independent

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[1270] *Ibid.*

[1271] Barber, *supra* note 977 at 132.

[1272] Power, *supra* note 597.

[1273] For example, C. Hood, C. Scott, O. James, G. Jones and T. Travers, *Regulation Inside Government: Waste-Watchers, Quality Policy and Sleaze-busters* (Oxford: Oxford University Press, 1999).

oversight mechanisms reviewing the operations of government-sanctioned self-regulatory actors, as well as a curtailment of their powers and a greater involvement of parallel government mechanisms to assert control.

The converse – a largely unaffected perception of risk, sustained trust, and effective accountability mechanisms – may result in much more limited demands for greater regulatory control, as can be seen in the Canadian systems. Although the blood scandal did in fact result in control moving from a non-governmental actor to a governmental agency, in general the other scandals provoked lesser responses. While in Manitoba patient-safety-directed reforms have occurred subsequent to the WHSC scandal, these reforms have proceeded on the basis that the core regulatory assumptions of self-regulation should be maintained and any new regulatory initiatives should be designed to support professionals rather than coerce them. It is for the most part a similar story in other provinces/territories. The SARS scandal resulted in the Canadian public health system undergoing, as Wilson describes it, "… a process of transformation in response to the outbreak and management of severe acute respiratory syndrome (SARS)."[1275] Canada's *public health* system certainly saw structural change, especially the development of better coordination mechanisms, and investment at the provincial and federal levels, but demands for greater control were not strong in other parts of the health system.[1276] Change has occurred incrementally, primarily spearheaded by professional organizations, with a greater reliance on self-regulation and co-regulation.

Conclusion

The sheer numbers of scandals in the NHS in Britain, and their frequency, particularly in the later part of the 1990s and early 2000s, have an accumulated force when it comes to explaining the impetus for significant change within the regulatory framework supporting the NHS in Britain. That so many scandals occurred within such a short period of time across all facets of the NHS, from hospitals to general practice to public health, was an indicator

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[1274] Power, *supra* note 597.

[1275] Wilson, "Structural Reform", *supra* note 904 at 345.

[1276] C. Beach *et al.*, eds., *Health Services Restructuring in Canada: New Evidence and New Directions* (Kingston: John Deutsch Institute for Public Policy, 2005).

that there were serious systemic problems with the NHS, but more particularly with the way the NHS was regulated. That so many of these scandals occurred over a long period of time with, at best, ineffectual action by those responsible for policing the conduct of health professionals and hospitals, further reinforces a sense that these actors could not be trusted and that existent accountability mechanisms were ineffective. It is difficult to make counter-claims that events are aberrations in an essentially sound system and that existing regulatory arrangements are strong, when independent inquiries are, one after another, finding serious problems with those systems. It is also difficult to sustain an argument that change is not required in such circumstances.

The impact on the public of a multitude of negative findings about the safety and quality of the health system and, accordingly, deficits in existing regulatory structures entrusted with monitoring that system are also clearly evident. Risks are highlighted, trust in institutions – particularly those entrusted with regulating the NHS – diminishes, and demands for real prospective and retrospective accountability increase. Davies suggests that the impact of scandals within the NHS was to cede "moral high ground to government." [1277] Government could proceed with the changes they were ideologically inclined to make (discussed in the previous chapter) irrespective of and in the face of any dissent from hitherto key institutional players. This accords with the conclusions reached by Butler and Drakeford that "scandals do not appear in a policy vacuum; rather they develop in very particular contexts at very particular times." [1278] Stanley and Manthorpe agree that "inquiries may chime with debates and policy initiatives, and may be picked up as examples for the need for reform." [1279] The impact of these scandals made it difficult for these institutional actors, especially the medical profession, to oppose any government reforms, having been fairly comprehensively discredited by the scandals. Any opposition could have been portrayed as being self-interested, rather than as being in the public interest. Significant reforms to the existing regulatory framework occurred because of a change in political norms (discussed in the previous chapter) <u>and</u> because events drove change – each informed each other, and as a result the impetus was towards further control.

[1277] Davies, "Regulating the Health Care Workforce", *supra* note 825 at 56.
[1278] Butler & Drakeford, *supra* note 817 at 1.

Conversely, in Canada, events played a significantly lesser role in regulatory change. While the blood scandal and SARS could be described as being significant in terms of regulatory change, this change was narrowly construed and limited to specific subsectors within the system, i.e. blood and public health. The events in Canadian health systems on the whole did not illustrate bedrock failures in current regulatory configurations, did not undermine trust in most regulatory actors or indeed in most actors, and accountability mechanisms were, in general, reasonably effective. Ultimately, though, one key factor explaining the difference is that there were few significant events in Canada. Dwyer summed up the situation in Canada nicely in saying, "Like Britain's system in the 80s and 90s, our [the Canadian] system has never gone seriously wrong — as far as we know. There is no public pressure to change it, and so nobody will."[1280] Lacking any evidence in the form of a number of scandals, the impetus for significant reforms to what seems to be a generally satisfactory system is lessened.

In this, and the previous chapter, I have asserted that changing political norms, combined with the impact of events, have created the conditions for a change to the regulatory consensus in Britain. Scandals are important, but real change may still not result unless these scandals occur at a time of policy receptivity where there is an opportunity to move in a different regulatory direction.[1281] This movement may include a flight from institutions or organizations that have become a focus of public disenchantment or positive mistrust.[1282] In contrast, I assert that relative political stasis and a relative absence of scandals within health systems have resulted in adherence to the regulatory consensus, albeit with incremental modifications, in Canadian health systems. The next chapter describes the regulatory framework in place in each jurisdiction in 2005 and measures divergence or convergence with the 1980 frameworks.

[1279] Stanley & Manthorpe, *supra* note 818 at 6.
[1280] Dwyer, *supra* note 1173.
[1281] Tuohy, "Logics" *supra* note 35.
[1282] Butler & Drakeford, *supra* note 817.

Chapter 7
Trust but Verify vs Trust and Collaborate: New Directions in the Regulation of Patient Safety

Introduction

The last two chapters of this thesis critically assessed two factors: political norms and scandals, and their impact on the pre-1980s convergence in respect of patient safety regulation. In these chapters, I argued that the effect of political norms and scandals resulted in Britain diverging from its pre-1980s regulatory framework for patient safety. I also argued that the lesser impact of these factors in the Canadian context saw its regulatory framework remain largely congruent with the pre-1980s model, displaying only incremental changes.

This chapter revisits the framework first introduced in Chapter 2. That Chapter illustrated how, by 1980, a discernable convergence could be seen in Britain and Canada about the legitimate scope of state regulation of patient safety. A mix of regulatory instruments was considered appropriate and there was a high degree of faith that health professionals and health-providers would self-regulate. In Chapter 2 the elements of the pre-1980s regulatory convergence were demarcated.

There were five essential elements. The first element saw governments retain the ultimate power to sanction individual health professionals through the use of the criminal law (a tool of very limited use in Canada). The second element of the pre-1980 convergent frameworks in Britain and Canada enabled patients to seek fiscal redress for harm through instigating civil proceedings against health-providers and health professionals. By bringing civil proceedings, patients invoked the retrospective and prospective functions of regulation by litigation to establish and enforce standards for professional practice. This was supplemented with the third element, the government-sanctioned self-regulation of many of the professions that provided health services. Government-sanctioned self-regulation was designed to allow the professions to set standards in respect of qualifications for practice and to ensure the accountability of members both to the public and to the profession. In return, the public gained some basic consumer information and protection. Limited direct

regulation of safety and quality issues associated with facilities was the fourth element of the regulatory framework, although there was still significant autonomy accorded in practice to facilities, as regulatory attention was primarily, almost exclusively, focused on input regulation. The fifth element saw government retain the capacity to determine how significant an issue of patient safety was in general, or in regard to specific cases, by using its investigatory powers associated with public inquiries and coronial inquests.

Both Canada and Britain adhered to this basic framework. Minor divergences could be seen in the historically slightly higher use of the criminal law as a regulatory mechanism against health professionals in Britain, and the institution of slightly more prescriptive or expansive mechanisms of direct regulation in Britain. These divergences, though, were matters of emphasis rather than significant cleavage. In subsequent chapters, I argued that factors specific to the context of each jurisdiction resulted in a divergence in the scope, extent and purpose of the employment of regulatory instruments in this area after 1980.

The pre-1980s regulatory frameworks in this area were premised, as Mello et al put it: "an unparalleled faith in the ability of medical professionals [and other health-providers] to regulate themselves."[1283] But in Britain, changes in political norms and the impact of scandal in the period 1980-2005 were such that trust was now qualified – the approach summed up in Reagan's phrase "trust but verify". In Canada, with few scandals and less dramatic shifts in political norms in the same period, traditional patterns of trust towards key governance actors remained largely undisturbed; verification was not required. In 2005 while both jurisdictions remain nominally convergent with the pre-1980s frameworks, in that they employ criminal law, civil proceedings, government-sanctioned self-regulation, direct regulation, and public inquiry processes, in 2005 the manner, extent, and scope of instrument use in the jurisdictions had diverged. A greater reliance on meta-regulatory mechanisms is also seen in Britain.

This chapter extends the analysis of the character of regulatory regimes, begun in Chapter 2, by examining the regulatory frameworks in place in each jurisdiction in 2005. The purpose of this chapter is to identify and assess the degree of divergence between the two

jurisdictions with respect to the shape and scope of the regulatory frameworks in Canada and Britain, as well as an exposition of how each element within that framework is employed. In the first section, I provide an overview of key claims established in Chapter 2. Using the analytical framework in Chapter 2 I then evaluate evolutions in the five governance mechanisms outlined in that chapter: criminal law; civil proceedings; government-sanctioned self-regulation; direct regulation; and public inquiry processes. Government sanctioned self-regulation is broadened in this chapter to become professional regulation, recognising that the regulation of health professionals may encompass government-sanctioned self-regulation, associational self-regulation, meta-regulation, and direct regulation mechanisms. A new category of meta-regulation is established as a distinct and more widely applied technique of regulatory governance.

Regulatory Convergences and Divergences

As a preliminary comment, during this period patient safety became a focus of policy, if not regulatory, attention. In Britain, there were a number of White Papers or other government reviews raising the issues of patient safety and healthcare quality (discussed in Chapter 5), in addition to the seventeen public inquiries that occurred during this period (discussed in Chapter 6). Government set the agenda for action in Britain.

Although in Canada some federal, provincial, and territorial first ministers and deputy ministers' meetings discussed healthcare quality, safety and quality were not a primary focus of their attention, and matters were discussed but seldom implemented (see discussion in Chapter 5). In 2001, the Royal College of Physicians and Surgeons of Canada recognized that patient safety was a serious issue confronting Canadian health systems. It convened a one-day workshop to discuss the issue and consequently formed a National Steering Committee on Patient Safety. After broad consultation with various stakeholders, including governments, the committee issued a report proposing a national integrated strategy to

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[1283] Mello, "Fostering Regulation", *supra* note 5 at 375.

improve patient safety.[1284] The 2003 First Ministers' Accord on Health Care Renewal stated that:

> [T]he implementation of a national strategy for improving patient safety is critical. Health Ministers will take leadership in implementing the recommendations of the National Steering Committee on Patient Safety.[1285]

While the steering committee's work was supported by Canadian governments, it was a strategy initiated, created, driven, and led by the professions. And, for the most part, this is the pattern seen in the governance of patient safety in Canada, where the activities of the professional groups and health system administrators are supported by the actions of the state. Most of the provincial regulatory reforms relating to patient safety (with the exception of those relating to the health professions) occurred after the national strategy was formulated and after the accord.

Criminal Law[1286]

The criminal law is and always has been the ultimate sanction that a state can impose upon an individual or institution to condemn their conduct and to hold them to account for actions or omissions that were not in the public interest.[1287] As discussed in Chapter 2, although rare, in both jurisdictions there is a long history of criminal charges (manslaughter or criminal negligence causing death or grievous bodily harm)[1288] being brought against health professionals for negligent professional practice.[1289] The use of criminal charges is

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[1284] National Steering Committee on Patient Safety, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care,* (2002) online: RCPSC <http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf>.

[1285] Canada, Health Canada, *2003 First Ministers' Accord on Health Care Renewal,* (Ottawa: Health Canada, 2003). Online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/index_e.html>.

[1286] Analysis in this section has been previously published in McDonald, "Criminalisation", *supra* note 113.

[1287] *Ibid.*

[1288] In Britain, the charge is manslaughter by gross negligence and in Canada criminal negligence causing death or criminal negligence causing grievous bodily harm where the victim does not die. Criminal negligence and manslaughter are broadly equivalent.

[1289] McDonald, "Criminalisation", *supra* note 113; Ferner, *supra* note 119.

held to have an important prospective effect in that it is said to encourage improved standards of practice and thus is an important tool to create prospective accountabilities.[1290]

Since the beginning of the 1980s, the practice of laying criminal charges against doctors[1291] for alleged negligence in their professional practice has dramatically increased in Britain, while remaining at low levels in Canada, both in terms of numbers of charges and in terms of convictions (see Figure 4).[1292] In Britain, 44 doctors were charged with manslaughter between 1980 and 2005. In contrast, in Canada only nine doctors have been charged with *either* criminal negligence causing death or the lesser charge of criminal negligence causing grievous bodily harm.[1293] Higher relative numbers are to be expected given that Britain has both a higher population[1294] and greater numbers of registered health professionals than Canada. As McDonald notes, even taking these differences into account, doctors are more likely to face criminal charges in Britain.[1295] Doctors are also more likely to be convicted in Britain which has a conviction rate of around 30 per cent[1296] versus a 6.67 per cent rate in Canada.[1297]

[1290] H.L.A. Hart, *Punishment and Responsibility: Essays in the Philosophy of Law* (Oxford: Clarendon Press, 1968) and H.L.A. Hart, "Negligence, *Mens Rea* and Criminal Responsibility" in A.G. Guest, ed., *Oxford Essays in Jurisprudence: A Collaborative Work,* (London: Oxford University Press, 1961) at 29.

[1291] There is no hard data about charging rates for those from other health professions in either country.

[1292] A minor spike in the Canadian figures does not indicate an upwards trend, but rather four physicians being charged in respect of one incident – the quality of Canadian blood supplies in the 1980s. The Canadian Red Cross pled guilty to distributing contaminated blood supplies and a charge of criminal negligence against it was dropped. Four doctors involved in the management of blood supplies and a pharmaceutical company also faced various criminal charges including, most seriously, charges of criminal negligence. In 2008, a judge found the doctors not guilty, concluding that the defendants had acted responsibly and appropriately in carrying out their responsibilities. *Armour, supra* note 866.

[1293] If the British figures included grievous bodily harm, the figures would most likely be higher.

[1294] In 2005, the British population was estimated to be 60,209,500 and the Canadian population was estimated to be 32,299,500. U.K., Statistics, *supra* note 883; Canada, Statistics, *supra* note 884.

[1295] McDonald, "Criminalisation", *supra* note 113.

[1296] Ferner, *supra* note 119.

[1297] McDonald, "Criminalisation", *supra* note 113.

Figure 4 Physicians Facing Serious Criminal Charges[1298] for Alleged Negligence in Professional Practice: Comparison of Charging Rates in Britain and Canada 1980-2005.[1299]
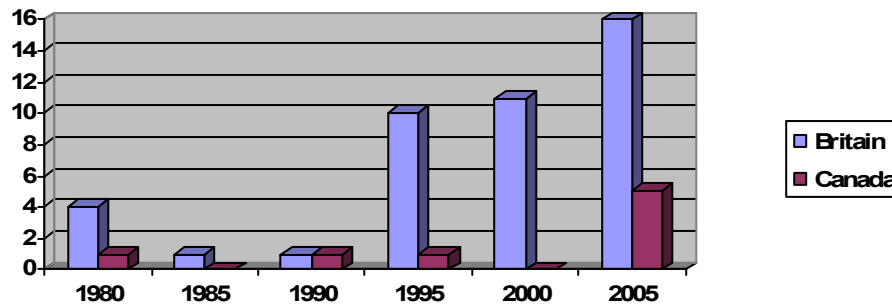
What explains these differences? At the global level, some suggest that the increased rates of criminal charges faced by British doctors are linked to changes in the social and cultural order in that country – the evolution of the risk society, the post-trust society, and the blame society – resulting in demands for greater accountability.[1300] While explanations that point to profound transformations in the social order have their attractions, it would be oversimplifying the matter to suggest that changes to the social and cultural order provide a complete explanation of the shift. Canada, as another developed country, a former colonial dependency of Britain, a member of the British Commonwealth, and a country which moreover is a close geographical neighbour of the US, would not be immune from the general currents of change to social and cultural orders[1301] – and yet the rates of criminal charges faced by doctors in Canada remain low.[1302] It appears then that changes to the social and cultural order may be situationally specific. In other words, although societies may indeed be seeing changes in the social and cultural order in a general sense, the expression of that change may be felt differently in different situations and jurisdictions depending upon the levels of risk perception, the decrease in trust, and concerns about effective accountability.

[1298] This means manslaughter or criminal negligence causing death or criminal negligence causing criminal bodily harm.

[1299] Data for this figure was obtained from McDonald, "Criminalisation", *supra* note 113 and Ferner, *supra* note 119.

[1300] See discussion in McDonald, "Criminalisation", *supra* note 113.

[1301] See discussion in Chapter 4.

[1302] McDonald, "Criminalisation", *supra* note 113.

Quick suggests that what he terms "fallout" in Britain, from the scandals discussed in Chapter 6, may contribute to public and media pressure for justice to be seen to be done, a pressure felt most acutely by the police and the prosecutorial service.[1303] In addition, the Shipman[1304] and Allitt[1305] cases may have resulted in a climate where the British police scrutinize patient deaths more carefully and are more likely to be called in by hospitals, relatives, or the coroner. In fact, the increased likelihood and importance of police investigations into patient care within the NHS has been explicitly recognized with the finalization, in 2006, of a memorandum of understanding between the police, the NHS and the Health and Safety Executive about the investigation of serious patient safety accidents.[1306] Included within this memorandum are explicit guidelines for when a NHS Trust should involve the police.

As discussed in Chapter 6, this pressure seems absent from the Canadian context, with the events in the health sector not resulting in damage to the public trust in social institutions within the Canadian health systems to anywhere near the same extent as in Britain.[1307] Nor did the events that occurred in Canada suggest that traditional modes of accountability, such as actions in negligence or disciplinary actions before health professional bodies, were inadequate to safeguard the public interest.

There are also more prosaic explanations. One of these is that rates of prosecutions in Britain appeared to increase after the Crown Prosecution Service was established in 1986.[1308] But what Quick saw when he investigated more deeply was that charging patterns for medical manslaughter in Britain since 1970 are geographically mal-distributed.[1309] Quick postulates that increased charging rates within one geographical area may be a sign of increased prosecutorial confidence in that region due to successful prosecutions in the past.

[1303] Quick, "Prosecuting", *supra* note 123.

[1304] Shipman Inquiry, *supra* note 859.

[1305] Allitt Inquiry, *supra* note 849.

[1306] U.K., National Health Service, Association of Chief Police Officers, & Health and Safety Executive, *Memorandum of Understanding Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health & Safety Executive* (2006) at 1. Online: Department of Health <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4129918>.

[1307] See, for example, McDonald, "Criminalisation", *supra* note 113.

[1308] Quick, "Prosecuting", *supra* note 123.

This confidence may be particularly important as there is a generally low conviction rate for medical manslaughter vis-à-vis manslaughter more generally.[1310] In other words, past success predicates future action.

In contrast, criminal charges in Canada are geographically dispersed and occur across time (Table 3).[1311]   While the *Criminal Code* is federal law, prosecution occurs at the provincial level making the system somewhat similar to the regionalism seen in Britain in terms of geography, but without the impact of a national prosecution agency. The impact of a federal system is perhaps likely to result in differences between provinces about whether to lay charges, and little cross-provincial learning.   The low success rates in Canadian prosecutions[1312] presumably are likely to discourage rather than encourage criminal charges from being laid within each province. As noted by McDonald:

> The outcome of the most recent case, where four doctors were acquitted after facing charges of criminal negligence and public nuisance relating to the management of the Canadian blood system, may further discourage prosecutions for criminal negligence.[1313]

The blood prosecutions were highly public and highly publicized, prosecutors had expressed great confidence in the strength of their case going into the trial, yet there was a complete, and some might say crushing, acquittal.[1314]

[1309] *Ibid.*

[1310] *Ibid.*

[1311] McDonald, "Criminalisation", *supra* note 113.

[1312] Due to one guilty plea, 6.67 per cent of Canadian prosecutions have been successful. McDonald, "Criminalisation", *supra* note 113.

[1313] McDonald, "Criminalisation", *supra* note 113.

[1314] *Armour, supra* note 866.

Table 3 Case Distribution in Canada.

Province	Number of physicians charged	Dates of cases
Alberta	1	1972
British Columbia	2	1935, 2005
Manitoba	1	1995
Ontario	6	1939, 1992, 2005
Québec	5	1962, 1972, 1976, 1984

Past successes may encourage future action, especially when the courts indicate that the ambit of cases where gross negligence may be found should be widened. Critics suggest that some of the recent convictions are inappropriate given the nature of the events in question which, while negligent, did not, in the opinion of critics, amount to gross negligence.[1315] In many cases, the convictions related to medication errors – what Reason would term mistakes or slips, and lapses.[1316] Some argue mistakes, slips, and lapses are more properly addressed through other mechanisms, such as civil liability, because moral culpability is generally at the lesser end of the scale.[1317] This is particularly so because the evidence suggests that mistakes, slips, and lapses are more likely to be caused or contributed to by systemic factors within the environments in which they work. There also seems to be a sense that the British courts may be conflating the seriousness of the outcome with the degree of negligence displayed – something that the Canadian courts have been careful to avoid.[1318]   At least one Canadian court, while refusing to bring a guilty verdict in respect of a nurse charged with criminal negligence causing death, has also made explicit reference to policy considerations – that the use of the criminal law for medication error cases may inhibit open disclosure and hence learning about error – an outcome that is not in the public interest.[1319]

In summary, while the use of the criminal law remains a common part of the regulatory framework in both jurisdictions its employment in Britain has spiked, from the middle of the 1990s. Although its use is still relatively rare in absolute terms, the increasing employment of the criminal law in Britain focuses attention on the issue of patient safety. The use of the

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[1315] See, for example, Holbrook, *supra* note 21; McCall Smith, *supra* note 119; McCall Smith, "Negligence", *supra* note 119; Merry, *supra* note 21.

[1316] Reason, *supra* note 1188.

[1317] See discussion in McCall Smith, "Negligence", *supra* note 119; Merry & McCall Smith, *supra* note 21; McDonald, "Criminalisation", *supra* note 113.

[1318] McDonald, *ibid.*

criminal law indicates that the state recognizes there is a real public interest in ensuring the safe practice of health professionals and that it is increasingly willing to use its most coercive powers to safeguard the public interest and to create very real incentives for health professionals to comply with standards of practice.

Civil Proceedings

In both jurisdictions, the ability of a patient to bring civil proceedings if they sustained harm as the result of receiving health services remained a core part of the regulatory framework. A key difference between the jurisdictions, identified in Chapter 2, was the approach adopted by the courts. In Canada, the courts created a distinction between matters connected to technical skill and expertise (to which deference is afforded to professional opinion) and conduct which can be evaluated by the layperson,[1320] and introduced the concept of informed consent.[1321] In contrast, until the late 1990s, British courts repeatedly rejected any advancement of the traditional standard that doctor knows best.[1322] However, this position was relaxed somewhat after the 1998 Bolitho case, where the court held that in rare circumstances it would be wrong to decide a matter in accordance with professional opinion that is "not capable of withstanding logical analysis."[1323] While not approaching the Canadian standard, this approach does allow the courts to make a choice between two sets of conflicting expert opinion based on which seems most logically probative.[1324] However, although heralded as a significant change to the approach in Britain, some commentators suggest that it appears to have made little real difference to the approach adopted by the courts.[1325]

One of the barriers to the institution of civil proceedings for clinical negligence has been that patients lacked the knowledge that an adverse event had in fact occurred.[1326] In both

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[1319] *R. v Omstead* [1999] O.J. 570.
[1320] Woolf, *supra* note 186.
[1321] *Hopp v Lepp,* [1980] S.C.J. No. 57, [1980] 2 S.C.R. 192 (S.C.C.); *Reibal v Hughes,* [1980] S.C.J. No. 105, [1980] 2 S.C.R. 880 (S.C.C.).
[1322] Woolf, *supra* note 186.
[1323] *Bolitho v. City & Hackney Health Authority* [1998] AC 232 (H.L.) at 243 [*Bolitho*]. See also Woolf, *ibid.*
[1324] Woolf, *ibid.*
[1325] Harpwood, *supra* note 181; J. Gilmour, *Patient Safety, Medical Error and Tort Law: An International Comparison* (Ottawa: Health Canada, 2006) [Gilmour].
[1326] Harpwood, *supra* note 181; Gilmour, *ibid.*

jurisdictions, the common law adapted to this reality by creating what amounts to an disclosure obligation created as part of tort law, where health professionals are required to disclose to their patients adverse events associated with their treatment or care.[1327] This obligation has been suggested to arise from informed consent, or consent in the British context, the fiduciary nature of the treatment and care relationship, fraudulent concealment, or battery.[1328] In any event, this development in the law resulted in patients being more likely to know that an adverse event has occurred. It appears that disclosure requirements do not result in larger numbers of claims being brought – as claim patterns in Canada remained fairly static in the period in question.[1329]

In both jurisdictions, the 1980–2005 period saw a review of the tort system. In Canada, the Pritchard Report was commissioned in the late 1980s by the Conference of Deputy Ministers of Health in response to a perceived malpractice crisis.[1330] It recommended the maintenance of the current tort system, with the addition of a no-fault compensation scheme for injuries resulting from preventable adverse events. In the event, no changes to the system resulted. Gilmour notes that generally proposals for procedural reform of negligence claims in the Canadian context have been directed at controlling the costs of such proceedings and awards, not towards reducing adverse events.[1331] A steady decline in the frequency of claims against doctors has been reported, and payment levels were reported to have been reasonably stable in the period 1999–2004.[1332] Aside from the continuing development of the common law, little change is seen in the systems for civil proceedings in Canada.

In Britain events have taken a somewhat different turn, with a greater focus on centralizing litigation risk and managing litigation processes to increase fairness and justice, while at the same time addressing the issue of patient safety and healthcare quality. Prior to 1990, each DHA was responsible for managing its own litigation risk and employees were responsible

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[1327] See *Chester v. Afshar* [2005] 1 A.C. 134 [*Chester*]; *Stamos, supra* note 986; *Kueper v. McMillan* (1986) 30 D.L.R. (4th) 408, 37 C.C.L.T. 318 (N.B. C.A.); *Shobridge v. Thomas* (1999) 47 C.C.L.T. (2d) 73 (B.C.S.C.). See also Robertson, "When Things go Wrong", *supra* note 986; T. Faunce & S. Bolsin, "Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Healthcare Events" (2005) 12 J. Med. & L. 478.

[1328] Robertson, "When Things go Wrong", *ibid.*

[1329] See Gilmour, *supra* note 1325.

[1330] J. Pritchard, *Liability and Comprehension in Health Care* (Toronto: University of Toronto Press, 1990) [Pritchard]; Gilmour, *ibid.*

[1331] Gilmour *ibid.* at 74.

for defending themselves. The government's 1990 introduction of the NHS indemnity aimed to clarify the position of the NHS and resulted in it assuming legal responsibility for claims of clinical negligence against its employees.[1333] Strickland notes that the expansion of NHS responsibility and the increasing threat of negligence claims widened the ownership of clinical risk, making it an institutional, and a systemic, responsibility.[1334] Such claims would no longer be viewed outside of their systemic context. This was an important step given that placing the focus on an individual can protect an unsafe system from scrutiny, preclude that institution from learning and improving its systems for the provision of treatment and care.[1335] Claims increased dramatically in the late 1990s and early 2000s, and then stabilized.[1336]

The system was further centralized in 1995 when the National Health Service Litigation Authority (NHSLA) was established to manage negligence claims against the NHS.[1337] The NHSLA handles negligence claims through a number of different schemes. The most relevant is the post-1 April 1995 claims program. This is risk pooled, so that NHS Trusts' fiscal contributions are assessed on the basis on the adequacy of their risk management standards and claims history. The sliding scale rewards NHS Trusts whose policies are adequate and whose practices reduce the incidence of adverse events. A second scheme covering events arising before 1995 is not risk pooled and is funded by the Department of Health. The NHSLA's role was also to improve claims processing within the NHS. It has done this through encouraging mediation, explanations, and apologies, controlling costs, conducting pilot project for the speedy resolution of low-value claims, and so on.[1338] The NHSLA was to defend unjust claims robustly, promptly settle justified claims, and contribute to incentives to reduce claims by improving cost-effective clinical and non-clinical risk

[1332] *Ibid.*

[1333] R. Seth, "NHS Indemnity for Medical Negligence its Implications" (1991) 15 Psychiatric Bull. 79; Harpwood, *supra* note 181.

[1334] C. Strickland, "The Ownership of Clinical Risk in Acute Hospitals in England – An Historical Perspective" in A. Garland-Gowers, J. Tingle & K. Wheat, eds., *Contemporary Issues in Healthcare Law and Ethics* (Edinburgh: Elsevier, 2005) 61.

[1335] S. Dekker, "Discontinuity and Disaster: Gaps and the Negotiation of Culpability on Medication Delivery" (2007) J. L. Med. & Ethics 463 at 467.

[1336] Harpwood, *supra* note 181.

[1337] The NHSLA is a special health authority. It is established by the *NHS Litigation (Establishment and Constitution Order 1995,* S.I. 1995/2800. Agencies were established to perform similar functions in Wales, Scotland, and Northern Ireland post-devolution.

[1338] See also Gilmour, *supra* note 1325.

management processes.[1339] As such, the NHSLA's activities were aimed at claims resolution, but also constituted a form of associational self-regulation by offering rewards to NHS Trusts that performed well at controlling incidence, or at least managing it, so that civil claims were not made.[1340] It was a process that aimed to contribute to improving patient safety as much as it could be expected to do, as well as providing timely compensation to those who sustained harm.

Despite the efforts of the NHSLA, Lord Woolf's 1999 review of civil litigation concluded that the legal system failed to meet the needs of applicants, especially in the context of clinical negligence cases.[1341] In the context of medical malpractice, there were lower success rates, less cooperation between parties, and unmeritorious claims pursued and clear-cut claims defended for too long.[1342] Lord Woolf noted:

> [T]he medical profession and NHS administration must demonstrate their commitment to patients' wellbeing by adopting a constructive approach to claims handling. It must be clearly accepted that patients are entitled to redress, and that professional solidarity or individual self-esteem are not sufficient reasons for resisting or obstructing valid claims.[1343]

He further noted that patients were entitled to expect explanations and apologies, and litigation should be preserved as a last resort. Most of his proposals to reform the court system were accepted by government, but these were largely procedural aimed at speeding and rationalizing the claims process within the civil proceedings system.[1344]

A further review of the civil litigation system in the context of clinical negligence occurred in 2003 as a response to a recommendation of the Bristol Inquiry that the civil proceedings

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[1339] U.K., Department of Health, *The National Health Service Litigation Authority: Framework Document* (London: Department of Health, 2002).

[1340] Gilmour, *supra* note 1325.

[1341] U.K., Lord Woolf, *Access to Justice: Final Report to the Lord Chancellor on the Civil Justice system in England and Wales,* (London: HMSO, 1996) [Woolf, *Access to Justice*].

[1342] *Ibid.*

[1343] *Ibid.* c. 15, para 3.

[1344] Gilmour, *supra* note 1325.

system should be replaced with a no-fault system for clinical negligence.[1345] The Chief Medical Officer (CMO) conducted the review, which focused on improving safety and quality standards as well as preventing litigation.[1346] Although it noted significant problems with the current system, it rejected the institution of a no-fault system, largely because of cost. It recommended the introduction of several programs, including one focused on birth damages and the institution of what was termed an NHS Redress program to more effectively manage low value (under £20,000) claims. Part of this program would involve an investigation, the provision of an explanation, action to prevent recurrence, as well as compensation and the provision of a package of care. It also recommended increasing the use of mediation and the establishment of a statutory duty of candour.

An *NHS Redress Bill* was introduced in 2005 to implement some of the CMOs recommendations, especially the development of a program to deal with lower-value claims outside of the court system. This was to reform clinical negligence processes, but only in respect of a cohort of claims (those of lower value). The program for birth-related injuries and the institution of a statutory duty of candour were not proceeded with. Patient redress investigations were to be monitored by the Healthcare Commission, and the program was to be administered locally, but eligibility determinations and compensation were to be the responsibility of the NHSLA, retaining a degree of centralization. A further limitation was that those accessing this program must qualify for liability in tort. Civil litigation was to be precluded if compensation was accepted. The Bill was ultimately passed into law in 2006, but with amendments.[1347]

Comparing the two jurisdictions, it was largely business as usual in Canada, whereas in Britain regulators reflected upon how the litigation system impacted upon patient safety and quality. There is no doubt that some of the impetus for reforms in this area were associated with fiscal considerations as well as concerns for justice, but a key focus was on how best to use the litigation system to leverage safety and quality improvements. Three important

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[1345] BRI Inquiry, "Learning from Bristol", *supra* note 287.

[1346] U.K., Department of Health & L. Donaldson, *Making Amends: A Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS* (London: Department of Health, 2003); Gilmour, *supra* note 1325.

[1347] After some revisions, this Bill was subsequently passed as the *NHS Redress Act 2006* (U.K.), 2006, c. 44. See discussion of this in Harpwood, *supra* note 181.

factors were: the NHS indemnity, which placed responsibility with the NHS Trusts for the actions of employees and centralized concerns about patient safety within an institutional framework; the creation of a centralized agency to manage litigation; and risk pooling arrangements that provided incentives for trusts to institute appropriate risk management and safety and quality procedures. The combined impact of these factors was to create further incentives for the NHS as an organization to coherently address and manage the cause of litigation – poor-quality care.

Voluntary Self-Regulation

Accreditation continued to play an important role in the Canadian context in respect of hospitals and other facilities with accreditation rates continuing to grow and thousands of facilities gaining accredited status.[1348]

Professional Regulation

The premise of professional regulation, as seen in the 1980 consensus, was that the professions could be trusted and sanctioned by government to self-regulate as they were "responsible political actors"[1349] or "virtuous" actors.[1350] But as argued in the previous two chapters, changes to political norms in Britain, coupled with events that shook trust in the professions (the medical profession in particular) as regulators, resulted in that premise being contested. The accepted framework of government-sanctioned self-regulation was in some senses strengthened and was bolstered by associational self-regulatory strategies and meta-regulatory mechanisms. In Canada, the traditional model was modernized to somewhat increase state control. Two provinces introduced forms of meta-regulation. In this section I first discuss government-sanctioned self-regulation, then associational self-regulatory strategies, followed by meta-regulation.

[1348] Accreditation, *supra* note 207.

[1349] McDonald, "Working to Death" *supra* note 110.

[1350] *Ibid.*

Government-Sanctioned Self-Regulation

The traditional government-sanctioned self-regulatory framework for health professionals focused on two elements: registration and retrospective Fitness to Practise (FTP) mechanisms (i.e. examinations of the conduct and performance of health professionals in response to complaints about their practice). By 2005, a third element was added – prospective FTP procedures determining whether all registered professionals are competent to practise prior to any complaint or concern being raised. In addition, these regulatory stages must be considered in the context of the broader governance arrangements impacting on how the regulatory bodies exercise their power.

As the regulation of health professions is a provincial responsibility under the Canadian Constitution,[1351] the framework for such regulation differs from province to province. In 2005, most provinces retained the traditional model, similar to that described in Britain, where registration was through a process of certification and in some cases also licensure, and the primary focus was on retrospective FTP mechanisms for health, at times performance, and discipline. Each province had increased lay representation in the governance of the professions. There was limited accountability to provincial governments and limited oversight. However, in four provinces (Alberta, British Columbia, Ontario, and Québec), health professional regulation had been subject to regulatory modernization, and the analysis in this section therefore focuses on these provinces.

How to best regulate the health professions has been examined by a number of reviews and commissions in both jurisdictions over the years. Between 1980 and 2005, there were no British reviews directly examining government-sanctioned self-regulation. However, several of the inquiries into scandals within the NHS system examined, either in passing or directly, government-sanctioned self-regulation, primarily in the context of an examination of the GMC's governance of the medical profession. The most notable of these inquiries from this perspective was the Shipman Inquiry which, in 2004, examined the GMC's processes in some detail.[1352] All examinations of government-sanctioned self-regulation occurred during this period in the context of governance scandals involving the GMC.

[1351] *Constitution Act, 1867, supra* note 477 s. 92(13).
[1352] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.

Conversely, Canadian reviews of government sanctioned self-regulation primarily seem to have come about in the context of a concern for regulatory modernization. In 1994, Alberta's Ministers of Health and Labour established the Health Workforce Rebalancing Committee to review the province's system for regulating health professions. The committee's final report in 1995 developed guiding principles for a new regulatory system, stating it must: protect the public; be flexible about scopes of practice; be transparent; be fair; and must support the efficient and effective delivery of health services.[1353] Based largely on the recommendations of the committee, the government introduced the *Health Professions Act* (HPAA) in 1998, and in December 2001 the HPAA was proclaimed in part.[1354] The transitional phase to regulation under the HPAA saw each profession becoming regulated under the HPAA when government approved profession-specific regulations, and the profession's schedule in the HPAA was proclaimed. By the end of 2005, there were still professions, such as the medical profession, who were not regulated by the HPAA.[1355]

British Columbia commissioned two reviews of health professional regulation: a Royal Commission of Inquiry into Health Care and a review by the Health Professions Council (HPC). The Seaton Commission on Health Care in British Columbia concluded, in its 1991 report, that the system for the regulation of health professionals was rife with inconsistencies between the health professions recommending the creation of a consistent framework.[1356] In 1994, the minister asked the HPC to review scopes of practice and the legislative framework for all recognized health professions. The HPC's 2001 report, *Safe Choices*, made a number of recommendations in respect of changes to the regulatory structure for health professions in British Columbia, many of which basically related to the use of umbrella legislation to ensure consistency of regulation between professions.[1357] The HPC also recommended that a

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[1353] Alberta, Alberta Health Workforce Rebalancing Committee, *Principles and Recommendations for the Regulation of Health Professionals in Alberta: Final Report of the Health Workforce Rebalancing Committee* (Edmonton: Alberta Health Workforce Rebalancing Committee, 1995) at 2.

[1354] *Health Professions Act*, R.S.A. 2000, c.H-7 [HPAA].

[1355] F. McDonald, *Health Professional Regulatory Regimes: A Comparative Analysis – Report for Manitoba Health*, (Winnipeg: Manitoba Health, 2006) [McDonald, *A Comparative Analysis*].

[1356] British Columbia, Royal Commission on Health Care and Costs, *Closer To Home. The Report of the British Columbia Royal Commission on Health Care and Costs,* (Victoria, British Columbia Royal Commissioner on Health Care and Costs, 1991) at D-30.

[1357] British Columbia, Health Professions Council, *Safe Choices: A New Model for Regulating Health Professionals in British Columbia,* (Victoria: Health Professions Council, 2001).

process should be put in place to provide general oversight of the regulatory boards' performance. The HPC concluded that reserved titles served an important function, as they enable patients to distinguish the qualified from the unqualified, and those who are regulated from those who are not. The HPC concluded that a regulatory framework of overlapping scopes of practice and narrowly defined reserved acts enhances a number of policy ends, including: the creation of a system offering greater choice and accessibility; reducing paternalism by enabling informed choice; and enhancing interdisciplinary practice. The HPC noted that some acts present a significant risk of harm, and provision of these particularly dangerous acts should be limited to members of specific professions who are qualified to perform them; not all registrants would necessarily be qualified to undertake the reserved acts assigned to that profession. It further noted that it should be the responsibility of the profession to determine who is qualified and competent to perform that function.

Ontario, too, commissioned a review of health professional regulation.[1358] The Health Professions Legislation Review (HPLR) resulted in significant changes to the process for regulating health professions in Ontario in the late 1980s.[1359] This was followed by a review by the Health Professions Regulatory Advisory Council (HPRAC) of the new framework. HPLR's report noted that Ontario had earlier moved to a licensing system based on exclusive scopes of practice. The review highlighted a number of deficiencies including that the exclusive scopes of practice were too broad, ill-defined, included acts that other professions could undertake, and created tensions and reduced cooperation between the professions.[1360]

In response to HPLR's recommendations, government introduced a new framework for regulating Ontario's health professionals in the form of the *Regulated Health Professions Act, 1991*,[1361] as well as 21 profession-specific Acts. Ontario considers itself to be a "… leader in

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[1358] The Health Professions Regulatory Advisory Council was also asked to further review the system in 2006, a period outside the scope of this thesis.
[1359] Ontario, Health Professions Legislation Review, *Striking a New Balance: a Blueprint for the Regulation of Ontario's Health Professions,* (Toronto: The Review, 1989).
[1360] *Ibid.*
[1361] RHPA, *supra* note 1123.

the regulation of health professions."[1362] In Ontario, umbrella legislation, the *Regulated Health Professions Act, 1991* (RHPA), provides a common framework for regulating health professions governed by the Act. The model also uses profession-specific Acts to address issues relating to individual professions. These Acts include a brief scope of practice statement that describes the profession, provides title protection provisions, and sets out a list of which, if any, controlled acts the profession is authorized to perform.

Québec, on the other hand, did not undertake a formal review, but in 1999 the minister responsible for professional legislation announced an action plan to update the professional system. The minister established a number of working groups that furnished reports guiding legislative reforms, reforms implemented in 2002.[1363] They intended to ensure more flexibility in the processes for regulating health professionals, including the creation of overlapping scopes of practice.

Registration

Beginning with registration, the traditional model is certification, where an authority certifies that an individual has satisfied particular educational and training requirements which are judged relevant indicators of competence to perform a range of professional services.[1364] This model does not stop others from providing the same services, but non-professionals cannot identify themselves with the title reserved for the exclusive use of the professional group (also called 'right to title' or 'reserved title' regimes).[1365]

A more recent innovation in regulation has been the introduction of licensing models. Under a licensing model, only licensed professionals are legally entitled to provide health services of a particular description to patients.[1366] Licensing can create an exclusive scope of practice or a non-exclusive scope of practice, combined with controlled acts (acts which

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[1362] Ontario, Health Professions Regulatory Advisory Council, *Regulation of Health Professions in Ontario: New Directions,* (Toronto: Health Professions Advisory Council, 2006) at 1 [Health Professions Regulatory Advisory Council].

[1363] Regrettably, these documents have not been translated but can be accessed at <http://www.opq.gouv.qc.ca/index.php?id=22>.

[1364] F. McDonald, "The Regulation of Health Professionals" in B. White, F. McDonald & L. Willmott, eds., *Health Law in Australia,* (Sydney: Thomson, 2010) 509 [McDonald, "Regulation"].

[1365] *Ibid.*

[1366] *Ibid.*

create risks to patient safety so only certain people are permitted to undertake them). An exclusive scope of practice authorizes a profession to exclusively carry out the functions specified in the scope of practice. Another profession may only perform activities in another profession's scope of practice with explicit legislative authorization.[1367] A non-exclusive scope of practice authorizes a professional to carry out the functions specified in the scope of practice for members of that profession. The regulatory framework anticipates that there would and should be a degree of overlap between professions in terms of functioning and that this is desirable. Certification is less restrictive and prescriptive than licensing.

Britain continues to use certification processes for all applicants for registration in all regulated health professions. Registration authorities certify that applicants are in good physical and mental health, have attained the qualifications necessary for registration, are of good character, and have paid the requisite fees. Apart from the ability to place conditions on registration and provide specialist registration, there was no real attempt to limit or define a health professional's scope of practice through the processes of registration. Alberta, British Columbia, Ontario, and Québec adopted hybrid certification/licensing models (and this is generally the case across Canada). They all used non-exclusive scopes of practice with a prescribed series of controlled acts.[1368] Title protection is afforded titles in British Columbia and, in a limited fashion, in Ontario and Québec.[1369]

Prospective FTP

Prospective FTP processes involve the creation of mechanisms to ensure the competence and fitness to practise of all professionals throughout their professional life. The activities of the GMC in this regard are discussed in the associational self-regulation section below. In summary, in Britain, while by 2005 processes of revalidation of competence had not yet been put in place, work was proceeding to institute prospective FTP processes.

In Canada, prospective FTP processes are present in each of the four modernized jurisdictions, although they differ in their requirements. In Alberta, regulatory bodies are required to establish continuing competence programs within five years of commencing

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[1367] *Ibid.*
[1368] F. McDonald, *A Comparative Analysis, supra* note 1355.

regulatory activities under the HPAA.[1370] Continuing competence programs generally assess the registrant's current professional competence through processes such as patient and peer assessment. In Alberta, continuing competence programs must create mechanisms to enable registrants to maintain and develop their competence, and in this respect it may amount to a requirement to undertake continuing professional development and report on it, rather than any real external assessment of performance. Some profession-specific legislation in Alberta authorizes some regulatory bodies to use practice visits (inspections and assessments of professional practice) as part of their continuing competence programs. Registrants are required to cooperate with practice visits.[1371] If there are concerns, the regulatory body may recommend remedial action or refer the matter for investigation as a complaint.[1372]

In British Columbia, regulatory boards were also required to establish continuing competency requirements.[1373] In its review, the HPC noted that the professions had a responsibility to ensure quality practice, but also accepted that mandatory continuing education does not significantly alter the behaviour of health professionals. The HPC agreed that it should be up to the professions to determine the appropriate means of ensuring quality practice.

Ontario, too, requires regulatory boards to develop continuing competence mechanisms, but these are more prescriptive than in British Columbia. The Code requires each regulatory board to make regulations establishing a quality assurance program, which was defined as, "a program to assure the quality of the practice of the profession and to promote continuing competence among the members."[1374] There is considerable flexibility to develop programs, so there is some variability.[1375] Through regulations to their profession-specific acts, the CPSO developed a quality assurance program that includes peer assessments, physician reviews, and physician enhancement programs; and the College of Pharmacists a program

[1369] *Ibid.*
[1370] HPAA, *supra* note 1354 s. 50.
[1371] *Ibid,* s 51(3)-(4).
[1372] *Ibid*, s. 51.1(2).
[1373] *Health Professions Act,* R.S.B.C. 1996, c. 183, s. 16(e) [HPABC].
[1374] RHPA, *supra* note 1123, s. 1(1), 80.
[1375] Health Professions Regulatory Advisory Council, *supra* note 1362 at 24.

that includes random practice reviews and remediation and the maintenance of a continuous learning portfolio.[1376]

Competence is said by the Conseil Interprofessionnel du Québec to be a "fundamental value of the professional system" of which the "professional orders are the guardians and promoters."[1377] Theirs is a twofold role: to set standards regarding admission into the profession so as to verify the competence and integrity of candidates; and to ensure these are maintained throughout the person's professional life. The continuing competence system in Québec has both proactive and reactive elements. Proactively, members of a profession must in some circumstances comply throughout their professional life with specific training requirements prescribed by regulation.[1378] In addition, to "ensure that professional activities are being practiced at the expected quality level", the regulatory boards are to verify the continuing competence of registrants through an inspection process.[1379] Each regulatory board was required to establish a Professional Inspection Committee (PIC) to supervise the practice of the profession through inspections of records, medications, poisons, substances, equipment, and so on, but the legislation does not specify any form of actual performance review.[1380] Within Canada, Ontario's requirements were clearly the most developed in the sense of prospectively assessing performance; all other programs were limited.

Retrospective FTP

For many professional bodies, especially the GMC, the traditional regulatory focus was on input regulation, with output regulation only occurring in respect of 'deviant' members of the profession. Parry and Parry have noted that, for the medical profession in Britain what constitutes 'deviance' evolved over time. Initially, the focus of regulatory action was on 'quacks' and sexual conduct, then competition and self-promotion, and then drink and drugs.[1381] The GMC, in particular, traditionally had very little interest in intervening in any matter that relates to clinical negligence, deeming it a matter for the courts, even though the

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[1376] *Medicine Act, 1911,* O.Reg. 114/94, s.27; *Pharmacy Act, 1991,* O.Reg. 202/94, s.42.
[1377] Conseil Interprofessionnel du Québec, *The Professional System in Québec* at 3.5 & 3.5.1 [Conseil], online: Professions Québec <http://www.professions-Québec.org/systeme_pro_ang.html>.
[1378] *The Professional Code* L.R.Q. c. C-26, s. 94(o) [*The Code*].
[1379] *Ibid.*
[1380] *Ibid* s. 109 and s. 112.
[1381] N. Parry & J. Parry, *The Rise of the Medical Profession* (London: Croom Helm, 1976).

courts do not have the power to stop a health professional from practising.[1382] The GMC was traditionally of the opinion that few, if any, cases of clinical negligence could constitute serious professional misconduct (SPM), a class of misconduct that it considered was limited to wilful or at least reckless conduct.[1383] As discussed in Chapter 6, screeners and committees within the GMC determined which cases went to discipline based on their perception of what might constitute SPM. The courts traditionally deferred to the GMC's discretion on this matter as long as the regulatory processes were fair.[1384] It was not until 1985 that the GMC formally recognized that some forms of negligence could form the basis of a charge of SPM, but its 1994 internal training manual appeared to indicate the opposite.[1385] It appears that in practice there was a high threshold for finding SPM and negligence allegations were almost routinely omitted from proceeding through FTP processes until the late 1990s when, confronted by a number of scandals, the GMC changed its practices. Particularly important in this regard, were the allegations of clinical negligence made in respect of the Bristol surgeons.[1386]

During this period, non-disciplinary FTP processes were developed to allow for health and performance assessments, creating three paths through which a complaint to the GMC could travel. What is evident from exhaustive examinations of the GMC processes by Stacey in the 1980s[1387] and Davies in 2007[1388] is that it was not so much the regulatory framework that was problematic, but rather its operationalization by the GMC. It appears that the process was captured by the interests of the profession: screeners and assessors routinely acted outside their powers and applied the wrong legal tests to determine whether a matter ought to proceed or not, and there was no oversight of the FTP processes by the GMC.[1389] Even the increasing involvement of lay persons in the FTP processes did not make a significant difference.

[1382] Davies, "*Self-Regulation*", *supra* note 19; Shipman Inquiry, *Safeguarding Patients, supra* note 1097.

[1383] Davies, *ibid.*

[1384] See, for example, *Ghosh v. GMC* [2001] UKPC 29; [2001] 1WLR 1915 (P.C.), but see *Stefan v. United Kingdom* (1998) 25 E.H.R.R. CD 130, *Wickramsinghe v. United Kingdom* [1998] E.H.R.L.R. 338, *Tehrani v. United Kingdom Central Council for Nursing Midwifery and Health Visiting,* (2001) S.L.T. 879 (Court of Session), *Priess v. General Dental Council* [2001] 1 W.L.R. 1926 where regulatory processes were criticized; and see discussion in Glynn, *supra* note 19.

[1385] Davies, "*Self-Regulation*", *supra* note 19.

[1386] *Ibid.*

[1387] Stacey, "*Regulating*", *supra* note 19.

[1388] Davies, "*Self-Regulation*", *supra* note 19.

Partially in response to the Shipman case, in 2001 the GMC proposed new FTP procedures said to provide greater protection for patients and the public, while remaining fair to doctors. In this new process, instead of three types of FTP procedures, the process reverts to the old model where all FTP matters are considered by the same process. The preliminary examination by GMC staff was to be made more flexible, and complaints would not be automatically closed if local complaints processes are still being pursued. A team of investigators would be employed by the GMC to gather evidence at the initial stage, with advice from lawyers. Once information is gathered, the case was to be examined by two case examiners to decide whether it should proceed to a hearing or be resolved through the issue of a warning. To ensure independence, the FTP panel will be comprised of non-members of the GMC. The Shipman Inquiry suggested a number of amendments to the proposal to ensure greater independence of the FTP panel, and to ensure there were standards against which to make decisions to refer on or not.[1390] The Shipman Inquiry concluded:

> they [the new mechanisms] are capable of providing a much improved method of protecting patients from doctors who might harm them. The success of the new procedures depends to a large extent upon the will and determination of the GMC to make them operate for the benefit of patients rather than, as the old procedures often operated, for the benefit of doctors.[1391]

Some immediate changes were made through legislation, notably the government empowered the Interim Orders Committee of the GMC to impose an interim suspension in the public interest or in the interest of the doctor.[1392] In addition, since 2000, the GMC has had a statutory duty to disclose to an employer or Primary Care Organization (PCO) that a complaint has reached a certain point in its processes.[1393]

[1389] *Ibid*; Shipman Inquiry, *Safeguarding Patients, supra* note 1097.

[1390] *Ibid*.

[1391] *Ibid* at 40.

[1392] *Medical Act 1983* (U.K.), 1983, c. 54, s. 41A [*Medical Act 1983*].

[1393] *Ibid*. s. 35B.

Retrospective FTP processes in Alberta, British Columbia, Ontario, and Québec generally include health, performance, and disciplinary processes. They are designed more efficiently than the processes seen in Britain, with fewer individuals and committees making decisions. It is difficult to know how these processes are working in practice. It is clear that the CPSO's processes in this regard were the subject of adverse comment in the TSAPP report.[1394] While it is clear that the CPSO took action to strengthen its prospective measures in respect of sexual abuse, i.e. increased education, clearer standards, reporting requirements, and so on, according to some commentators it is less clear that governance culture within the CPSO, and perhaps other regulatory bodies, actually changed.[1395]

Governance and Accountability
A key issue is how regulatory bodies are governed and how they are held accountable. In Britain and in Canada, lay representation increasingly became a part of governance processes within the regulatory bodies.[1396] There were also moves, in both jurisdictions, to increase the accountability of the regulatory bodies to the public. A side effect of this was arguably to constrain the power of the professions.

In terms of the broader governance framework of British health regulatory bodies, a primary accountability measure is the requirement to publish at least once a year a statistical report that, "indicates the efficiency and effectiveness of the arrangements it has put in place to protect the public from persons whose fitness to practice is impaired."[1397] All regulatory bodies are also required to submit an annual report detailing the exercise of its functions and its financial statements to the Privy Council (PC), which in turn tables the reports in both houses of Parliament.[1398] There is provision for the Privy Council to intervene if it considers that a regulatory body has failed to perform any functions which the PC believes it ought to have performed.[1399] The PC may also order an inquiry into any matter connected with the council's exercise of its functions.[1400] These provisions were intended to strengthen the

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[1394] TSAPP, *supra* note 867.
[1395] Rogers, *supra* note 901.
[1396] Davies, "*Self-Regulation*", *supra* note 19; Stacey, "*Regulating*", *supra* note 19.
[1397] See, for example, *Health Professions Order 2001,* S.I. 2001/254, art. 44(1) [HPO, 2001].
[1398] *Ibid,* art. 44(2) & (3).
[1399] *Ibid*, art. 43; *Medical Act 1983, supra note* 1392, s. 50.
[1400] HPO, 2001, *ibid* art. 47.

accountability of the professions by enabling early intervention and "occasional independent scrutiny."[1401]

Subsequent to the period under review in this thesis, the government has had the opportunity to respond to the recommendations and findings of the Shipman, Ayling, Kerr/Haslam and Neale inquiries and has recommended further reforms to the processes for government-sanctioned self-regulation.[1402] Apart from moves to introduce prospective FTP mechanisms and a strengthening of accountability to the state, there have been few developments in the framework surrounding government-sanctioned self-regulation in Britain. Scandals called into question how the GMC, in particular, exercises its governance responsibilities, suggesting that the difficulties are not with the regulatory framework per se but with how the regulatory bodies implement it.

In the four Canadian provinces under review in this section of the chapter, the role of the state also assumed greater proportions constraining to some extent the powers of the regulatory bodies. In Alberta, a regulatory body's regulations must be approved by the Lieutenant Governor in Council, and proposed by-laws that set out the profession's code of ethics and standards of practice must be reviewed by the Minister of Health and Wellness before adoption.[1403] Another important accountability provision requires regulatory bodies to submit annual reports to the Minister of Health and Wellness, who then must table them in the Alberta legislature.[1404] The minister is also empowered to require additional reports from colleges in order "to ensure that the requirements of this Act are met."[1405]

In British Columbia, a primary accountability mechanism for health professional bodies under the HPABC, or the other Acts, was to submit an annual report to the minister,

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[1401] U.K., Department of Health, *Establishing the New Health Professions Council* (London: Department of Health, 2001).

[1402] U.K., Department of Health, *Safeguarding Patients,* (London: The Stationary Office, 2007); U.K., Department of Health, *Trust, Assurance and Safety: Regulation of Health Professionals,* (London: The Stationary Office, 2007); U.K., Department of Health, *Good Doctors, Safer Patients: Proposals to Strengthen the System to Assure and Improve the Performance of Doctors and to Protect the Safety of Patients: A Report by the Chief Medical Officer* by Sir Liam Donaldson (London: Department of Health, 2006); U.K., Department of Health, *The Regulation of Non-medical Healthcare Professions: A Review by the Department of Health* (London: Department of Health, 2006); see also Davies, "*Self-Regulation*", *supra* note 19; Kuhlmann, supra note 19.

[1403] HPAA, *supra* note 1354 ss.131, 133.

[1404] *Ibid*, ss 4.

although the minister is not required to table the report in the legislature.[1406] An additional accountability requirement in British Columbia was that government approve rules or by-laws formulated by regulatory bodies.[1407] The government can request a regulatory board to amend or repeal a by-law, and if it does not can amend it itself. In its report, the HPC noted that the regulatory boards criticized these innovations, concerned that they eroded professional self-regulatory autonomy. However, the HPC noted that self-regulation is a privilege and not a right and that "the ability to review and scrutinise regulatory instruments is simply another means by which government supervises the grant of self-regulation."[1408] Further, it is important that the government, "maintain ultimate supervisory authority over the professions."[1409] The HPABC also authorizes the minister to appoint a person to inquire into the operation of a regulatory board or the practice of a health profession and to subsequently issue a directive requiring change.[1410]

Under the Ontario RHPA, the Minister of Health and Long-Term Care is responsible for the administration of the Act and has a general duty to ensure:

> …that the health professions are regulated and co-ordinated in the public interest, that appropriate standards of practice are developed and maintained and that individuals have access to services provided by the health professions of their choice and that they are treated with sensitivity and respect in their dealings with health professionals, the Colleges and the Board.[1411]

In order to fulfil this duty, and hold regulatory boards accountable, the minister has a number of powers, including: the power to review board activities; to require the submission of information and reports; to require a board to develop, change, or revoke a regulation; and a broad power to make a board do any act deemed necessary to carry out the RHPA's

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[1405] *Ibid*, ss 4(3).
[1406] HPABC, *supra* note 1373, s. 18(2).
[1407] *Ibid*, s. 19(5).
[1408] British Columbia, Health Professions Council, *Safe Choices: A New Model for Regulating Health Professionals in British Columbia,* (Victoria: Health Professions Council, 2001) at E. 1 [HPC, *Safe Choices*].
[1409] *Ibid* at E.2.
[1410] HPABC, *supra* note 1373, s. 18(1) and 18(2).
[1411] RHPA, *supra* note 1123, ss. 2-3.

objectives.[1412] Regulations developed by regulatory boards must be reviewed by the Minister of Health and Long-Term Care and approved by Cabinet.[1413]   They must also submit an annual report.[1414]

In Québec, each regulatory body must produce an annual report detailing its activities and providing its financial statements and provide copies to the Office of the Professions of Québec and the minister. The minister must table the report before the National Assembly.[1415] But, as is described below, Québec has a meta-regulatory layer of governance that perhaps precludes the need for any further formal powers to be provided to the minister.

In these Canadian provinces, the requirement that government approves regulations and by-laws issued by the regulatory body illustrates, at least in theory, a tighter degree of control over the activities of those bodies than is seen in Britain, although it is also important to note that in Britain the minister has some latitude to intervene in the governance of regulatory bodies on the basis of that body's report. Whether it actually results in any change in practice remains unclear. It may perhaps constitute a form of associational self-regulation in that the mere fact that such powers exist constitutes an impetus towards responsible governance. It is also important to note that the existence of meta-regulatory processes and tighter forms of direct regulation may mean that the constraints seem on professional powers conferred by legislation, as seen in Alberta, British Columbia, and Ontario are not required in Britain. Apart from a few provinces where government-sanctioned self-regulation is slightly more tightly regulated, the regulatory schemes in most Canadian provinces look similar to that in Britain. Perhaps a key difference was not so much the form of regulation but the regulatory cultures within each body determining how they balanced the public interest against the interests of the professions. Generally, the processes of government-sanctioned self-regulation remained consistent with their traditional form, although some incremental changes can be observed, especially in terms of registration and prospective FTPs. The most

[1412] *Ibid*, s. 5(1).
[1413] *Ibid*, s. 95(1).
[1414] *Ibid*, s. 6.
[1415] *The Code, supra* note 1378, s. 104.

substantive change – government increasing its oversight or the potential for oversight – occurred in both jurisdictions.

Associational Self-Regulation

Associational self-regulation occurs when one actor places pressure on another to encourage or compel more effective self-regulation.[1416] While this approach was not seen to any great extent in Canada, in Britain strategies to encourage, or compel, more effective self-regulation have been seen throughout the period. In the British context, concerns about the adequacy of the GMC, particularly as a regulator, prompted suggestions from government and other actors on various occasions that the GMC might or should lose its power to self-regulate. As discussed in Chapter 5, in 1998 a government White Paper placed professional regulators on notice that the public's trust in them was waning.[1417] This was followed by other similar statements (some set out in Chapter 6) and acts, all calculated to ensure that the GMC governed the profession in the public interest, instead of in the interest of the profession.

A self-regulatory initiative to emerge from the GMC in 2000 was a proposal that it should take proactive steps to ensure that registered doctors remained fit to practise, rather than just assuming they did until a serious complaint was made. This proposal emerged in the wake of the publicity around Dr Shipman's criminal offending and the other significant events involving failures by doctors.[1418] It emerged, it is suggested, because government placed pressure on the GMC to take action to ensure that its registrants were indeed competent to practise, with the implicit threat that if the self-regulatory actor continued to fail to act to ensure the public safety, the state would take direct action. A consequence of this would be a reduction of professional autonomy. Government passed amendments to the *Medical Act 1983* in 2002 giving the GMC the power to revalidate doctors.[1419]

As part of its proposal, the GMC suggested that every five years a doctor would apply for licence revalidation. As part of that application, the doctor's practice would be evaluated by a revalidation group, providing some form of assurance that the doctor's performance was

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[1416] McDonald, "Working to Death" *supra* note 110.

[1417] *A First Class Service*, *supra* note 714 para. 3.44.

[1418] Shipman Inquiry, *Safeguarding Patients, supra* note 1097.

consistent with professional standards. However, a pilot project undertaken by the GMC in 2002 indicated that revalidation was unpopular with doctors, expensive, and time-consuming. The GMC then revised its plans, deciding that a folder of evidence presented by the doctor was sufficient for revalidation, although of course a folder of documents provided no independent confirmation of the competency of the doctor. The Shipman Inquiry criticized this decision, stating that "In my view, the GMC's change of direction was made not for reasons for principle but of expediency."[1420] In other words, the inquiry's perception was that the GMC decided to act in a way that was easier for it and consistent with the wishes of many of its registrants, not because it had any principled disagreement with the concept of revalidation.

After further pressure from government the GMC again revised its revalidation proposal in late 2003 so that a doctor must produce a clinical governance certificate from his or her employer or PCO doing the revalidation process. The certificate would confirm that the doctor participated in an appraisal process and that nothing adverse was known about the doctor; it would not amount to a positive affirmation that the doctor was fit for practice. The Shipman Inquiry concluded that, "the bottom line is that a doctor will fail to be revalidated only if his/her professional performance is 'remarkably poor'. I do not think that this is a satisfactory state of affairs."[1421] The Shipman Inquiry made recommendations in 2005 that the GMC further strengthen its revalidation process.

The Shipman Inquiry also noted that "the disappointing feature [of the GMC's actions] is that all these changes appear to me to have been made as a reaction to some form of external pressure",[1422] rather than any true desire by the GMC to institute reforms. This in turn seems to validate the need for associational regulation, as the GMC was perceived to be regulating in the interests of the profession and not the public interest. Pressure was needed to change the GMC's internal culture. The Shipman Inquiry noted, "It is clear that the GMC did not recognise the need for change without some prompting from outside."[1423]

[1419] *Medical Act 1983, supra* note 1392, pt. IIIA.

[1420] Shipman Inquiry, *Safeguarding Patients, supra* note 1097 at 41.

[1421] *Ibid* at 42.

[1422] *Ibid* at 43.

[1423] *Ibid* at para. 27.287.

The development of the National Clinical Assessment Authority (NCAA) in 2002 was, in some senses, a form of associational regulation. In others it was an example of direct regulation by the government. As discussed in Chapter 5, the NCAA provided support, advice, assessments, education, and mediation services to the NHS in respect of concerns about the performance of an individual doctor or dentist. As a tool of direct regulation, the creation of this institution was a mechanism used to strengthen the powers of NHS management to address concerns about professional performance and constituted a way in which government could strengthen the ability of the NHS and the state to control its employees in the public interest. The explicit linkage between the activities of the NCAA and the GMC's performance-related assessment powers created additional pressure for the GMC to perform its performance-related functions adequately, as an independent agency was working closely with it and could observe if it did not.[1424]

The closest Canadian equivalent to this process was perhaps seen in respect of the concerns about how the CPSO addressed the issue of sexual abuse complaints. However, in that case, the associational pressure came from the public, advocacy groups, and the media, not from government per se. The commissioning of the TSAPP, the swift uptake of its recommendations in Ontario and throughout all Canadian jurisdictions appeared to indicate a different regulatory culture – one that was more responsive to public concerns.

Regulation by litigation was also used in the Canadian context to change the governance processes of the regulatory bodies. It was not used in Britain. It too places pressure on self-regulatory actors providing a form of associational self-regulation, although of course it moved from a threat of legal action to an actual legal action. In Canada, some persons, unhappy with the manner in which regulatory bodies performed their statutory investigation function, commenced civil proceedings alleging misfeasance in public office and negligence against a variety of statutory bodies. In one case, plaintiffs who had alleged that they had been sexually assaulted by a doctor, sued the College of Physicians and Surgeons of British

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[1424] Allsop, "Regaining Trust", *supra* note 711.

Columbia, which had not investigated their complaints.[1425] The British Columbian Court of Appeal affirmed the existence of a tort of negligent investigation in Canada.[1426] This private law mechanism places pressure on regulators to investigate matters effectively and efficiently and in a manner consistent with the public interest.

In Britain, an associational self-regulation approach was adopted by government, and other actors, to compel the GMC to exercise its regulatory responsibilities in a way commensurate with the public interest. In Canada, any associational regulatory impetus came largely as the result of the actions of private citizens raising concerns about specific incidents of perceived regulatory failure. It may be that Canadian governments generally perceived that health professional regulatory bodies were exercising their regulatory powers appropriately and official pressure was therefore not required to change regulatory culture. As noted in the previous section, it may be that accountability mechanisms were such that additional pressure was not deemed necessary.

Meta-Regulation

Meta-regulation is where government requires or directly oversees the processes of government-sanctioned self-regulation.[1427] Meta-regulation is said to encompass meta-risk-management schemes, enforced quality improvement, or enforced self-regulation.[1428] In the British context, meta-regulation most certainly occurred during this period with the creation of the CHRE in 2002 (originally known as the Council for the Regulation of Health Care Professionals)[1429] and the institution of clinical governance within the NHS. In Canada, only Québec saw the introduction of meta-regulation in respect of oversight of a regulatory body, and Manitoba in respect of mandated quality assurance.

[1425] *McClelland v. Stewart* [2004] B.C.J. No. 1852, 245 D.L.R. (4th) 162 (B.C.C.A.), leave to appeal to the S.C.C. refused [2004] S.C.C.A. No 492 (S.C.C.).

[1426] *Ibid.* See discussion in E. Shirlow & T. Faunce, "Australian Professional Practice Bodies and the Tort of Negligent Investigation" (2009) 17 J.L. Med. 46.

[1427] P. Grabosky, "Using Non-Governmental Resources to Foster Regulatory Compliance" (1995) 8:4 Gov. Int'l J. Pol'y & Admin. 527; Gunningham, *supra* note 116; McDonald, "Working to Death" *supra* note 110.

[1428] Braithwaite, "*Governance*", *supra* note 24. See also McDonald, "Working to Death" *supra* note 110.

[1429] The Council for the Regulation of Health Care Professionals is the name accorded to the agency by statute. The council issued a press release on 15 July 2004 stating that it had changed its name to the Council for Healthcare Regulatory Excellence. CHRE was established in the *National Health Service Reform and Health Care*

The CHRE is an independent agency accountable to the British, Scottish, and Northern Ireland parliaments/assemblies.[1430] Its functions are to: promote the interests of patients and the public; to ensure that when regulatory bodies exercise their functions, they do so in accordance with best practice; formulate principles relating to good professional regulation and to encourage compliance with those principles; and to promote cooperation between regulatory bodies.[1431] Each regulatory body within the remit of the CHRE has a duty, in the exercise of its functions, to cooperate with the CHRE.[1432] The CHRE can investigate and report on the regulatory body's performance of its functions, compare the processes and performance of regulatory bodies, and recommend changes to those processes.[1433] The CHRE may also, for the protection of the public, give directions to a regulatory body requiring it to make rules to achieve a desired policy outcome and the regulatory body must comply with its direction.[1434] The Act also creates provision for CHRE to investigate complaints against a health professional body.[1435]

Perhaps the most contentious aspect of the CHRE's role, certainly from the perspective of the professions, is its power to refer to the High Court (or the Court of Session in Scotland) 'relevant' decisions of the Fitness to Practise and Disciplinary panels or committees of the nine regulators that it oversees.[1436] 'Relevant decisions' are those that relate to directions as to penalty, decisions not to undertake disciplinary proceedings, or decisions to restore a person to the register, but do not include decisions in relation to health impairments, or decisions made by the regulator at preliminary or investigative stages.[1437] The CHRE may refer a matter to the courts if it considers that the decision or penalty is "unduly lenient" or a decision "should not have been made" and that it would be desirable for the protection of members of the public that the council takes action.[1438] The courts have clarified that the CHRE can refer an acquittal to the court for consideration of what was meant by "unduly

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Professions Act 2002, partly as a result of a recommendation made by the *Bristol Inquiry*. *Health Care Professions Act, supra* note 721, s. 25-29.

[1430] *Health Care Professions Act, ibid* s. 16.

[1431] *Ibid* s. 25(1).

[1432] *Ibid.*

[1433] *Ibid.* s. 26.

[1434] *Ibid.* s. 27(2).

[1435] *Ibid.* s. 28.

[1436] McDonald, *A Comparative Analysis, supra* note 1355.

[1437] *Health Care Professions Act, supra* note 721, s. 29

[1438] *Ibid.* s. 29

lenient" and in what circumstances it applied.[1439] Government thought that such referrals would be rare,[1440] but the CHRE has referred higher numbers of cases than was envisaged.[1441]

The closest approximation to meta-regulation in the Canadian context occurs in Alberta, Ontario, and Québec. In Alberta, the HPAA established a Health Professions Advisory Board (HPAB), an advisory body designed to increase public input on regulatory matters.[1442] Its role is to provide general advice on regulatory policy – it does not have any true oversight function in the sense required to constitute meta-regulation.[1443]

In Ontario, the RHPA established the Health Professions Regulatory Advisory Council (HPRAC), an independent advisory body.[1444] Similar to HPAB, HPRAC's duties are to provide advice to the minister.[1445] HPRAC also has extremely limited oversight responsibilities – namely, it has a statutory duty to monitor the patient relations program of each regulatory body and advise the minister of the program's effectiveness. It also reviews the effectiveness of each regulatory body's patient relations and quality assurance programs and complaint and discipline procedures relating to professional misconduct of a sexual nature.[1446] However, while the mandate of HPRAC is broader than Alberta's HPAB, its oversight functions are extremely limited and it really remains an advisory body. Also established was a Health Professions Appeal and Review Board, an independent agency, which conducts reviews and appeals of certain decisions made by regulatory boards in respect of registration and complaints.[1447] The Health Professions Appeal and Review Board states:

[1439] See discussion in Glynn, *supra* note 19 at 499–503.

[1440] See U.K., House of Commons Standing Committee A, *Hansard*, (13 December 2001) at col. 424-427 (per John Hutton); explanatory note to *The Health Act 1999, supra* note 694.

[1441] Glynn, *supra* note 19.

[1442] HPAA, *supra* note 1354, s. 22(1).

[1443] *Ibid*, s.23.

[1444] RHPA, *supra* note 1123 s. 7.

[1445] *Ibid,* s. 11.

[1446] *Ibid,* s. 6.

[1447] *Ministry of Health Appeal and Review Boards Act, 1998* S.O. 1998, c.18, Sch. H.

[t]hrough reviews and hearings, the Board monitors the activities of the Colleges' Complaints Committees and Registration or Accreditation Committees, in order to ensure they fulfill their duties in the public interest and as mandated by legislation.[1448]

The board performs a meta-regulatory function, but unlike meta-regulation in Britain and Québec (discussed below), it is not proactive, but reactive. Oversight by the board depends on an individual bringing a matter to its attention. It does not actively review decisions on its own initiative.

Meta-regulation does occur in Québec – perhaps not surprisingly given that its level of statism is the highest of the Canadian provinces. The Office of the Professions of Québec (Office des professions du Québec) (OPQ) is a government oversight agency whose mandate is to ensure that each professional body fulfils its function of protecting the public.[1449] OPQ also serves as an advisory body to government. In summary, OPQ ensures that each regulatory body adopts the required regulations and suggests changes to such regulations for voluntary adoption by the regulatory bodies.[1450] If those bodies do not adopt the recommendations, OPQ can recommend mandatory adoption to government. It may also set regulations establishing specific rules and standards.[1451] It has investigation powers that the minister may, in special circumstances, authorize it to use to examine the functioning of the regulatory body.[1452] In addition, the Québec Interprofessional Council was founded in 1995 as an association of the professional regulatory bodies and as an adviser to government on matters touching the regulation of professionals; as such, it is a purely advisory body.[1453] Québec is the only province to have a true meta-regulatory process for oversight of the health professions. It differs from the British model in that it has no power to refer disciplinary decisions to the courts for review, but other than this the two bodies have similar powers. It appears that a statist approach may be an indicator of the use of meta-regulatory mechanisms in the context of the oversight of regulatory bodies.

[1448] Ontario, Health Profession Review and Appeal Board, "About Us: Introduction to the Health Professions Review and Appeal Board" online: Health Profession Review and Appeal Board <http://www.hparb.on.ca/scripts/english/about.asp>.
[1449] *The Code, supra* note 1378 s. 12.
[1450] *Ibid.*
[1451] *Ibid.*
[1452] *Ibid.*

In Britain the *Health Act 1999* introduced requirements for the introduction of clinical governance which, as discussed in Chapter 5, is essentially an accountability framework for clinical practice.[1454] While the responsibility for introducing clinical governance was an institutional one, i.e. the NHS bore responsibility, it impacted on professional self-regulation in that it required clinical audit processes and in that sense could be considered to be meta-regulatory in effect.[1455] Similar measures were not really seen in Canadian jurisdictions. The closest perhaps to clinical governance was the Manitoban *Hospitals Standards Regulation*[1456] which requires Hospital Standards Committees to ensure medical audit programs are undertaken in each facility.

Direct Regulation of the Professions

As discussed in Chapter 5, in Britain the government steadily increased direct regulation of the professions through strengthening the employment relationships between the NHS and medical professionals and dentists, including reducing the powers of the professional peer review mechanisms (such as the three wise men), strengthening the power of the NHS to investigate concerns about conduct, competence, or performance, and to suspend or place conditions on a professional's ability to practise. Medical professionals, in particular, had their ability to self-regulate within the NHS severely limited, with the integration of clinical processes into the broader management of the NHS. Conversely, in Canada, the logics of the Medicare system meant that the medical profession was able to retain its separate governance structure within hospitals and maintain professional self-regulation in the workplace.

Co-Regulation

Both jurisdictions recognized that only so much could be done through top-down regulatory processes, and that at times the effective change occurred through bottom-up and/or collaborative processes. In that context, the state's role should, at best, be to facilitate and enhance these types of initiatives. It also should be to create processes to enable cross-

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[1453] Conseil, *supra* note 1377. See also McDonald, *A Comparative Analysis, supra* note 1355.
[1454] Flynn, *supra* note 671; Walshe, *Clinical Governance, supra* note 696; Davies & Mannion, *supra* note 691.
[1455] Davies, "Trust", *supra* note 698.

systemic learning. Both of those would facilitate the development and attainment of best practices in safety and quality. Accordingly, both jurisdictions saw the development of organizations to facilitate patient safety improvement.

In Canada, the 2003 federal budget announced the provision of $10 million annually to support patient safety initiatives, including the creation of the Canadian Patient Safety Institute (CPSI). The CPSI works collaboratively with governments and other stakeholders to improve the safety of Canadian health systems.[1457] It has no regulatory authority, but functions as a clearing house for information, funds patient safety research, and provides advice and leadership by fostering patient safety related programs.

Two provinces also introduced similar institutions. In 2004, the government of Manitoba established the Manitoba Patient Safety Institute, also an independent non-profit organization, pursuant to a recommendation made by the Manitoba Patient Safety Steering Committee. This committee had been in turn created to respond to the inquest into events at the WHSC. The Manitoba Patient Safety Institute's role was to promote, coordinate and facilitate patient-safety-related activities throughout Manitoba and to enhance the quality of healthcare for Manitobans.[1458] In British Columbia, the government established the British Columbia Patient Safety Taskforce, a provincial coalition for patient safety, also intended to promote, coordinate, and facilitate activities within that province.[1459] These were all agencies designed to facilitate collaborations between stakeholders in the area, bespeaking a co-regulatory mode of governance.

In Britain, the National Patient Safety Agency was established in 2002 as a special health authority.[1460] Its purpose was to inform, support, and influence health-providers to improve the quality and safety of health services. It collects voluntarily provided, anonymous, adverse

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[1456] *Hospitals Standards Regulation,* Man. Reg. 453/88R [*Hospitals Regulation (Manitoba)*].
[1457] Canada, Canadian Patient Safety Institute, "About CPSI" online: CPSI
<http://www.patientsafetyinstitute.ca/English/About/Pages/default.aspx>.
[1458] Manitoba Institute for Patient Safety, online MBIPS <http://www.mbips.ca/aboutus.html>. See also Downie, *supra* note 28.
[1459] British Columbia, Ministry of Health Services, News Release/Communiqué, "Provincial Taskforce to Improve Patient Safety" (7 May 2004) online Government B.C.
<http://www2.news.gov.bc.ca/nrm_news_releases/2004HSER0018-000280.pdf>. This entity no longer exists.

event reports, analyzes them, identifies risks, and recommends action. Similarly to the CPSI, it acts as a clearing house for information about patient safety, and provides support and leadership in respect of national initiatives aiming at improving safety. Both national agencies are facilitative in nature, and as such the initiatives in this particular aspect of the framework for regulating patient safety are remarkably similar.

Meta-Regulation

Meta-regulatory processes also occur in the context of the regulation of the health system more generally. It has been of limited effect in Canadian health systems. In most provinces and territories, legislation was used to require the creation of bodies within facilities to address patient safety and quality-related issues and Ministers were given powers to intervene in respect of safety and quality issues.[1461] For example, in Québec, the Act Respecting Health Services and Social Services[1462] required that each facility establish a risk and quality management committee. These committees were to: identify and analyze risks; support the patient and/or their relatives; and establish a monitoring system which was to include a local register of adverse events so that root cause analysis may be conducted.[1463] In Manitoba, the Hospitals Standards Regulation[1464] established the responsibilities of Hospital Standards Committees to ensure that a medical audit program is undertaken to provide surveillance of quality of care. However, these requirements are very general and leave the execution, form and functions of these mechanisms to be determined by each health-provider.[1465] Additionally, there are no mechanisms to enable to state to determine whether these mechanisms are functioning or to require the Minister to exercise his or her powers proactively.[1466]

However, meta-regulation became a significant part of the regulatory framework in Britain with the introduction of clinical governance as part of the 1999 NHS reforms. Flynn notes that, "[t]he genealogy of clinical governance can be traced back to these generic approaches

[1460] National Patient Safety Regulations, *supra* note 715.
[1461] Downie, *supra* note 28.
[1462] *Health Services and Social Services Act*, R.S.Q., chap. S-4.2, s. 182.2 [*Health Services and Social Services Act*].
[1463] *Ibid.*
[1464] *Hospitals Regulation (Manitoba), supra* note 1456.
[1465] Downie, *supra* note 28.
[1466] *Ibid.*

of managerialism [NPM] … ."[1467]   Generally, the implementation of clinical governance is said to have involved a shift of power from clinicians to managers and a cultural change within NHS systems.[1468]   As such, it was considered a powerful tool in reducing the autonomy of the professions.

The Department of Health has proffered various definitions of what exactly clinical governance is,[1469] including:

> A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.[1470]

A key facet of clinical governance was the creation of a statutory duty upon the NHS in respect of quality and safety (set out in Chapter 5). This duty constituted a requirement for NHS Trusts to "assure quality and continuously improve it."[1471] That duty was placed upon CEOs who would henceforth be held accountable for achievement of service quality, just as they were for the use of financial resources. The creation of a statutory duty of quality increases organizational attention to safety and quality issues, especially if organizational progress and commitment is to be monitored and actors may be held accountable.[1472]

NHS Trusts were to use a variety of mechanisms to ensure quality, including: reinvigorated clinical audit; clinical risk management; quality assurance; clinical effectiveness assessment; evidence-based decision-making; clinical supervision; learning from complaints; the identification and management of poor clinical performance; and staff and organizational development.[1473]   As Flynn notes, the scale and scope of clinical governance is far-

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[1467] Flynn, *supra* note 671 at 159.
[1468] K. Walshe, *Clinical Governance: A Review of the Evidence* (Birmingham: Health Services Management Centre, University of Birmingham, 2000); Flynn, *supra* note 671; S. Nicholls et al., "Clinical Governance: Its Origins and Foundations" (2000) Brit. J. Clinical Gov. 172 [Nicholls].
[1469] See discussion in Flynn, *supra* note 671.
[1470] *A First Class Service*, *supra* note 714 para. 3.2.
[1471] Flynn, *supra* note 671 at 158.
[1472] See, for example, Scally & Donaldson, *supra* note 1047; Davies & Mannion, *supra* note 691.
[1473] Flynn, *supra* note 671 at 158; Davies & Mannion, *supra* note 691.

reaching.[1474] Davies and Mannion have observed if managers must secure quality and safety improvements, it is an instinctual response on their part to introduce measures to check performance and coerce behavioural change.[1475] Thus not only did clinical governance strengthen the role of NHS managers; it also signalled an attempt to refashion organizational culture by reprioritizing issues of safety and quality. Mechanisms to address safety and quality were embedded throughout the fabric of the organization, with performance measures and accountabilities attached. Meta-regulation was a tool that allowed the tentacles of control to move from the state to CEOs, to line managers, and so on down the line. In return enhanced accountabilities go up the line.

Meta-regulation was a powerful tool employed by the British government to encourage greater priority to be accorded to safety and quality at the organizational level and greater incentives for managers to require increased oversight of performance, increased mentoring and review, and greater accountability for safety and quality. This level of verification and oversight was not dreamed of in Canada, where it was taken for granted that the professions should be doing this type of thing anyway, supported where relevant by the hospitals in which they were based or by the RHAs and enabled in a generic fashion by legislation.

<u>Direct Regulation</u>

Regulatory law grew to become an increasingly important tool in Britain during this period, whereas in Canada, although it was employed, it was to a lesser extent and with a different focus than in Britain.

Standards and Guidelines

A part of the state's bargain with the medical profession, a bargain that occurred on both sides of the Atlantic was that doctors would retain their professional autonomy, especially in matters touching upon clinical judgement. This included the power to establish professional standards and to create clinical guidelines. As discussed in previous chapters, the bargain was between the professions and the state was substantially renegotiated in Britain. Part of this renegotiation in Britain saw the state assuming at least some responsibility for the creation of

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[1474] Flynn, *supra* note 671 at 158.
[1475] Davies & Mannion, *supra* note 691.

clinical standards and guidelines. The ostensible reason for this was a quality issue. It was deemed troubling that a person with a medical condition, such as asthma, could have that condition managed in different ways depending upon where that person lived. An underlying theme of the NPM was rationality, but differences in treatment modalities depending on residence seem inherently irrational. The evidence should determine the standard of treatment that should be provided and that should be broadly consistent across the NHS. Accordingly, in 1999, the National Institute for Clinical Excellence (NICE) was established as a special health authority. Its aim is to provide guidance on public health, health technologies and clinical practice. In respect of the latter, it creates clinical guidelines and so strengthens the evidence base of medicine.[1476] But more than that, NICEs clinical guidelines were used as a basis to establish the standards against which organizational performance would be assessed by agencies such as CHI and the Healthcare Commission.[1477] Evidence of compliance with NICE's standards provides a basis for evidence-based decision-making. In addition, government developed National Service Frameworks (NSF), which established the standard of care in respect of certain services. NSFs were also used by CHI and the Healthcare Commission as a basis from which to assess performance. Thus, government established arms length agencies to assume a significant role in establishing clinical standards. But it also leveraged those standards into practice through the use of audit and monitoring processes.

Nothing commensurate occurred in Canada. While there were attempts by government to create clinical guidelines (as discussed in Chapter 5), these were short-lived and ineffective. The mode of governance was co-regulatory, involving for the most part partnerships with the professions in the development of the few guidelines that emerged from the process. Clinicians were encouraged to use the guidelines, but it remained a matter of their personal choice. There was no monitoring, no audit, and no accountabilities attached to the use of clinical guidelines by health professionals, health-providers or health-programs.

[1476] Allsop, "Regaining Trust", *supra* note 711.

[1477] U.K., Department of Health, *Standards for Better Health,* (London: Department of Health, 2004). The guidelines applied in England, Wales, and Northern Ireland from 2004.

Complaints

Complaints mechanisms are another manner in which safety and quality can be regulated. Their purpose is to identify issues, individual and systemic, and implement changes so that similar events do not occur again – in other words, complaints enable learning and the institution of preventative measures. Complaints processes also, of course, serve other ends in terms of displaying responsiveness to patient concerns and managing litigation risk. Complaints processes can be mandated by the state through processes of direct regulation, or they can be voluntarily instituted by individuals and facilities.

In the NHS during this period, it became mandatory for NHS facilities to have complaints management systems. For example, in 2004, regulations required NHS bodies to make arrangements to handle and consider complaints.[1478] Consistent with the NPMs priority to establish clear lines of accountability, a senior person must be designated as having the responsibility for ensuring both compliance with the regulations and that action is taken in light of the outcome of any investigation.[1479] The NHS body must also appoint a complaints manager. Additionally, the NHS is accountable to the Healthcare Commission in respect of its complaints processes, as it must provide it with an annual report on its handling of complaints. The Healthcare Commission also can review complaints (as long as the Health Service Ombudsman is not doing so) if the complainant is not satisfied or there is an unreasonable delay in resolving the complaint.

Since the early 1970s, Britain's Health Services Ombudsman was able to independently review complaints but only in relation to the non-clinical aspects of NHS services, and only after complaints had progressed unsatisfactorily through local levels. From 1993, its jurisdiction was expanded to also include clinical matters within the NHS.[1480]

Generally, in Canada complaints management has been left to the discretion of the self-regulatory actors – in others words, to hospitals and RHAs – in most provinces except Québec. In respect of patient complaints, there was limited independent or quasi-

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[1478] *The National Health Service (Complaints) Regulations 2004* (U.K.), S.I. 2004/1768 pursuant to *Health and Social Care (Community Health and Standards) Act 2003* (U.K.) s. 48.
[1479] *Ibid.*
[1480] *Health Service Commissioners Act 1993* (U.K.), 1993, c. 46.

independent review across the jurisdictions. In Alberta, the Health Facilities Review Committee was responsible for investigating patient complaints concerning "the care and treatment and standards of accommodation received by that patient or any other patient in the hospital."[1481] The committee did not investigate complaints about a health professional's conduct or patient abuse, which were addressed by other agencies. Complaints were to be in relation to a specific patient and could be about "any aspect of patient/resident care, safety or satisfaction," such as medication administration, the use of restraints, or food quality.[1482] Also in Alberta, the Ombudsman can, since 2003, review the operation of patient concerns resolution process within RHAs.[1483]

Québec also had a complaints system allowing patients to complain about the care they received in public institutions (but not in respect of the services provided by many health professionals).[1484] All public facilities are required to establish a complaints process.[1485] Any complaints are first dealt with at the regional or local level by a quality commissioner, a quasi-independent actor. If that is unsuccessful because the complainant believed the commissioner did not act in a timely way, or because the complainant is dissatisfied with the commissioner's conclusions; or because he or she is unhappy with the Health Authority's response to the commissioner's recommendations, the complainant can take the matter to the Health and Social Services Ombudsman. On the whole, in Canada, complaints systems remained in-house with little capacity for external agencies to play a role or to review in-house mechanisms.

In Britain, complaints processes were considered important and became mandatory. However, it was not sufficient that they were mandatory, government wanted to ensure accountability and compliance and so it established multiple review processes as a check on the exercise of the NHS body's discretion. In Canada, apart from Québec, complaints

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[1481] *Health Facilities Review Act,* R.S.A. 2000, c. H-3, s. 8 [*Health Facilities Review Act*].
[1482] *Ibid.*
[1483] *Ombudsman Act,* R.S.A. 2000, c. 08, s. 12.1.
[1484] *An Act Respecting the Health and Welfare Commissioner,* R.S.Q. c. C-32.1.1 [*Act Respecting the Health and Welfare Commissioner*]. See also Protecteur des usagers en matiere de sante et de services sociaux, "Brief History" [Protecteur], online: <http://www.protecteurdesusagers.gouv.qc.ca/fr/>; Downie, *supra* note 28.
[1485] *Health Services and Social Services Act, supra* note 1462.

systems remained up to the discretion of individual facilities or RHAs. Only in Québec and Alberta were independent complaints review mechanisms established.

Monitoring and Evaluation

Monitoring and evaluating service quality against accepted standards is suggested to be an important mechanism to ensure quality and safety. It is also a way in which accountabilities can be actualized because accountability requires enforcement. Sorrell argues that "it is not the *publication* of the standards but the *enforcement* of the standards that matters to whether trust is well placed."[1486] Conversely, it also can be argued that the professions who provide such services are in the best position to monitor and audit processes through peer review and assessment. We see each of these approaches taken in the jurisdictions under review in this thesis.

In Britain, the 'policing' approach was adopted for NHS hospitals and in respect of other health services, such as long-term care. The priority was to obtain an objective, independent assurance of service quality. If such an assurance was not to be found, it was to identify problems so that remedial action could be taken and the organization and persons could be held accountable. This was done through the creation of CHI in 2001[1487] (for NHS Trusts) and, in 2002, the National Care Standards Commission (for long-term care and other private facilties). CHI's initial function was to evaluate the implementation of clinical governance by undertaking local Clinical Governance Reviews (CGR). CGRs occurred randomly (usually in four year cycles) and involved site visits and peer assessment. The focus was on processes, and before each visit available data was analyzed and assessed to inform peer review processes.[1488] NHS Trusts were required to develop action plans to respond to the key areas for action identified in CHI's report, and their achievement of goals within that action plan formed part of the basis upon which star ratings (discussed below) were assessed. A problem, of course, was that how well or how poorly a NHS Trust constituted risk and quality processes might have no, or very little, bearing on the actual quality and safety of the services it provided.[1489] Accordingly, in 2002, as part of government's response to the Bristol

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[1486] Sorrell, *supra* note 1184 at 55.

[1487] *Health Act 1999, supra* note 694.

[1488] G. Bevan, "Changing Paradigms of Governance and Regulation of Quality of Healthcare in England" (2008) 10(1) Health, Risk & Soc'y 85 [Bevan].

[1489] K. Walshe, "Improvement Through Inspection? The Development of the New Commission for Health Improvement in England and Wales" (1999) 8 Quality in Health Care 191.

Inquiry, CHI became responsible for assessing the quality of care against national standards.[1490]

In 2004, CHI and the National Care Standards Commission were merged to create the Healthcare Commission.[1491] The Healthcare Commission was to independently inspect health services, publish regular ratings of NHS Trusts, and provide an annual report about the quality and safety of services across England and Wales (a similar agency operated in Scotland). It also developed an independent second stage for complaints, and could investigate allegations of serious failings in health services. In particular, the Healthcare Commission was to target its inspections and reviews towards NHS Trusts that were perceived to have difficulties. Thus, the government's commitment to safety and quality was operationalized by the implementation of a policing mechanism to evaluate compliance with NHS goals.

In Canada, the regulation of hospitals and other facilities still largely follows the traditional pattern discussed in Chapter 2.[1492] Government agencies lightly monitored hospitals across Canada, generally through processes of review and inspection, primarily of equipment.[1493] Perhaps the most public of these processes occurred in Alberta, where regular reviews of the quality of care provided in facilities were undertaken by the Alberta Health Facilities Review Committee, a quasi-independent committee.[1494] Its focus was on the quality of care, and not safety per se. The committee reports to the RHA, the facility and the Minister of Health and Wellness. Its annual report is also tabled in the legislative assembly. This is somewhat unusual as in the 1980–2005 period, reports of such reviews in other provinces and territories were generally not made public.

Only one province had a clear accountability structure around safety or quality during this period.[1495] In Québec, the minister was required to take measures to "ensure users the safe

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[1490] Bevan, *supra* note 1488.

[1491] *Health and Social Care Act, supra* note 723 s. 48.

[1492] See also Downie, *supra* note 28.

[1493] *Ibid.*

[1494] *Health Facilities Review Committee Act* R.S.A. 2000, c. H-3, s. 7.

[1495] Downie, *supra* note 28.

provision of health services and social services."[1496] In the Northwest Territories, the *Hospital Standards Regulations* created a health services committee in each facility to make recommendations to the hospital authority and, where necessary, the minister with respect of, among other things, "improving diagnostic and treatment standards within the hospital or hospitals."[1497] Governments tended to rely on hospitals seeking, for the most part voluntarily, accreditation from private accreditation agencies.[1498] So we generally see the light hand of government performing minimalist inspections of facilities, coupled with a reliance on largely voluntary processes of self-regulation through accreditation.

The establishment of Quality Councils in a few provinces did not really change this pattern. These bodies generally focused on enhancing and facilitating collaboration between providers and other stakeholders. They did have some form of monitoring function however, in this context 'monitoring' was used in a much looser sense than was the case in Britain. Saskatchewan's Health Quality Council's[1499] mandate included: monitoring and assessing the quality of Saskatchewan's health services; promoting quality improvement research, training, and education; and developing new clinical standards of care.[1500] In this context, quality included safety.[1501] The council provided advice to government, health authorities, and professionals on a number of healthcare quality and safety matters. It was required to publish public reports on its activities.[1502] In the context of this council's activities, monitoring meant using data, provided by Saskatchewan Health, to evaluate performance in certain areas, i.e. in respect of acute heart attacks. It did not involve any form of audit or any form of inspection of individual health professionals or providers. Its work was to provide an overview of the system, not components of that system. The council emphasized that its function was to act as a catalyst for quality improvement, through, among other things, the development and maintenance of close working relationships and strategic alliances with key stakeholders.[1503]

[1496] *Health Services and Social Services Act*, *supra* note 1462.

[1497] *Hospital Standards Regulations* N.W.T. Reg. 1990, c. T-6, s. 61(5)(a)(iii).

[1498] Downie, *supra* note 28.

[1499] An independent agency established in 2002.

[1500] *The Health Quality Council Act*, S.S. 2002, c. H-0.04, s. 5.

[1501] Downie, *supra* note 28.

[1502] *Ibid*.

[1503] See for example, Saskatchewan, Health Quality Council, *2004/2005: 100 Years of Health: Annual Report* (Saskatoon: Health Quality Council, 2005).

Alberta had a similar body, the Health Quality Council of Alberta, established in 2004, with patient safety as an explicit part of its quality mandate.[1504] It too undertook global analysis of the quality of the system using a framework that focused on: health status; characteristics; non-medical determinants of health; and performance (acceptability, accessibility, appropriateness, efficiency, effectiveness, continuity, competence, and safety).[1505] It too emphasizes collaboration and its role as a catalyst for change.[1506]

In Québec, the National Assembly adopted an Act instituting the office of the Commissionaire à la santé et au bien-être (Health and Welfare Commissioner).[1507] The Health and Welfare Commissioner was responsible for assessing the results achieved by the health and social services system.[1508] This was again assessed by measurement against global indicators, such as quality, access, integration, insurability, funding, determinants of health, ethics, medications, and technology.[1509] Hence, its monitoring function was also at a systemic and global level. Downie et al note that the commissioner did not appear to have a legislative mandate to address patient safety, but did have a quality mandate, which may be interpreted by the commissioner to include safety.[1510] Finally, in 2005, Ontario announced it was establishing a Health Quality Council to monitor and report publicly on health system outcomes as part of its *Commitment to the Future of Medicare Act, 2004*.[1511]

The difference in approach is apparent. In Britain, the focus is on a very specific assessment of an NHS Trust or other similar facility's quality and safety outcomes, and their processes. Performance indicators are clear; independent assessment occurs; and there are accountability mechanisms. In Canada, the focus is on the system more generally: it does not involve assessing individual providers, and a global, less intrusive, less prescriptive approach is preferred.

[1504] Alberta's Health Quality Council was established by Ministerial Order in 2004, but was already in operation as the Health Services Utilization and Outcomes in Commission.

[1505] Alberta, Health Quality Council of Alberta, *Annual Review 2003-2004: A Catalyst for Positive Change* (Calgary: Health Quality Council of Alberta, 2004).

[1506] *Ibid.*

[1507] *Act Respecting the Health and Welfare Commissioner, supra* note 1484.

[1508] *Ibid.*

[1509] *Ibid.*

[1510] Downie, *supra* note 28.

Information and Accountability

Evaluation of a system's strengths or weaknesses in respect of patient safety and service quality rely on good information. In both jurisdictions, little aggregate data had been collected on outcomes, with the focus for data collection being on inputs and outputs that are easier to measure. Also, in both jurisdictions, the collection of such data had traditionally been the preserve of the professions and was highly localized in effect. In other words, aggregate data was seldom collected. In Britain, as part of the monitoring and evaluation process, more extensive informational systems were developed. This enabled both assessment of an NHS Trust or health system's performance, but the data could also be used to inform a variety of accountability mechanisms. The accountability mechanism of choice was the issuance of public report cards. Public report cards involve the development of systems to collect, aggregate, and compare data relating to system performance, particularly in regard to safety and quality. The dataset is sufficiently broad to enable a clear conclusion to be reached about the performance of the organization relative to other similar organizations. A public 'report card' is then created and is made publicly available.

It is suggested that public reporting of performance ratings for individual organizations through a 'report card' might create a positive impact on the health system in two ways: consumer pressure will create upwards pressure on standards (even in public systems like the NHS); and concern about damage to the institution's reputation, or about public humiliation, will motivate quality and safety improvements.[1512] In fact, the system has been described as a naming and shaming mechanism.[1513] In Britain, the *Health and Social Care (Community Health and Standards) Act 2003*[1514] established a mandatory public report cards scheme for NHS organizations where each institution would be assigned a star rating. Under this scheme the CHI/Healthcare Commission, with the assistance of the organization whose performance is being examined, gathers data relating to safety and quality indicators. The Healthcare Commission then analyzes the data, compares it with other similar institutions, assigns a

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[1511] *Commitment to the Future of Medicare Act, 2004,* S.O. 2004, c. 5.

[1512] Newdick, "N.H.S.", *supra* note 26.

[1513] Bevan, *supra* note 1490 at 90.

[1514] *Health and Social Care Act, supra* note 723 s. 49 & 50.

performance rating, reports to government, and publicly publishes the data and the star rating. Compliance is mandatory.

It has been suggested that the use of public report cards engages management in a commitment to quality and safety and results in increased collaboration with clinical leaders to institute meaningful change.[1515] The star ratings awarded to NHS Trusts gradually improved against increasingly tougher performance indicators, indicating, according to the Healthcare Commission, improved performance overall.[1516] However, it is also suggested that star rating narrowed the focus to elements of clinical governance that could be scored, many of which may have been of little importance when considering actual safety and quality.[1517]

In Canada, a different approach was taken. A few provinces created legislatively mandated frameworks for province-wide adverse event reporting systems.[1518] Saskatchewan was the first province to institute mandatory reporting of adverse events to its Health Department.[1519] Their legislation also requires investigation of critical incidents and the production of a report detailing the circumstances surrounding the incident, any factors that may prevent a recurrence, past actions, and future steps to be taken as the result of the investigation, and any other recommendations.[1520] In Québec, any person working in an institution providing health services was legally required to report accidents or incidents within the facility in which they work.[1521] Anonymized reports must also be submitted to the regional board. Manitoba passed legislation in June 2005 containing mandatory critical incident reporting requirements, similar to those in Saskatchewan, but the Act was not proclaimed as of 30 December 2005.[1522]

[1515] R. Steyn, "Evidence for Quality Improvement" (Panel discussion at the International Conference on the Scientific Basis of Health Services, September 2005).

[1516] U.K., Healthcare Commission, News Release/Communiqué, "Star Ratings Show NHS Improving Against Tougher Targets" (27 July 2005) online: Healthcare Commission <http://www.healthcarecommission.org.uk/NewsAndEvents/PressReleases/PressReleaseDetail/fs/en?CONTENT_ID=4018735&chk=kAV%2BG2>.

[1517] Bevan, *supra* note 1490.

[1518] Downie, *supra* note 28.

[1519] *Regional Health Services Act,* R.S.S. 2002, c. R-8.2, s. 58; Downie, *supra* note 28.

[1520] *Regional Health Services Act, ibid.*

[1521] *Health Services and Social Services Act*, *supra* note 1462, s. 233.1.

The Canadian Institute for Health Information collects data about a very limited range of safety indicators, and results are publicly published.[1523]   However, individual institutions are not given a performance ranking on the basis of the indictors which, in any case, are too few to make such an assessment. Until the end of this period there was no real way of knowing in Canada just how well or how poorly health facilities were performing and how safe the care within those facilities.

Public Inquiries

In Chapter 2, central inquiry mechanisms were identified as public inquiry processes convened pursuant to statutory authority contained either in a general public inquiry-type act or in specific provisions in the legislation establishing the health system. There were also non-statutory inquiries and parliamentary inquiries. In addition, coronial inquiries (inquests) may occur. The general conclusion was that these mechanisms were used sparingly in the context of patient-safety-related issues.

From the period 1980–2005, as identified in Chapter 6, there were many patient-safety focused inquiries in the British context. This led Walshe and Higgins, in 2002, to reach a number of conclusions. First, the number and scope of inquiries seemed to be increasing (inside and outside healthcare). Second, inquiries increasingly focused on matters of clinical performance. Third, problems that may have in the past been dealt with internally are now subject to greater external scrutiny and transparency. Fourth, considerable duplication appears to occur between multiple inquiry processes.[1524]   So many inquiries were in fact convened and called for that the Cabinet Office issued guidance as to the circumstances in which a public inquiry should be held.[1525]   These guidelines suggested that consideration needed to given as to whether serious harm or loss had occurred; whether the circumstances raise new or poorly understood issues of concern; and whether the events caused widespread

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[1522] *The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*, S.M. 2005, c. 24.
[1523] The Canadian Institute for Health Information is an independent agency funded by the provinces/territories and federal government to collect, analyse and publish statistical health information. Online at: CIHI <http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=home_e>.
[1524] Walshe, *supra* note 295.
[1525] U.K., Cabinet Office Central Secretariat, *Guidance on Inquiries,* (London: Cabinet Office, 2001).

public concern and loss of confidence.[1526] The number of inquiries inside and outside the NHS led to what some commentators describe as a sense of inquiry fatigue.[1527]

Further than this, though, concern about the performance of the NHS was so great that the institution of the further specialised process for independent inquiry into the operations and performance of the NHS was felt to be an imperative. One of the functions of the Commission for Health Improvement, established in 2001 (now the Healthcare Commission) is:

> the function of carrying out investigations into, and making reports on, the management, provision or quality of health care for which Health Authorities, Primary Care Trusts or NHS trusts have responsibility.[1528]

Thus, the practices of public inquiry were ritualized within the system through the creation of an entity charged with, among other things, investigating aberrations within systems of care. It did not only ritualize inquiry processes; the step of establishing such an inquiry sends a message to the public that the current system is in such a state that there will most certainly be further instances of failures in service provision warranting independent review. Actions taken by authoritative social actors such as government are, as MacGregor phrases it, "in a sense, regenerative and len[d] additional credence and validity to concerns already being expressed in the media."[1529] So in Britain, a greater employment of and an expansion of available public inquiry mechanisms within the health sector can be seen. This is consistent with the general approach of the NPM, which creates mechanisms for greater oversight (and control) of operational measures by the central state in the name of enhancing accountability and transparency.

Conversely, there were few patient-safety-related inquiries in the Canadian context during the period in question. There was no similar development of a specialist inquiry entity in any Canadian jurisdiction, other than what already existed. The existing mechanisms for public

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[1526] *Ibid.*
[1527] Butler & Drakeford, *supra* note 817; Stanley & Manthorpe, *supra* note 818.
[1528] *Health Act 1999, supra* note 694, s 20(1)(c).
[1529] MacGregor, *supra* note 969 at 261.

inquiry were obviously deemed adequate to manage any issues that might arise. Many such matters would remain the purview of an internal review.

Conclusion

What the analysis in this chapter demonstrates is a shift in the forms of regulation used to assess patient safety issues within each jurisdiction. In examining the regulatory configuration in Canada, we see measured incremental change that remains broadly consistent with the pre-1980s regulatory consensus. This consensus relies to a great extent upon what Mello termed "an unparalleled faith in the ability of medical professionals [and other health-providers] to regulate themselves."[1530] Although the tenets of the NPM caused some transference of authority from the hospitals to regional health authorities, and some – largely unsuccessful – efforts to rein in expenditure associated with the provision of medical services by a doctor; in general faith remains a strong underpinning of the framework. While the latter part of the period saw some patient-safety-directed initiatives, these were generally intended to support professional initiatives. In short, governments trust and collaborate or co-regulate with the professions.

In Britain, the regulatory direction changed markedly over the period with a greater use of mechanisms to control the activities of professionals and the NHS. The increasing layers of control, with increased use of monitoring and audit activities, are the hallmarks of a regulatory framework that has lost faith in key institutional actors. While keeping those actors in place, the state has instituted layers of regulatory controls to monitor performance, especially service safety and quality, in the public interest. In Britain, trust is only possible through what Power describes as "rituals of verification".[1531]

There is at this stage no evidence to suggest that one regulatory approach achieves greater patient safety or service quality over another, and indeed that is not the focus of this analysis. What the differences do suggest is that the inherent logics of a system, combined with external factors such as a shift in governance styles and numbers and character of scandals and the associated perceptions of risk, can result in a significant regulatory realignment. In

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[1530] Mello, "Fostering Regulation", *supra* note 5 at 375.

the absence of those factors, we see more incremental and minor shifts, remaining largely consistent with the pre-existing regulatory logics.

[1531] Power, *supra* note 597.

Chapter 8
Conclusion

Research Findings

Between 1980 and 2005 patient safety emerged as a pressing issue of social and political concern. Evidence demonstrated that many thousands of people die or are injured as the result of preventable adverse events associated with the provision of treatment and care. The total cost to health systems and to communities more generally is high, both in terms of its fiscal effect on the economy and the operation of health systems,[1532] but also its effect on family, community, and society. The emergence of patient safety as an important policy issue during this period raised a number of questions. Do governments regulate the common issue of patient safety differently? If they do, why do they? More specifically, why did Britain and Canada, which had similar regulatory frameworks to address patient safety in the 1980s, subsequently choose to regulate patient safety differently? What factors led to the divergences in their regulatory frameworks? Understanding how the state's regulatory initiatives address patient safety is an important public issue that warrants scholarly analysis, both for what it can tell as about the factors leading to the reform of regulatory frameworks and the substance and shape of those frameworks and because of the potential impact of these frameworks on the welfare and wellbeing of the millions of people who access health services each year. The analysis in this thesis highlights factors that influence government's determination that regulation is required and shapes the choice of regulatory instruments that it employs.

In 1980 Britain and Canada had very similar regulatory frameworks addressing patient safety related concerns. The underlying rationale driving the design of these regulatory frameworks was, to quote Mello et al, "an unparalleled faith in the ability of medical professionals [and other health-providers] to regulate themselves."[1533] Other social needs, such as compensation for those harmed due to the provision of health services and deterrence, were achieved by supplementing the self-regulatory premise with the mechanisms of tort and

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[1532] As an example, in 2000 the U.K., Department of Health estimated that the cost to the NHS of the additional hospital days alone amounted to £2 billion per year. U.K., Department of Health, *An Organisation with a Memory,* (London: Department of Health, 2000).

[1533] Mello, "Fostering Regulation", *supra* note 5.

criminal law. Law was also used to establish basic minimum standards for the operation of health facilities.

At least until 1980, differences in overall regulatory contexts and in the structures of health systems did not make any difference to the convergences in the existent regulatory frameworks for patient safety. However, divergences in the broader governance context and in health system design created the conditions or system logics that would influence the shape of any future regulation. In Britain, the health system, although corporatized and devolved, was also centralized and statist, creating a logic supporting further centralizing impulses by the state. In Canada, the health system was decentralized and often co-regulatory in its habits of governance. These respective logics would shape and influence future regulation within health systems in the decades to come.

The differences in constitutional structures were perhaps the weakest source of divergence in terms of its significance for influencing any future regulatory direction; no surprise given that the implications of constitutional contexts on regulation are contested by many. Bearing these limitations in mind, I suggest that constitutional structures can matter for processes of substantive policy transformation. Unitary states, like Britain, are said to be more inclined to institute significant regulatory change whereas federal states, like Canada, can be generally less inclined to institute significant change. There is some kernel of truth in this, but exceptions to this rule are also easily identified. What does seem to be the case is that if a Canadian province or territory undertakes a significant regulatory reform (one that is not due to cross-provincial negotiations), the rest often adopt an approach of simply observing whether it works or not and evaluating whether local conditions require similar reforms. The habits of governance in each jurisdiction may also be sufficiently dissimilar to create a point of subsequent divergence, although this point too is contestable. The relevance of this point to patient safety comparisons between Britain and Canada is that the habits of executive federalism in Canada may permeate other levels of policy and regulatory action, to create, in general, a co-regulatory governance impulse at the federal/provincial level and in the provincial approach to working with other actors within the health system. In contrast, the centralizing tendencies at the heart of the British system somewhat mitigate against a similar co-regulatory approach. Lastly, I argued that changes to cultural perceptions about health

systems, the levels of risk associated with such systems and trust relationships with dominant social actors have been experienced differently in each jurisdiction. Canadian society has been somewhat less affected by the concepts and attitudes of risk and post-trust societies, at least in the context of healthcare, than Britain.

Not surprisingly, the extent to which the tenets of the NPM permeated into the clinical sphere in the requisite health systems was another source of divergence. In Britain, the strong ideological convictions of the Thatcher Conservative government, deeply suspicious that the NHS was captured by the interests of the professions facilitated the deep penetration of the NPM into the formerly sacrosanct clinical sphere. This process continued with even greater conviction under the 'New Labour' government, because of that government's centralizing tendencies and due to the pressure of events. Within the multiplicity of Canadian governments at the federal and provincial levels, NPM was also at least somewhat influential. However, in general, the penetration of the tenets of the NPM within health systems was limited and the sphere of professional autonomy over clinical matters was largely maintained. I argued that this was due to a lesser degree of ideologically driven suspicion of the professions, the logics of the Canadian health systems with their arms-length accommodation between governments and the medical profession, especially in regard to clinical issues, and the co-regulatory logic of these systems.

The analysis in this thesis illustrates that events may be a powerful driver of change if certain conditions are met. In Britain, a significant number of scandals within the health system, separately and in aggregate, raised questions about the accepted regulatory norms in respect of patient safety. These scandals raised the public's perception of the risks associated with the provision of health services, illustrated reasons why trust in established actors could be questioned, and raised concerns about the adequacy of existing prospective and retrospective forms of accountability. This cycle placed the acceptability of existing regulatory norms in question and created a demand for greater control by the state of the health system and of the delivery of healthcare in general. Conversely, in Canada the relative paucity of scandals did not do much to heighten public perceptions of risk, except arguably in the narrow context of public health. The few scandals that emerged indicated that current governance mechanisms seemed largely (except in the public health context) to be working, hence trust

in processes and actors was maintained. Accountability mechanisms also seemed to be reasonably effective. Accordingly, the acceptability of regulatory norms in patient-safety regulation in Canada was not seriously in question, and there was no overwhelming demand for greater state control through regulation.

By 2005 the regulatory convergence about patient-safety regulation, evident at the end of the 1970s in both jurisdictions, was in tatters with significant divergences seen in each jurisdiction's regulatory framework. While Canada has remained largely faithful to the shape and form of the pre 1980s regulatory norms, Britain has not. The scope and shape of Britain's framework for regulation of patient safety has been subject to a fairly radical reinterpretation where the state assumes greater responsibilities within the sector for ensuring, as much as it is possible to do so, patient safety.

Thus, at one end of the regulatory spectrum we have the hyper-regulation that is said to characterize British governance.[1534] This process of regulation is said to strengthen state power through the monitoring and oversight of actors within the health system (a top-down approach) that goes with state regulation. Towards the other end of the spectrum, we have Canadian governments which, certainly in the health context, have tended to favour collaborative measures drawing upon the expertise and professionalism of health professionals, supported by government (a bottom-up approach).

So why do governments regulate the same issue, patient safety, in very different ways? What governments chose to do and how they choose to do it is a function of the perceived need for action and the dominant social and political norms within that society. Regulatory action in the patient safety context is also influenced by the logics of the health system, constitutional structures, and the habits of governance within each jurisdiction. It appears that context is everything in the formulation of regulatory approaches to address pressing social problems.

[1534] See, for example, Moran, *British Regulatory State, supra* note 820.

Implications for Governance, Regulation, and Policy

The conclusions of this thesis have important implications for the practice of governance, regulation, and policy formation. Understanding the context in which regulation is formed is important. From a theoretical perspective, it is important to assess the interaction of law with society and society with law, and accordingly how law, or regulation in this context, affects and is affected by the behaviour of individuals, groups, and organizations.

From a more functional perspective, a comparative analysis of the origin and shape of regulatory frameworks allows us to learn more about the characteristics and norms of our legal frameworks and their sites of operation in our society. It further allows us to learn from the experiences of others and to assess what motivates regulation in different contexts. In practice, regulatory actors look across borders to draw upon the ideas and experiences of others, a phenomenon only enhanced by technology and globalization, but we must be wary of approaches that simply look elsewhere and lift promising-looking regulatory innovations for use in other contexts. Comparative analyses place regulatory innovations in their context, illustrating the rationales for regulation, and behind choices of regulatory instruments. As such, comparative examinations enable evaluation of the likely success of any proposed policy and regulatory innovation, in terms at least of its implementation, in one's own jurisdiction. This research may therefore help us understand how regulatory innovations from other countries may or may not be readily adaptable to different social, legal, and political contexts.

Patient safety is a significant problem in health systems internationally: "[i]f errors were a disease, we would call it an epidemic."[1535] It is also a significant challenge: "[t]he real problem isn't how to stop bad doctors from harming, even killing, their patients. It's how to prevent good doctors from doing so."[1536] There is no one way of addressing patient-safety issues, but it is an issue that is receiving increasing attention both from a policy and regulatory perspective. If policy-makers intend to employ regulation in this area, they need to be aware of history and context and the role that these factors have played in determining

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[1535] John M. Eisenberg cited in M. Graham, *Democracy by Disclosure: The Rise of Techno-Populism,* (Washington DC: The Brookings Institution, 2002) at 104.
[1536] A. Gawande, "When Doctors Make Mistakes" *The New Yorker* (1 February 1999) 40.

whether there should be regulatory intervention and in what form. Top-down approaches to the regulation of patient safety are not solely directed only at the patient-safety problem; there are also a variety of other political and policy ends being served. Bottom-up or collaborative approaches to regulation are also not solely about patient safety; there are other reasons and rationales that support the choice of one form of regulation over another.

Contributions to Scholarship

This thesis makes several important contributions to scholarship. In terms of the literature, while the instruments of the regulation of patient safety have been the focus of much attention from the clinical and policy perspective, comparative analysis of the development of regulation in this area has been, at best, slight. This thesis, then, addresses this important issue and remedies the gap in existent research. In so doing, it makes a contribution to comparative health policy scholarship and to comparative regulatory scholarship. It also makes a contribution to the literature focusing on sociology of law as it explores the social forces which bring about evolution or changes in the law.

In terms of theory, my thesis makes several contributions. Path dependency and similar theories have been criticized for not providing a necessary or sufficient condition to understand or explain the processes leading to policy change[1537] – its orientation is fundamentally to answer 'how' questions. This thesis then contributes to the theory's ability to ask 'why' questions, by integrating within it social, regulatory, and public policy (governance) theory. An inquiry focusing on why governments chose certain regulatory instruments for application in a highly complex, highly politicized arena (the health system) to address a problem which, like patient safety, raises a multiplicity of challenges touching on individual and organizational psychology, requires interrogation through a sophisticated paradigm of analysis. My thesis further contributes to theory by extending conventional policy-cycle analysis to include the important (certainly in the context of the audit, risk, and blame societies paradigms) variable of accountability. The application of this extended policy cycle to classify scandals, rather than the traditional examination of their content or focus,

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[1537] Kay, *supra* note 47.

also enables us to better explain why some scandals result in regulatory change, while others do not.

Future Research and Final Comments

While there is increasingly more discussion of different facets of patient-safety regulation in the literature, a focus on comparative examinations of cross-national regulatory regimes remains sparse. Research that raises the 'why' question and attempts to trace divergences and convergences in the development and direction of the regulation of patient safety in a comparative context is even rarer. There is much potential here for future work, as many questions remain unanswered.

This thesis examines some aspects of the 'why' and 'how' of regulation in Britain and Canada, but does not touch upon the enduring "Well, does it really work?" question. Does the hyper-regulatory audit culture seen in Britain result in safer care for patients, as compared with the Canadian professionalism model, or is there no difference at all? I am particularly interested in assessing what impact, if any, regulatory initiatives actually have on organizational culture but that must remain a project for the future.

Another direction of inquiry could be in regard to constitutional arrangements: are these an important variable to determine regulatory direction? Does another federal country, like Australia, have a similar regulatory framework for regulating patient safety to that seen in Canada? If not, what are the important variables that dictated why and how Australia regulated patient safety? Are there convergences or divergences between the unitary states of Britain and New Zealand, both countries in which NPM saw the greater penetration into the public sector?

This research ends in 2005, but there have been a number of developments in both jurisdictions since that date. Canada, for example, has seen the advent of several high-profile scandals relating to health services, including screening practices in Newfoundland[1538] and

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[1538] Newfoundland & Labrador, Commission of Inquiry on Hormone Receptor Testing, *Commission of Inquiry on Hormone Receptor Testing* by M. Cameron (St. John's: Queens Printer, 2009).

pathology practices in Ontario[1539] and New Brunswick.[1540] It remains to be seen whether these scandals, and any others that may arise, will seriously affect the trust vested in the management of Canadian health systems, in health professional regulators, and in the health professions to prevent or to respond appropriately to matters of public concern. It is also interesting to continue to watch developments in Britain, particularly in the context of government-sanctioned self-regulation which continues to be the cause of some concern. From 2011, the independent Office of the Health Professions Adjudicator will make decisions on fitness-to-practise cases brought forward from the GMC and the General Optical Council (these include health, performance and disciplinary matters).[1541]

The internationalization of the problem of ensuring patient safety is also worthy of attention. As a problem of global concern, a broad consensus seems to emerging in terms of bottom-up approaches to patient safety, for example, the near universal adoption of hand-washing campaigns to prevent the spread of infection. It is uncertain at this time whether globalization will have the same effect on the regulatory context resulting in regulatory convergence or whether national divergence will continue to be the norm.

What is undoubtedly and incontestably true is that the health system will continue to be the subject of analysis and reform and that patient safety will remain a focus of attention. If nothing else, it will remain so because we all owe a duty, whether it be moral, ethical, or legal, to take all possible steps to ensure the safety of those accessing health services. The consequences and costs to us all of the unnecessary and preventable deaths and injuries of family members, friends, or – as Lord Atkin's famous dictum in *Donohue v Stevenson*[1542] would put it, our neighbours – as a result of adverse events within our health systems are too high.

[1539] Ontario, Inquiry into Forensic Pediatric Pathology in Ontario, *Inquiry into Forensic Pediatric Pathology in Ontario: Report* by S. Goudge (Toronto: Queen's Printer, 2008).
[1540] New Brunswick, Inquiry into Pathology Services at the Miramichi Regional Hospital, *Inquiry into Pathology Services at the Miramichi Regional Hospital* by P. Creaghan (Fredericton, Department of Health, 2008).
[1541] *Health and Social Care Act 2008* (U.K.), c.14, pt 2.
[1542] *Donoghue, supra* note 177, per Lord Atkin.

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