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EDITOR'S NOTE — OPEN ACCESS TO LEGAL SCHOLARSHIP

Josh Wilner*

Open access could be the next step in a tradition that includes the printing press and penny post, public libraries and public schools. It is a tradition bent on increasing the democratic circulation of knowledge ...¹

What began four years ago as an ambitious, student-initiated pilot project called the *McGill Health Law Publication* is today reborn as a full-fledged academic journal. It is with great pleasure that I present on behalf of our team of volunteer student editors the inaugural issue of the *McGill Journal of Law and Health* ("MJLH") / *Revue de droit et santé de McGill* ("RDSM"). With the drafting of our constitution we have planted the seed of our very own living tree—an embodiment of what is sure to be a lasting institution at McGill's Faculty of Law. We are a new voice in legal publishing, a field that is in need, in particular, of more specialist journals.²

À tous ceux qui ont donné leur support à cette initiative croissante dès son instauration il y a à peu près quatre ans — et particulièrement au doyen Nicholas Kasirer, aux professeures Angela Campbell et Lara Khoury, et à l'ensemble de notre comité consultatif — j'aimerais exprimer mes remerciements les plus sincères. J'aimerais aussi remercier ma collègue et amie Virginie Marier, qui me succèdera comme rédactrice en chef pour le prochain volume de la revue, pour sa vision et son leadership dans notre renaissance comme le *RDSM*.

In making its peer-reviewed content available free of charge on the internet (see www.mjlh.mcgill.ca), the *MJLH* is unique among Canadian law journals. The advent of so-called "open access" publishing offers a new model for the operation of scholarly journals, and its promise is reflected in the expanding literature—both general³ and specifically legal⁴—devoted to this pioneering concept. An oft-quoted definition of "open access" stems from a meeting convened in Budapest by the Open Society Institute in 2001, the purpose of which was to "accelerate progress in the international effort to make research articles in all academic fields freely available on the internet":

* Editor-in-Chief, *McGill Journal of Law and Health*, Vol. 2.

¹ John Willinsky, *The Access Principle: The Case for Open Access to Research and Scholarship* (Cambridge, Massachusetts: MIT Press, 2006) at 30.

² Bruce Ryder, "The Past and Future of Canadian Generalist Law Journals" (2001) 39 *Alta. L. Rev.* 625.

³ See e.g. Leslie Chan, "Supporting and Enhancing Scholarship in the Digital Age: The Role of Open-Access Institutional Repositories" (2004) 29 *Canadian Journal of Communication* 277; Dominique Foray, *The Economics of Knowledge* (Cambridge, Massachusetts: MIT Press, 2004); R. Kling & E. Callahan, "Electronic Journals, the Internet and Scholarly Communication" (2003) 37 *Annual Review of Information Science and Technology* 127; R.P. Peek & G.B. Newby, eds., *Scholarly Publishing: The Electronic Frontier* (Cambridge, Massachusetts: MIT Press, 1996).

⁴ See e.g. *Declaration on Public Access to Law*, online: World Legal Information Institute <<http://www.worldlii.org/worldlii/declaration/>>; Science Commons Open Access Law Program, online: Open Access Law Program <<http://sciencecommons.org/projects/publishing/oalaw/>>; Open Access Law Canada, online: OALC <<http://www.openaccesslawcanada.ca/>>; Caroline Christiansen, "Electronic Law Journals" (2002) 30 *Int'l J. Legal Info.* 337; Dan Hunter, "Walled Gardens" (2005) 62 *Wash. & Lee L. Rev.* 607; Richard A. Danner, "Applying the Access Principle in Law: The Responsibilities of the Legal Scholar" (2007) 35 *Int'l J. Legal Info.* 355; and the numerous articles resulting from a recent symposium on open access in law, including Lawrence B. Solum, "Download It While It's Hot: Open Access and Legal Scholarship" (2006) 10 *Lewis & Clark Law Review* 841; Michael J. Madison, "The Idea of the Law Review: Scholarship, Prestige and Open Access" (2006) 10 *Lewis & Clark Law Review* 901; Michael W. Carroll, "The Movement for Open Access Law" (2006) 10 *Lewis & Clark Law Review* 741; Ann Bartow, "Open Access, Law, Knowledge, Copyrights, Dominance and Subordination" (2006) 10 *Lewis & Clark Law Review* 869.

By “open access” to this literature, we mean its free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited.⁵

This touchstone definition of “open access” defines a model that is susceptible of many forms and degrees of application. “Open access” is, in reality, an umbrella concept that comprises numerous variations in practice: for John Willinsky, Professor of Education in the Department of Language and Literacy at the University of British Columbia, there are ten “flavours” of open access.⁶ In what might be considered a recognition of the merits of open access, the Supreme Court of Canada is presently considering posting court files online.⁷

L'application de ce principe multiforme mais aussi unifiant dans le domaine juridique ne peut pas procéder sans considération de la nature même de la doctrine juridique. Comme l'a dit Madison, «Open access for law reviews really invites a hard look at law reviews and legal scholarship in general»⁸. Le modèle libre accès se prête particulièrement bien au domaine juridique, comme le reconnaît la professeure américaine Jessica Litman, réputée dans le domaine des droits d'auteurs: «Law journal publishing is one of the easiest cases for open access publishing»⁹. L'application d'un principe de libre accès au Québec invite à réfléchir sur le caractère privilégié—auprès des juridictions de «common law»—de la doctrine comme source formelle de droit dans les juridictions de droit civil.

Implementing open access in legal publishing also invites reflection on the placement and role of law journals within law faculties. According to one commentator,

When law reviews are based in law schools, they serve a larger purpose — they proclaim that law schools are not trade schools, but are citizens of the scholarly community and the broader public community, participating in contemporary debates. By their existence, law reviews remind us that law is not only a practice, but also an intellectual discipline and pursuit.¹⁰

In terms less political, working on a legal journal can be considered part of, not an addition to, a legal education; the work of editors is curricular, not extra-curricular. In terms more political, law faculties and law students are citizens of the greater communities within which they exist and live, contributing to debate and dialogue by engaging in public fora.¹¹

The open access format of the *MJLH* reflects the journal's institutional commitment that high-quality, peer-reviewed research is a public good that should be available to all. The journal's mandate is informed by the *access principle*, which articulates an ethical obligation

⁵ See online: Budapest Open Access Initiative <<http://www.soros.org/openaccess/>>. To date, the Initiative has 5,225 signatories, including Université de Montréal, Université Laval, the Conférence des recteurs et des principaux des universités du Québec, the Canadian Library Association, the Fonds québécois de la recherche sur la nature et les technologies Québec, the United Nations Food and Agriculture Organization, and Massachusetts Institute of Technology Libraries.

⁶ See Willinsky, *supra* note 1 at 212-217, appendix A. The ten flavours of open access are homepage, e-print archive, author fee, subsidized, dual-mode, delayed, partial, *per capita*, indexing, and cooperative.

⁷ Janice Tibbetts, “High court weighs putting files online: Decision expected this fall on electronic access” *Ottawa Citizen* (28 July 2008) A2. Mick Ryan, chair of the Canadian Bar Association committee that has been working with the Supreme Court on this issue, is quoted in the article as saying, “I think it's inevitable that it will happen because the courts are really concerned about having an open access policy and being transparent.”

⁸ Madison, *supra* note 4 à la p. 902.

⁹ Jessica Litman, “The Economics of Open Access Law Publishing” (2006) 10 *Lewis & Clark Law Review* 779 à la p. 783.

¹⁰ Donna Grescher, “Law Reviews as Cultural Narrative” (2001) 39 *Alta. L. Rev.* 616 at 623.

¹¹ For a novel argument that Wikipedia should be used as a tool for engaging law students in their education, allowing for collaboration, participation, and debate, see Beth Simone Noveck, “Wikipedia and the Future of Legal Education” (2007) 57 *J. Legal Educ.* 3.

for journals and other institutions of learning to disseminate the work they publish as widely as possible:

“The access principle”: A commitment to the value and quality of research carries with it a responsibility to extend the circulation of such work as far as possible and ideally to all who are interested in it and all who might profit by it. What follows on this principle, given the current transformation of journals from print to online formats, is that researchers, scholarly societies, publishers, and research libraries have now to ask themselves whether or not they are using this new technology to do as much as can be done to advance and improve access to research and scholarship.¹²

The access principle is more than a mere theoretical aspiration. It has recently found concrete expression in the granting policy of the Canadian Institutes of Health Research (“CIHR”), the primary federal agency responsible for funding health research in Canada. In unveiling the *Policy on Access to Research Outputs*¹³ in September 2007, former CIHR President Dr. Alan Bernstein stated:

With the development of the internet it is now feasible to disseminate globally and easily the results of research that we fund. As a publicly-funded organization, we have a responsibility to ensure that new advances in health research are available to those who need it and can use it—researchers world-wide, the public and policy makers.¹⁴

The National Institutes of Health, part of the U.S. Department of Health & Human Services, has a similar *Public Access Policy*.¹⁵ In March 2008, notably, the Harvard Law Faculty voted unanimously to make each faculty member’s work available online for free.¹⁶ These significant developments are evidence of an increasing recognition that with the creation of knowledge comes a responsibility for its dissemination. The *MJLH* is proud to be a part of this developing trend.

Le potentiel du libre accès, néanmoins, n’est pas encore complètement réalisé. Le concept d’*accès*, comme celui de *libre accès*, est une question de degré. La prochaine étape dans le mouvement vers le libre accès sera d’adapter les moteurs de recherche à la doctrine publiée en ligne pour rendre leur découverte aussi facile que celle des autres outils de recherche dans les banques de données.¹⁷

To accomplish this goal, more information is required *about* information. Scholarship published online can be catalogued using descriptive “metadata tags” and thereby made searchable from a centralized database. This is what the Budapest Open Access Initiative means when it refers to “crawling” open access articles for indexing. A prime example of the full potential of open access publishing, albeit in nascent form, is OAIster,¹⁸ which “harvests” metadata and centralizes it in a searchable directory.

As Danner notes, “... information technology is changing the traditional roles and future possibilities for the existing parties in the system of scholarly communications: scholars (as both creators and users of scholarly information), publishers, and libraries.”¹⁹

¹² Willinsky, *supra* note 1 at xi [emphasis omitted].

¹³ See online: CIHR <<http://www.cihr.ca/e/34846.html>>.

¹⁴ CIHR, News Release, 2007-32, “Open access to health research publications: CIHR unveils new policy” (4 September 2007), online: CIHR <<http://www.cihr-irsc.gc.ca/e/34851.html>>.

¹⁵ See online: U.S. Department of Health & Human Services <<http://publicaccess.nih.gov/>>.

¹⁶ Harvard Law School, News Release, “Harvard Law faculty votes for ‘open access’ to scholarly articles” (7 May 2008), online: Harvard Law School <http://www.law.harvard.edu/news/2008/05/07_openaccess.php>.

¹⁷ Madison, *supra* note 4 à la p. 917 note 49.

¹⁸ See online: OAIster <<http://www.oaister.org/>>.

¹⁹ Richard A. Danner, “Electronic Publication of Scholarly Information in Law: A View from the United States” (2000) 28 Int’l J. Legal Info. 465 at 467-8.

Avec toutes ces possibilités de développements excitants à l'horizon, le futur de la plus jeune revue de la Faculté de droit de McGill, la *Revue de droit et santé de McGill*, est des plus prometteurs.

À votre santé!

POLICY BY PROCRASTINATION: SECONDARY USE OF ELECTRONIC HEALTH RECORDS FOR HEALTH RESEARCH PURPOSES

*Patricia Kosseim and Megan Brady**

Driven by government priorities and significant financial investments, stakeholders in Canada are working actively to develop and deploy pan-Canadian, interoperable electronic health record (EHR) systems. Efforts to date have concentrated primarily on health care purposes only. However, limiting the design and incremental roll out of such systems for this primary purpose now will only increase the complexity of allowing access to electronic health records for secondary research purposes later.

The likely effect of deferring questions concerning secondary uses will be an exacerbated policy dilemma that drives solutions further away from the well-established norm of voluntary and informed consent as a core component of privacy protection. We argue that such a shift—if or when it happens—should not occur without critical reflection, open policy debate, and a democratic decision-making process. In particular, a shift away from consent as a key pillar of privacy protection in the health system must not, in our view, be motivated solely by technological design and feasibility considerations—issues that arise as an automatic consequence of other, merely pragmatic choices being made today.

To avoid succumbing to technological pressures and letting practical expedience determine fundamental public policy choices, we need to examine what viable alternatives exist that could permit access to EHR data for research purposes, and under what conditions this might be accomplished. In this paper we outline what some of those policy alternatives might be, beginning with specific informed consent and moving towards broad consent, implied consent, no consent, consent waiver, and retroactive deemed consent. Through this spectrum of options we attempt to demonstrate why legal and policy considerations require early reflection and up-front integration into systems as they are being designed. By setting out a range of policy options to address research access to EHR systems and discussing their implications, this paper aims to support informed deliberations about available choices before technological imperatives pre-determine the selection for us.

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INTRODUCTION

Driven by government-announced priorities and significant public and private sector investments, stakeholders in Canada are working actively on developing and deploying pan-Canadian, interoperable electronic health record (EHR) systems. Efforts to date have concentrated primarily on developing and deploying interoperable EHRs for care and treatment purposes only. The design and incremental roll out of EHR systems for this limited purpose *now* will increase the complexity of determining access rights to EHRs for secondary purposes *later*.

The likely effect of deferring questions concerning secondary uses is an exacerbated policy dilemma that drives solutions away from the current and well-established norm of voluntary and informed consent. We argue that such a shift should not occur without critical reflection, open policy debate, and a democratic decision-making process. In particular, a shift away from consent as a key pillar of privacy protection in the health system must not, in our view, be driven solely by technological expedience and design and feasibility considerations—issues that arise as an automatic consequence of other, merely pragmatic choices being made today.

There are many potential secondary uses for electronic health data. These include uses in furtherance of public health surveillance, health system planning and management, quality assessment, health research, mandatory reporting, employment, insurance, drug marketing, and law enforcement purposes. This article, however, will examine the specific case of health research as a secondary use. We focus primarily on the fundamental issue of consent.

I

BACKGROUND

A. The Expansive Vision of EHRs

In 1997, an Advisory Council on Health Info-Structure was commissioned by the Federal Minister of Health. The purpose of the Advisory Council, made up of independent experts, was to provide strategic advice on how information technologies and systems could best support and promote more informed decision-making by health professionals, administrators, planners, policy-makers, and individual Canadians. Its mandate was to guide the development of an integrated Canadian health information info-structure by ensuring, among other things, that both health care and broader public health requirements would be addressed throughout Canada.¹ The pan-Canadian info-structure was envisaged as a broad, powerful, and seamless information resource that would facilitate the integration of health services and enable continuous improvement through evidence-based decision-making and more optimal policy choices resulting from enhanced empirical research.

In the press release dated September 30, 1998, which accompanied the Advisory Council's public call for comments on its interim report *Connecting for Better Health: Strategic Issues*, Alan Rock, the then Minister of Health, was quoted as saying:

We must harness information technology to create a coherent, seamless system, one that will collect, integrate, and provide reliable and consistent information – from clinical decisions to laboratory research, from policy development to disease prevention, and from hospital management to quality control. This, I believe, will contribute to more responsible decision making by all those involved in health care.²

¹ Health Canada, News Release, "Advisory Council on Health Info-Structure established" (August 20, 1997), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/1997/1997_49_e.html>.

² Health Canada, News Release, 1998-65, "Advisory Council on Health Info-Structure asks Canadians for comments on interim report" (30 September 1998), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/1998/1998_65_e.html> [emphasis added].

In its Final Report dated February 1999, titled *Canada Health Infoway: Paths to Better Health*, the Advisory Council articulated this holistic and multi-faceted vision of a pan-Canadian health info-structure as follows:

The Canada Health Infoway empowers individuals and communities to make informed choices about their own health, the health of others and Canada's health system. In an environment of strengthened privacy protection, it builds on federal, provincial and territorial infostructures to improve the quality and accessibility of health care and to enable integrated health services delivery. It provides the information and services that are the foundation for accountability, continuous improvement to health care and better understanding of the determinants of Canadians' health.³

The Advisory Council's vision was accompanied by four strategic goals which clearly contemplated the integration of strengthened health care services and enhanced health research:

1. To empower the public by providing Canadians with equitable and affordable access to credible information, helping them make health lifestyle choices and allowing them opportunities to become involved by holding the health system accountable and providing input into health policy.
2. To strengthen and integrate health care services by providing health care professionals and providers with communication and information tools, and the supporting environment they need to improve the quality, accessibility, portability and efficiency of health care services.
3. To create strategic information resources for ensuring that Canada's health system continues to improve and becomes accountable to Canadians, including integration of standardized data to allow comparisons and new insights, expanded or new data coverage, data exchange and connectivity, increased analytical expertise and dissemination of results.
4. To improve privacy protection by harmonizing legislative rules for the use of personal health information across public and private sectors, for health care treatment as well as secondary uses such as health research.

Central to the vision of a pan-Canadian health info-structure, and critical for the achievement of its strategic goals, was the EHR.

Subsequent policy documents continued to emphasize that the integrated purposes of interoperable EHR systems included both health care and health research purposes. This continued commitment to the holistic vision of a pan-Canadian health info-structure catalyzed ongoing support for the development of interoperable EHR systems.

For example, in October 2002, the Standing Senate Committee on Social Affairs, Science and Technology, chaired by Senator Michael Kirby, released its final report titled *The Health of Canadians – The Federal Role*.⁴ The Committee commented on EHRs as follows:

An important characteristic of an EHR system is that it can make patient data available to health care providers and institutions anywhere on a need-to-know basis by connecting interoperable databases that have adopted the required data and technical standards. Not only can an EHR system greatly improve quality and timeliness in health care delivery, it can also enhance health care system management, efficiency

³ Advisory Council on Health Infostructure, *Canada Health Infoway: Paths To Better Health* (Ottawa: Health Canada Publications, 1999) at 6, online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/ehealth-esante/1999-paths-voies-fin/index_e.html> [*Paths To Better Health*] [emphasis omitted].

⁴ Standing Senate Committee on Social Affairs, Science and Technology, *The Health of Canadians – The Federal Role: Recommendations for Reform*, vol. 6 (Ottawa: October 2002) (Chair: Michael Kirby).

and accountability. Moreover, the data collected from an EHR system can provide very useful information for the purpose of health research.⁵

A month later in November 2002, the Romanow Commission issued *Building on Values: The Future of Health Care in Canada*.⁶ The Romanow Report committed an entire chapter to “Information, Evidence and Ideas” and described how different “pieces of the puzzle” were linked:

To take full advantage of the potential of information, evidence and ideas in the health care system, the necessary information infrastructure must be in place. This requires action on three important fronts: putting essential information management and technology systems in place, improving our ability to assess and manage the potential benefits of health care technologies, and expanding our applied research capacity across the country. These three aspects are clearly linked. Putting the information management and technology infrastructure in place means that essential information can be collected, compiled and used to make better decisions and improve quality and care within the system. Improving our ability to assess new technology means that only the most effective new treatments, prescription drugs or equipment would be purchased and used in Canada’s health care system. With better information management and technology in place, researchers can assess the impact and value of different treatments and approaches to delivering health care services in addition to developing and testing new discoveries and cures. Together, these three “pieces of the puzzle” can create a 21st century information and evidence infrastructure that will guide and inform the future of Canada’s health care system, improve its efficiency, and most importantly, improve the health of Canadians.⁷

The Romanow Report went on to emphasize the importance of EHRs as “one of the keys to modernizing Canada’s health care system and improving access and outcomes for Canadians.”⁸ In addition to ensuring that health care providers would “have access to clinical decision support tools to assist them in making decisions based on the best available evidence”,⁹ EHRs were touted as advantageous to the extent that they would “provide aggregate data that can be used in health research and in health surveillance, tracking disease trends and monitoring the health status of Canadians.”¹⁰

B. The Incremental Approach to Implementation

In contrast to the strategic policy advice received since 1999, which has consistently promoted the creation of an integrated, holistic health info-structure, the government’s response to implementing that vision has been more narrowly focused and deliberately incremental.¹¹

⁵ *Ibid.* at 175.

⁶ Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: November 2002) (Roy Romanow, Commissioner), online: <<http://www.hc-sc.gc.ca/english/care/romanow/index1.html>> [*Romanow Report*].

⁷ *Ibid.* at 76.

⁸ *Ibid.* at 77.

⁹ *Ibid.* at 79.

¹⁰ *Ibid.* at 78.

¹¹ This incremental approach seems to be typical among various countries and provinces adopting EHR systems. This approach commences with the implementation of access rules for primary use purposes. It then addresses necessary rules for allowing secondary uses of anonymized data, followed by secondary uses of identifiable data. Roy & Fournier comment:

[R]ecent discussions and documents indicate, and not only in Canada, that multiple secondary uses of PHI [personal health information] are also a core objective, not just a to-be-hoped-for serendipitous spin-off, in the creation of [national] EHRS systems. The power and knowledge that will potentially derive from access to millions of interlinked health records underpins the high expectation within many circles of society and of the health care system for secondary uses of a [national] EHRS system.

David Roy & François Fournier, *Secondary Use of Personal Information Held on National Electronic Health Record Systems: Key Developments, Issues and Concerns* (Montreal: Centre for Bioethics, Clinical Research Institute of Montreal, 2007) at 29, online: *Institut de recherches cliniques de Montréal* <http://www.ircm.qc.ca/bioethique/english/whatsnew/EHR_Secondary_Use_Report.pdf>. This report was prepared with funding support from the Office of the Privacy Commissioner of Canada.

Following the Final Report of the Advisory Council, First Ministers across Canada committed in September 2000 to work together to strengthen a Canada-wide health infrastructure to improve quality, access, and timeliness of health care for Canadians. This included a pledge to develop EHRs.¹² Specifically, this commitment resulted in the creation of Canada Health Infoway Inc. (hereafter “Infoway”) in January 2001. Infoway was incorporated as an independent, not-for-profit organization. Its membership is comprised of federal, provincial, and territorial Deputy Ministers of Health. At its inception, Infoway was mandated to “foster and accelerate the development and adoption of electronic health information systems with compatible standards and communication technologies on a pan-Canadian basis, with tangible benefits to Canadians.”¹³

Infoway’s annual reports and business plans reveal that the federal government has strategically ear-marked funds to drive a deliberate incremental approach to the deployment of EHRs. For instance, initial funding of \$500 million was allotted to enable the creation of five initial building blocks or target investment programs, centered primarily on facilitating the development of EHRs for care and treatment purposes:

- A common architecture and standards to ensure interoperability between EHR systems;
- client, provider and location registries;
- drug information systems;
- diagnostic imaging systems; and
- laboratory information systems.¹⁴

In February 2003, the Government of Canada increased its investment in Infoway by another \$600 million. Its mandate was expanded to include the development of a tele-health strategy to encompass the provision of health information expertise and services in various settings over distances.¹⁵

In March 2004, the Government of Canada further increased its investment in Infoway by another \$100 million to develop in collaboration with federal, provincial, and territorial governments an integrated Public Health Surveillance System. This would signal a long-term, clinically robust and permanent approach to support Canada’s increasing public health needs.¹⁶

¹² Canadian Intergovernmental Conference Secretariat (CICS), News Release, 850-089/004, “First Ministers’ Accord On Sustaining and Renewing Health Care For Canadians” (23 January 2003), online: CICS <http://www.scics.gc.ca/cinfo03/850089004_e.html>. First Ministers subsequently confirmed this commitment to prioritize, further invest in, and accelerate the development of EHRs in 2003 and in 2004: see 2003 First Ministers’ Accord on Health Care Renewal, online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/index_e.html>; and 2004 First Minister’s Meeting on the Future of Health Care, online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2004-fimm-rpm/index_e.html>.

¹³ Canada Health Infoway Inc., online: Canada Health Infoway—Who We Are <<http://www.infoway-inforoute.ca/en/WhoWeAre/Overview.aspx>>.

¹⁴ Canada Health Infoway Inc., *Annual Report 2002: Accelerating the Development of Electronic Health Information Systems for Canadians* at 7, online: Canada Health Infoway <<http://www.infoway-inforoute.ca/en/ResourceCenter/ResourceCenter.aspx>>.

¹⁵ Canada Health Infoway Inc., *Building Momentum: 2003/04 Business Plan* at 9, online: Canada Health Infoway <<http://www.infoway-inforoute.ca/en/ResourceCenter/ResourceCenter.aspx>>.

¹⁶ Canada Health Infoway Inc., *Coming Together (2003-2004 Annual Report, Corporate Plan Summary 2004-2005)* at 12, online: <<http://www.infowayinforoute.ca/en/ResourceCenter/ResourceCenter.aspx>>.

In 2007, the federal budget invested an additional \$400 million for Canada Health Infoway. These funds will support early movement towards patient wait times guarantees through the development of health information systems and EHRs.¹⁷

Looking forward to its future agenda, Infoway seeks to have established a baseline EHR for the entire Canadian population by 2015. This would contain registries, diagnostic imaging, laboratory, medication, hospital and clinical reports, and immunization data created for every Canadian.¹⁸ After this goal is met, subsequent steps will include integrating and enabling the seamless flow of information across primary care settings, enabling advanced order entry and decision support in acute care settings, and empowering patients by enabling them to be active partners in their own care.¹⁹

As a result of the incremental mandate and funding it has been given to date, Infoway's primary and overarching priority is focused on deploying EHRs to enable the sharing of information among *providers* of direct patient care. Meanwhile, legislators, policy-makers, system vendors, and developers have yet to articulate, both in principle and in practice, how EHRs will eventually support and enable health research. Use of EHRs for secondary health research purposes was originally conceived of as a pillar and driver of improved health care and is still recognized as something that will eventually happen.²⁰ Indeed, health research has been identified as an eventual component of the overall architecture.²¹ However, how that will be operationalized and under what conditions have yet to be worked out.²²

A number of recent initiatives across the country have begun to address the secondary use of EHR data. A pan-Canadian Privacy Forum was launched in November 2007. The Forum,

¹⁷ Department of Finance Canada, *The Budget Plan 2007: Aspire to a Stronger, Safer, Better Canada* (Ottawa: Public Works and Government Services Canada, 2007) at 59, online: Department of Finance Canada <<http://www.budget.gc.ca/2007/pdf/bp2007e.pdf>>.

¹⁸ Canada Health Infoway Inc., *2015: Advancing Canada's Next Generation of Healthcare* (Toronto: Canada Health Infoway Inc., 2005) at 24, online: Canada Health Infoway Inc. <<http://www.infoway-inforoute.ca/en/ResourceCenter/ResourceCenter.aspx>> [Canada Health Infoway Inc., 2015].

¹⁹ *Ibid.* at 16.

²⁰ Canada Health Infoway Inc., *Building on our Successes: Corporate Business Plan 2005-06* at 14, online: Canada Health Infoway <<http://www.infoway-inforoute.ca/en/ResourceCenter/ResourceCenter.aspx>>. The report suggests the need to continue to widen the circle by engaging "new stakeholder groups," such as patients and researchers, in order to extend the reach of electronic health record solutions. See also Canada Health Infoway Inc., *EHRs Blueprint: an interoperable EHR framework, Version 2*, April 2006, online: Canada Health Infoway <<http://www.infoway-inforoute.ca/en/WhatWeDo/Infostructure.aspx>> [Canada Health Infoway Inc., *EHRs Blueprint, version 2*] which recognizes at 5 that "[w]hile [patient care] is the primary goal of the EHR Infostructure, a lot can be said for the healthcare value derived from being able to use this information for research, analysis and health prevention initiatives." "[O]ne of the great dimensions of value of the EHR for the healthcare system", the *EHR Blueprint* further states at 41, "is its ability to provide data (de-identified or not) for authorised secondary uses such as surveillance, research ...".

²¹ Canada Health Infoway Inc., *Electronic Health Records Infostructure (EHRi) Privacy and Security Conceptual Architecture, Version 1.1* (June 2005) at 62, online: Canada Health Infoway Inc. <<http://knowledge.infoway-inforoute.ca/EHRSRA/doc/EHR-Privacy-Security.pdf>>. See also Canada Health Infoway Inc., *EHRs Blueprint version 2*, *ibid.* at 5, which anticipates health research as a future potential application that will require a separate and interoperable deployment model with the capability of compiling, aggregating, and consolidating EHR data. The *Blueprint* document goes on to contemplate, at 10, that from an architectural standpoint, "[t]he data stored in the EHRi will be optimized for patient/client driven access performed by healthcare professionals in the context of providing services to individuals. This is usually not very conducive for research and statistical analysis types of applications that need to perform queries addressing large subsets of data. In most cases, to sustain the purposes of research and analysis, it is understood that the preferred approach would be to extract large sets of data from the EHRi and load such data into the Health Information Data Warehouse where it can be optimized and massaged for research purposes."

²² See Canada Health Infoway Inc., *White Paper on Information Governance of the Interoperable Electronic Health Record (EHR)* (Toronto: Canada Health Infoway Inc., 2007) at 14, which identifies as an issue the fact that "there are no agreed-upon best practices for informing patients in a readily understandable manner about the secondary uses of their personal health information. Current practices vary among jurisdictions and healthcare institutions."

created and facilitated by Infoway, is comprised of representatives from privacy oversight bodies and ministries of health across various jurisdictions. The Forum is exploring a variety of information governance topics from a policy perspective, including the secondary use of EHR data. Moreover, legislators in some provinces have begun adopting mechanisms, such as the creation of special data stewardship committees, to manage disclosure of information contained in various health data banks for health planning and research purposes.²³

Even as legislators, policy-makers, system developers and interested stakeholders are now beginning to turn their minds to health research after several years of silence on the issue, it appears as though a fissure has developed between access to EHRs by health care providers for the purpose of integrating the delivery of health care, and the related use of EHRs by health researchers for the purpose of improving the quality of Canadians' health and health care services.

C. Privacy Implications of the Incremental Approach

While there are many sound business reasons for adopting an incremental approach to the development of a pan-Canadian health info-structure—indeed, some could plausibly argue there is simply no other practical, feasible way to implement such huge information technology initiatives—such an approach has important implications for privacy protection.

For one, privacy legislation typically requires that consent for the use of personal information, for any anticipated purpose, be provided at or before the time personal information is collected with full knowledge of the purposes for which the personal information will be used.²⁴ Yet, EHR data are currently being collected based solely on individuals' implied and potentially qualified²⁵ consent for health care purposes. These consent processes are completely silent with respect to the possible research uses that may be made of the data. Once research uses are eventually enabled, as it seems they inevitably will be, the opportunity to obtain consent up front at the time of collection will have been missed. This will require that individuals provide consent all over again *before* researchers can access the data, lest a fundamental data protection principle be violated. Given the sheer size of the Canadian population, re-contacting every individual in order to obtain his or her consent for research uses of their EHR data already seems pre-ordained as an impracticable option.

Additional complexity is introduced by the technological design choices that must presently be made as EHR solutions are developed and strategic investment funds are being committed and spent.²⁶ Deferring questions about the eventual use of EHR data for health research purposes, while at the same time accelerating the implementation of interoperable EHR systems, may require the costly re-engineering of existing or legacy information systems when these issues do eventually get addressed. Managing consent directives, creating consent registries, designating authorized researchers, controlling access rights based on pre-determined conditions, creating appropriate governance structures, and implementing de-identification capabilities are just some of the many outstanding design features that will be difficult to build in after the fact.

²³ See *e.g.* *E-Health (Personal Health Information Access and Protection of Privacy) Act*, S.B.C. 2008, c. 38.

²⁴ See *e.g.* *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, Sch. 1, s. 4.3 Principle 3—Consent.

²⁵ Some jurisdictions permit individuals to qualify their consent to the collection, use, and disclosure of personal health information through the use of possible opt-out mechanisms such as masking, “lock-box,” and other options.

²⁶ Michael Wolfson, Assistant Chief Statistician of Statistics Canada, comments: “Secondary uses [of EHR data] should be co-equal with primary uses – they should be planned, for example in terms of architectures and functional requirements, just as much as primary uses.” Roy & Fournier, *supra* note 11 at 22.

While the law does allow consent exceptions for research under certain conditions, these conditions vary significantly from jurisdiction to jurisdiction. Infoway identifies privacy and consent legislation as a key enabler of its ultimate vision for health information technology in Canada.²⁷ This echoes the Advisory Council's 1999 indication that harmonizing legislative rules for the use of personal health information for both care and research purposes would be essential for realizing the vision of a Canadian health info-structure.²⁸ Yet to date, policy-makers have predominantly focused on harmonizing legal requirements around an implied or deemed consent model to enable the integration and interoperability of health care services. The need to harmonize legal rules around secondary uses such as health research continues to be overlooked, despite the fact that privacy and consent norms as currently conceived in Canadian law are neither amenable to, nor in some cases capable of, retrospective application.

Meanwhile, even as many of these legal and technological issues remain outstanding, the pressure to access what will eventually become invaluable "cradle to grave" EHR data for research purposes continues to mount. Several authors anticipate that the scale of secondary use of information will increase substantially as EHRs become more pervasive.²⁹ Some have described this trend as follows:

[I]n a context where "the volume of data in an EHR may lead to increased pressure by analysts and researchers to access the information", there may be mounting pressure to render health information governance – structures, legislation, policies, practices – more "flexible" to allow optimal exploitation of health information rich EHRs for the benefit of the 'common good'

...

The multipurpose value of health information stimulates the appetites of governments, researchers, health-care planners, administrators, insurers, and others for more and ever more data. This phenomenon is bound to become more apparent as EHR systems are more widely established and become more effectively interoperable.³⁰

As long as the issue of consent for the use of EHRs for health research purposes remains outstanding, this massive treasure trove of valuable data for health research will linger in legal and ethical limbo.

In the remainder of this paper, we describe the legal rationale for consent as a means of controlling access to one's EHR data for health research purposes. We explain why informed consent remains the default legal standard for research use of personal information irrespective of the method used. In view of the growing recognition that informed consent may not always be a feasible standard for all types of health research, we then consider a number of other policy alternatives which deviate from the informed consent model and have yet to be more fully explored in an open, transparent, and inclusive public policy debate. These alternatives range from introducing a broad consent model for future, yet unspecified research purposes; de-identifying data and removing them altogether from the scope of application of data protection laws; extending the implied consent model by reconceptualizing research as

²⁷ Canada Health Infoway Inc., 2015, *supra* note 18 at 24.

²⁸ *Paths To Better Health*, *supra* note 3 at 11: "... legislation should define what constitutes informed consent, as well as provide a clear statement of principle to the effect that informed consent should be the basis for sharing information. It should define 'exemptions' to this requirement for informed consent and give clear guidance on how to balance the right of privacy with the public good for research purposes."

²⁹ Donald J. Willison *et al.*, "Alternatives to Project-specific Consent for Access to Personal Information for Health Research: What Is the Opinion of the Canadian Public?" (2007) 14:6 *Journal of the American Medical Informatics Association* 706 at 707. See also Khaled El Emam *et al.*, *Pan-Canadian De-Identification Guidelines for Personal Health Information* (Ottawa: Children's Hospital of Eastern Ontario Research Institute, 2007), at 3 and 6-7, online: Electronic Health Information Laboratory <<http://www.ehealthinformation.ca/documents/OPCReportv11.pdf>> [El Emam *et al.*, "Pan-Canadian"]. This report was prepared with funding support from the Office of the Privacy Commissioner of Canada.

³⁰ Roy & Fournier, *supra* note 11 at 28-29. See various excerpts cited by the authors at 32 for further support for this projected phenomenon.

part of the primary health care purpose; resorting to statutory consent exemptions for research purposes; and amending legislation to retroactively eradicate the need for consent altogether.

By setting out a range of policy options to address research use of EHR data and discussing the implications of these options, this paper aims to support informed deliberations about available choices before technological imperatives predetermine the selection for us.

II

INFORMED CONSENT AS A DEFAULT STANDARD FOR RESEARCH

Informed consent is a fundamental pillar of most, if not all, modern data protection regimes recognized internationally. In Canada, all federal, provincial, and territorial data protection laws start from the general proposition that personal information should only be collected, used, and disclosed with the consent of the individual to whom it relates.³¹ In some cases, data protection legislation expressly specifies certain conditions that must be satisfied for consent to be valid. Typically, consent must be informed, revocable, given freely and obtained lawfully, and without deception.³² While every regime incorporates various exemptions to this requirement, informed consent remains the default expectation whenever information that can identify persons will be collected, used, or disclosed.

Informed consent, as a key component of data protection legislation, represents a concrete and express manifestation of the fundamental principles of individual autonomy, dignity, and liberty that have emerged as the basis for the protection of personal information at common law³³ and the right to privacy under the *Canadian Charter of Rights and Freedoms*.³⁴ In this

³¹ Patricia Kosseim, Adam Kardash & Antonella Penta, eds., *Compendium of Canadian Legislation Respecting the Protection of Personal Information in Health Research*, 2d ed. (Ottawa: Public Works and Government Services Canada, 2005) at 129-67, online: CIHR <http://www.cihr-irsc.gc.ca/e/documents/ethics_privacy_compendium_june2005_e.pdf>.

³² *Ibid.* at 129.

³³ The common law governing the confidentiality of the physician-patient relationship is particularly relevant here. EHR data, unlike other data sources, such as administrative databases for example, will always run up against the inescapable aura of confidence which surrounds this data at common law. EHR data by its inherent nature is highly sensitive, and will have originated in the context of the fiduciary relationship between patient and health service provider. This relationship of trust imports a clearly defined duty on the part of the health service provider to keep the information confidential, and a corresponding expectation on the part of the patient that this confidence will be respected—particularly if no discussion of other possible uses has taken place. By confiding personal information to their provider in this context, patients can reasonably expect that their interest in, and control over, their EHR data will continue no matter where the data ultimately flow.

³⁴ *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11 [*Charter*]. *Charter* jurisprudence helps inform a consideration of the standard of consent that would apply to the use of personal health information in electronic health records for health research purposes for a number of reasons. First, *Charter* jurisprudence informs the acceptable limits on the reasonable expectation of privacy as balanced against other legitimate societal needs (*R. v. O'Connor*, [1995] 4 S.C.R. 411) [*O'Connor*]. Second, the *Charter* may apply directly to the actions of certain government actors involved in the health research enterprise such as government sponsors of health research and, where there are sufficient indicia of government control, hospitals or universities (*Eldridge v. British Columbia (Attorney General)*, [1997] 3 S.C.R. 624 at para. 43; *Douglas/Kwantlen Faculty Assn. v. Douglas College*, [1990] 3 S.C.R. 570). Third, the *Charter* may further apply to statutorily-created bodies charged with interpreting and applying data protection legislation, such as research ethics boards, since legislators cannot permit administrative decision-makers to do indirectly that which legislators cannot do directly (*Slaight Communications Inc. v. Davidson*, [1989] 1 S.C.R. 1038; see also *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307). Fourth, *Charter* values will inform the interpretation and application of legislation or the common law where there is any ambiguity (*R. v. Rube*, [1992] 3 S.C.R. 159 at 160; *R. v. Salituro*, [1991] 3 S.C.R. 654 at 678). This may be particularly relevant given the ambiguity that exists in most data protection laws in respect of the conditions necessary for consent to be truly valid, and for the various research exemptions to apply. Finally, over and above the extent to which *Charter* values or the *Charter* itself may be invoked to inform the validity, interpretation, and application of data protection statutes, *Charter* values are relevant to the debate about access to EHRs for research purposes simply to the extent that they represent a concrete expression of fundamental social values and the reasonable expectation of privacy in modern society.

section, we set out to explain why informed consent constitutes the default statutory requirement for the collection, use, and disclosure of personal information for health research purposes, whatever the research method used.

A. Clinical Research

Clinical research typically involves an experimental intervention which deviates from the recognized standard of medical care. This could include the administration of a new drug, a new use of an existing drug, a novel medical device, or an innovative prophylactic, diagnostic, or surgical procedure in order to test for safety and efficacy in comparison with the standard course of diagnosis or treatment. Because clinical research tends to involve some physical interference with the human body, the legal requirement for informed consent is generally incontrovertible.³⁵

Informed consent to medical interventions is a longstanding requirement of the traditional physician-patient relationship; it constitutes the legal means by which patients exercise their fundamental right to control what is done or not done with their body.³⁶ To render the necessary consent meaningful, a physician must answer any specific questions posed by the patient as to the risks involved and must disclose, without being asked, the nature of the proposed intervention, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. The contours of the physician's duty of disclosure are defined by what a reasonable person in the patient's particular position would want to know and understand in order to make an informed choice about whether or not to undergo the proposed intervention.³⁷

In the clinical research context, the proposed intervention is not carried out exclusively for the benefit of the individual patient, but for the potential benefit of society as a whole. In this context, a researcher's duty to disclose risks associated with a research intervention is even more exacting than the duty owed by the ordinary physician providing standard medical care. In one of the very few Canadian cases dealing with this question, the Saskatchewan Court of Appeal determined that:

... [t]here can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice ... The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.³⁸

In *Weiss v. Solomon*, the Quebec Superior Court held that the researcher conducting experimental treatment must specify *all* risks, no matter how rare or remote, especially when those risks may have grave consequences. This disclosure, of course, remains subject to review and approval by an institutional research ethics board charged with verifying whether or not the threshold is met for each research protocol.³⁹

Clearly, for clinical research which potentially involves some intervention which is not the recognized standard diagnosis or treatment, and which is not carried out for the exclusive benefit of the individual, the doctrine of informed consent requires the researcher to meet that

³⁵ Although the requirement of informed consent in the context of clinical research is well-established and accepted as a matter of principle, its application in practice continues to preoccupy research ethics boards and regulators as they struggle to review lengthy and protracted consent forms.

³⁶ This principle was encapsulated in a well-known statement by Cardozo J. in *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92 (1914): "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."

³⁷ *Hopp v. Lepp*, [1980] 2 S.C.R. 192 and *Reibl v. Hughes*, [1980] 2 S.C.R. 880 at 899-900.

³⁸ *Halushka v. University of Saskatchewan et al.* (1965), 52 W.W.R. 608 at 616 (Sask. C.A.).

³⁹ *Weiss v. Solomon*, [1989] A.Q. 312 (Qc. Sup. Ct.).

higher threshold of disclosure before consent will be found to be valid.⁴⁰ Moreover, because clinical research aims to use information about the individual's health outcome in order to advance general societal knowledge, the additional risks to privacy and confidentiality have also become part of that higher cluster of risks which the researcher must impart to potential research subjects in order to inform their consent to participate in the research. In accordance with widely accepted international ethical principles for clinical research, researchers have a duty to protect not only the life and health of human research subjects, but their privacy and dignity as well: "[e]very precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject."⁴¹

But what of research which involves solely the collection, use, or disclosure of personal information, with no clinical intervention *per se*? Does the same default requirement of informed consent apply or is a different standard of consent warranted in such circumstances?

B. Epidemiological Research

Epidemiological studies are primarily designed to monitor health patterns or trends among large-scale populations; identify potential determinants of health or causes of disease; evaluate the cost-effectiveness of health services; assess the quality and impact of treatments, prevention strategies, or policies; and/or assemble study populations.⁴² These types of studies typically depend on access to already-existing health records originally created for treatment purposes, such as hospital, physician, laboratory, or pharmaceutical records. These health records might then be linked with other existing administrative databases originally created for other purposes, such as provincial and federal billing and registration data; birth and death records; socio-demographic data; cancer registry data; and employment records. This research method involves mostly data analyses with no need to enter into direct contact with the individuals involved. In some cases, however, individuals may be contacted in order to carry out a survey either by telephone, in writing, or in person, to collect further qualitative data from research participants about their perceptions of their own health, their assessment of the health system, their quality of life, behavioural or lifestyle factors, or other relevant information.

Even though this research method does not typically involve any physical intervention, like in clinical research, informed consent remains the default legal requirement. This is because the courts have recognized, both at common law and under the *Charter*, that every individual has the fundamental right to control not only what shall be done with his or her body, but also *the right to control what is done with his or her personal information*.

At common law, medical records are recognized as repositories of highly private personal information to which legitimate expectations of privacy and confidentiality attach. Control over

⁴⁰ Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. (Toronto: Carswell, 1996) at 150.

⁴¹ World Medical Association, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002, and note of clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004 [*Declaration of Helsinki*], online: World Medical Association <<http://www.wma.net/e/policy/pdf/17c.pdf>>.

⁴² See Canadian Institutes of Health Research, *Secondary Use of Personal Information in Health Research: Case Studies* (Ottawa: Public Works and Government Services Canada, 2002) for a fuller description and concrete examples of research studies which rely on secondary use of data, online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/pdf_15568.htm>.

one's personal information is a defining principle of the doctor-patient relationship. It underlies a patient's rights and a health provider's corresponding obligations in Canadian medical law. In 1928, the Supreme Court of Canada had little difficulty confirming that a patient has a *prima facie* right to confidentiality in the medical "secrets" kept between himself and his physician. The Court held that "that right is absolute, unless there is some paramount reason which overrides it."⁴³

In the seminal case of *McInerney v. MacDonald*,⁴⁴ the Supreme Court of Canada elevated the legal protection afforded to medical information by recognizing the doctor-patient relationship as a special relationship of trust. The physician's fiduciary duties include the duty to act with utmost good faith and loyalty in the best interests of his patients, to keep patients' personal information confidential, and to provide patients with access to their own personal information. The patient who entrusts highly sensitive and personal information to a physician does so with the legitimate expectation that the physician will respect these duties. The patient has a continuing interest in what happens to the personal information he shares with his physician and in retaining control over others' access to it; this personal information remains in a fundamental way his own and his interest in that personal information continues even as his physician shares it with other health providers.⁴⁵

The case of *R. v. Dyment* is also instructive with respect to the question of non-consensual secondary uses of personal health information originally collected for medical treatment and subsequently used for a different purpose. In *R. v. Dyment*, a physician collected, for medical purposes, a vial of free-flowing blood from a car accident victim. Mr. Dyment, who was unconscious at the time, did not consent to the taking of his blood sample. When the patient later explained that he had consumed a beer and medication before the accident, the physician offered the blood sample to police in the absence of a warrant. In determining that this transaction resulted in an unconstitutional search and seizure within the meaning of section 8 of the *Charter*, Justice La Forest held that Mr. Dyment

may, for some purposes perhaps, be deemed to have impliedly consented to a sample being taken for medical purposes, but he retained an expectation that his privacy interest in the sample continue past the time of its taking. Indeed, the doctor, in extracting the blood, placed himself in a situation where, pursuant to professional ethics and likely to hospital management regulations as well, he was charged with a duty to use the blood only for medical purposes. Under these circumstances, the sample was surrounded by an aura of privacy ...⁴⁶

In so finding, La Forest J. considered and adopted what was then the novel proposition that there are three equally important zones of privacy—territorial, personal, and informational. An individual has not only the right to assert autonomous control over her own property or person, she also has the right to assert autonomous control over her personal information. La Forest J., borrowing from the work of a 1972 Task Force established jointly by the Departments of Communications and Justice,⁴⁷ concluded that information, like one's property or person, warrants privacy protection:

Finally, there is privacy in relation to information. This too is based on the notion of the dignity and integrity of the individual. As the Task Force put it (p. 13): "This notion of privacy derives from the assumption that all information about a person is in a fundamental way his own, for him to communicate or retain for himself as he sees fit." In modern society, especially, retention of information about oneself is extremely important. We may, for one reason or another, wish or be compelled to reveal such information, but situations abound where the reasonable expectations of the individual that the information shall remain confidential to the persons to whom, and restricted to the purposes for which it is divulged, must be

⁴³ *Halls v. Mitchell*, [1928] S.C.R. 125 at 136.

⁴⁴ [1992] 2 S.C.R. 138 [*McInerney v. MacDonald*].

⁴⁵ *Ibid.* at para. 22.

⁴⁶ [1988] 2 S.C.R. 417 at para. 31 [*Dyment*].

⁴⁷ Canada, Report of a Task Force established jointly by the Department of Communications/Department of Justice, *Privacy and Computers* (Ottawa: Information Canada, 1972) [*Privacy and Computers*].

protected. Governments at all levels have in recent years recognized this and have devised rules and regulations to restrict the uses of information collected by them to those for which it was obtained. See, for example, the *Privacy Act*, S.C. 1980-81-82-83, c. 111.⁴⁸

From this line of reasoning, a legal conception of privacy has emerged that may be best crystallized as the *prima facie* right to choose for oneself what is done with one's information. As the Supreme Court of Canada stated in the 1990 decision *R. v. Duarte*: “[p]rivacy may be defined as the right of the individual to determine for himself when, how, and to what extent he will release personal information about himself.”⁴⁹ This right attaches to “all information about a person”⁵⁰ and not merely information that may objectively be deemed to be sensitive or worthy of privacy protection.

Also of note is the fact that the right to assert autonomous control over one's personal information, like one's personal space and effects, requires preemptive protection. The Supreme Court has emphasized that section 8 of the *Charter* “requires a means of preventing unjustified searches before they happen, not simply of determining, after the fact, whether they ought to have occurred in the first place. This, in [the Court's] view, can only be accomplished by a system of prior authorization, not one of subsequent validation.”⁵¹ Like the need to obtain a warrant in the law enforcement context, the requirement to obtain prior informed consent to the collection, use, and disclosure of personal information has evolved as a legal safeguard intended to proactively protect privacy and protect against unauthorized and unjustified intrusions that may not be remediable.

In various contexts, Canadian jurisprudence has clearly and consistently recognized that individuals maintain a legitimate expectation of privacy in and control over their personal health information and health records. This standard of autonomous control is manifested in data protection regimes as the legal requirement to obtain prior informed consent to the collection, use, and disclosure of personal information. Though deviation from this recognized legal standard may be desirable for certain types of health research, such as epidemiological research for instance, it must be justified and warranted in law according to clear terms and conditions.

C. Creation of Research Platforms

Given rapid advances in information technology, the explosion of genomic research and the growing movement towards data sharing and integration, the health research enterprise is increasingly turning towards the creation of large-scale research registries, repositories, or data warehouses which collect data on whole populations or sub-populations and serve as platforms for future research. Once these platforms are created, they enable researchers to subsequently draw on the same source of data to carry out what could be hundreds of individual research projects and/or to assemble study cohorts—for yet further potential research. These platforms could be national or sub-national in scope; they could be of a specialized nature to study potential determinants of a specific disease or more wide-ranging in nature to assess the health status of populations in general. They could be designed on a cross-sectional basis, which would involve the collection of data at a single point in time, or on a longitudinal basis, which would involve ongoing data collection in order to study health changes in the cohort population over long periods of time. Finally, these research platforms may involve the additional collection of biological samples, particularly given the increasing importance of understanding underlying genetic factors and their impact on the health status and/or disease susceptibility of populations.

⁴⁸ *Dyment, supra* note 46 at 429.

⁴⁹ *R. v. Duarte*, [1990] 1 S.C.R. 30 at 46.

⁵⁰ *Dyment, supra* note 46 at 429.

⁵¹ *Ibid.* at 430, citing Dickson J. in *Hunter v. Southam Inc.*, [1984] 2 S.C.R. 145 at para. 27 [emphasis omitted].

In our view, and for the reasons set out above, the requirement to obtain informed consent for the prospective collection of data (including biological samples) directly from the study population for inclusion in a research platform continues to apply as the default legal standard. However, the issue which arises in this context is whether broad, general consent for all future research purposes is sufficient, or whether specific, informed consent is legally required each time an individual research project is carried out using data from the research platform. As will be canvassed below, there may be valid policy reasons not to require specific, informed consent for each individual research project, given the difficulty inherent in re-contacting individuals and the significant impediment this may have on important research. Nonetheless, a review of the common law and *Charter* jurisprudence may help us to understand why informed consent appears to be the default standard for each research project, and why any departure from this standard must be justified.⁵²

An individual's freedom to make decisions of fundamental personal importance free from state interference is protected under s. 7 of the *Charter*. In *R. v. Morgentaler*, Wilson J. explored the contours of the section 7 right to liberty. Adopting an expansive and purposive approach, Wilson J. described the right to liberty as being linked to human dignity and the right to exercise autonomy in making private choices:

[A]n aspect of the respect for human dignity on which the *Charter* is founded is the right to make fundamental personal decisions without interference from the state. This right is a critical component of the right to liberty. Liberty, as was noted in *Singh*, is a phrase capable of a broad range of meaning. In my view, this right, properly construed, grants the individual a degree of autonomy in making decisions of fundamental personal importance.⁵³

I would conclude, therefore, that the right to liberty contained in s. 7 guarantees to every individual a degree of personal autonomy over important decisions intimately affecting their private lives.⁵⁴

In subsequent cases, the Supreme Court further specified that the relevant sphere of personal autonomy encompasses those matters that can be characterized as being “fundamentally or inherently personal such that, by their very nature, they implicate basic choices going to the core of what it means to enjoy individual dignity and independence.”⁵⁵

EHRs contain data which are fundamentally and inherently personal.⁵⁶ They reveal sensitive information about highly personal issues like one's physical health, mental health, family situation, and genetic make-up. The decision to disclose such highly sensitive information, including biological samples, for some research purposes and not others may in

⁵² Timothy Caulfield and Nola Ries likewise conclude from their review of Canadian common law that “given the ever expanding details required in order to make a consent properly informed, especially in relation to research, and given that it will be impossible for the initial consent to contain information about specific research projects, it seems fair to conclude that, from a technical legal perspective, a re-consent will often be required.” See Caulfield & Ries, “Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context” (Supplement, 2004) Health L.J. 1 at 29.

⁵³ *R. v. Morgentaler*, [1988] 1 S.C.R. 30 at 166.

⁵⁴ *Ibid.* at 171.

⁵⁵ *Godbout v. Longueuil (City)*, [1997] 3 S.C.R. 844 at para. 66 [*Godbout*]. See also *R. v. Malm-Levine*; *R. v. Caine*, 2003 SCC 74, [2003] 3 S.C.R. 571 [*Malm-Levine*].

⁵⁶ See *McInerney v. MacDonald*, *supra* note 44 at 148: “Of primary significance is the fact that the records consist of information that is highly private and personal to the individual. It is information that goes to the personal integrity and autonomy of the patient.” See also *O'Connor*, *supra* note 34 at para. 118, citing *R. v. Plant*, [1993] 3 S.C.R. 281 at 293: “[Section] 8 of the Charter should seek to protect a biographical core of personal information in which individuals in a free and democratic society would wish to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individual.’ Although I prefer not to decide today whether this definition is exhaustive of the right to privacy in respect of all manners of documents and records, I am satisfied that the nature of the private records which are the subject matter of this appeal properly brings them within that rubric. Such items may consequently be viewed as disclosing a reasonable expectation of privacy which is worthy of protection under s. 7 of the Charter.” [Emphasis omitted.]

some cases be based on one's deeply personal and moral beliefs. Such decisions could be regarded as falling within that "irreducible sphere of personal autonomy wherein individuals may make inherently private choices free from state interference" and which, by their very nature, implicate basic choices "going to the core of what it means to enjoy individual dignity and independence."⁵⁷

Accepting this premise, the jurisprudence surrounding the liberty interest in section 7 may serve as a guide for giving meaningful effect to individuals' reasonable expectations of privacy and control over decisions of such fundamental personal importance. In order for individuals to exercise their right to make such personal and private choices about what research can be carried out or not with their personal information, they must be able to turn their minds to each specific research study and evaluate for themselves the worthiness of the research aim, the legitimacy of the hypothesis, the potential uses to which the results will be put, and the degree to which they themselves wish to personally contribute to that particular research venture. Will the research be for commercial or non-commercial purposes? Could it have as a possible outcome the denial of coverage and accessibility to certain treatments that prove to be economically non-viable and highly risky, but for some, represent their only hope for survival? Could the research possibly result in the development of standardized genetic screening tests that might over time affect the biological diversity of human life as we presently know it? Does the research involve controversial reproductive technologies that some might find acceptable and even necessary, while others might find morally reprehensible? Will the research have the potential of uprooting communities, disrupting their self-dependence and exploiting their traditional ways of life? Might research results pertaining to the health characteristics of certain groups lead to possible discriminatory practices?

One option is to obtain from individuals a single, broad consent to the use of personal data for research and then entrust to research ethics boards the responsibility for reviewing and approving specific projects in accordance with widely accepted ethical principles and governing conditions of the research platform. Such a broad consent, however, though made freely, may not constitute informed consent in law. Research participants cannot provide their informed consent if they have no knowledge of what they are consenting *to*. One cannot truly consent to that which is unascertained and thus unknown.

As will be discussed below, there may be persuasive public policy reasons for moving towards a broad consent model—not the least of which are the sheer practical issues associated with informed consent processes on a project-specific basis. However, the liberty interest engaged by such fundamentally and inherently personal choices regarding what use may be made of one's highly sensitive personal information is sufficiently strong that it must, in our view, continue to inform the default standard of consent, and any departure therefrom must be legally justifiable.

III

POLICY OPTIONS FOR ALLOWING RESEARCH USE OF EHRs

The common law and *Charter* jurisprudence governing the privacy and confidentiality of personal information surveyed above relies directly or inferentially on informed consent as a proxy for the legal protection afforded to fundamental principles of autonomy, human dignity, and liberty. These foundational principles of human dignity, liberty, and autonomous control over personal information inhere in the rights of the individual. Their relevance and application seem to persist irrespective of the proposed research use or method.

⁵⁷ *Godbout*, *supra* note 55 at para. 66.

As canvassed above, informed consent in the context of *clinical* research is grounded in the right to control what shall be done with one's body and to limit undue physical intrusions upon the person. In the context of *retrospective* research involving secondary use of data originally collected for a purpose unrelated to the objective of the secondary use research, informed consent is grounded in the *right to control what is done with one's personal information and to limit unjustified invasions of one's reasonable expectation of privacy*. In the context of *prospective* research studies based on data collected for the purpose of creating a research registry or platform, informed consent arguably remains the default standard as well, based on the *right to exercise autonomy over decisions affecting fundamentally important aspects of one's life*.

As a result, the jurisprudence suggests that it may be difficult, as a matter of principle and absent justifiable reasons, to shift away from the concept of "informed consent" as the default standard for access to EHR data for research purposes, even absent clinical intervention.

We now turn to a discussion of a range of policy options that may be available to address the dual need to respect the fundamental principle of informed consent, while at the same time, enable access to EHR data for health research purposes. We begin with the option of informed consent which is most closely aligned with the current state of the law. We then explore other, more feasible, policy alternatives that may inevitably be required by the continued, incremental deployment of EHRs. Each of these policy alternatives has significant implications that need to be carefully considered.

A. Obtaining Informed Consent for Each Specific Research Study

In keeping most closely with the prevailing standards set out above, the first policy option is maintaining and complying with the current default rule, informed consent.

As we have seen, this standard of consent would require the researcher to provide, at a minimum, the information necessary for an individual to maintain a continuing interest in what happens to his personal information. In order to provide individuals with a meaningful opportunity to exercise their right to consent or withhold or revoke consent on an ongoing basis, the health researcher would have a corresponding and continuing duty to disclose sufficient information about the specific research study being proposed and its evolution.⁵⁸

The informed consent model seems to require that researchers create and maintain the conditions required for individuals to retain control over access to their personal information. The researcher must give practical meaning to the legal imperative which asserts that the individual's "information remains in a fundamental way his own, for him to communicate or retain for himself as he sees fit."⁵⁹ The individual must be able to decide for himself, with sufficient autonomy and without interference by others, when, how, and to what extent he will release his personal information for a specific purpose that cannot be extended to other

⁵⁸ Prior to researchers establishing direct contact with patients, many health information statutes and ethics guidelines require that health service providers or health information custodians obtain *prior* consent in order to permit the disclosure of contact and other identifiable information to researchers before they may enter into communications with patients for the purposes of recruitment. See e.g. *Health Information Act*, R.S.A. 2000, c. H-5, s. 55 [HIA]; *Personal Health Information Protection Act*, S.O. 2004, c. 3, s. 44(6)(e) [PHIPA]. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council & Social Sciences and Humanities Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998, with 2000, 2002, and 2005 amendments), online: Interagency Advisory Panel on Research Ethics <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf>; and Canadian Institutes of Health Research, *Best Practices for Protecting Privacy in Health Research* (Ottawa: Public Works and Government Services Canada, 2005), Element 6: Recruiting Potential Research Participants at p. 63, online: <http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf>.

⁵⁹ *Dyment*, *supra* note 46 at 429, citing *Privacy and Computers*, *supra* note 47.

purposes or disclosed to third parties without his consent. As EHR data in particular clearly relate to matters that are fundamentally and inherently personal and go to the core of what it means to enjoy individual dignity and independence, the individual must be provided with sufficient freedom to exercise these rights autonomously.

Where participation involves some physical intervention, as in clinical research, the law clearly requires specification of all risks, no matter how rare or remote, especially when the materialization of those risks may have grave consequences. In light of the evolving privacy and confidentiality principles set out above, informed consent for research involving use of personal information, even with no clinical intervention *per se*, would still appear to require an elevated duty of disclosure in order to be meaningful. That might include information about the following:

1. the researchers, their affiliation, their contact details, and the source of funds or sponsorship;
2. what the specific purpose of the research is, what personal information is needed for that purpose and why;
3. what exact EHR data elements will be collected, what use will be made of said data, and what further uses may be made of the data in future (*e.g.* any potential follow-up or spin-off studies);
4. whether the researcher has a plan to link the data with other datasets, and if so, which ones, under what conditions, and for what purpose;
5. which third parties may potentially gain access to personal data (*e.g.* sponsors, regulators, university administrators, research ethics boards, law enforcement);
6. how long the research data will be retained, and whether it will be anonymized or destroyed afterwards and if so, when and how;
7. how the data will be safeguarded against risk of privacy or security breach, and what will happen in the event of breach;
8. how the research results will be reported, and where and in what form;
9. how one can exercise one's right to withdraw consent and what the exact implications of such withdrawal are;
10. contact information to obtain more information about the study at any time; and
11. anything else the individual asks about.

Legally, this policy choice would not require many—if any—amendment to existing legislative schemes. While data protection regimes in some jurisdictions expressly require consent to be *informed*, others do not state this requirement explicitly. Nonetheless, for reasons explained in our survey of the current state of the law above, it is our view that, even in these other jurisdictions, consent would be afforded the same significance ascribed at common law and interpreted in accordance with *Charter* values, and thus, would have to be meaningfully informed.

Though this policy option would provide individuals with the greatest effective control over their personal information and likely engender the greatest public trust, particularly in the context of clinical trials, there is some evidence to suggest that the adverse impact on epidemiological or population-based research could be significant.⁶⁰ This is because of the reduced amount of data that would be available for research due to the elevated cost and

⁶⁰ See Khaled El Emam *et al.*, “Pan-Canadian”, *supra* note 29 at 59-70.

practical difficulty of recruiting participants and obtaining individual consent, particularly for large-scale studies. This model could further impede research by introducing potential bias into results, due to general attitudinal or other characteristic differences between individuals who tend to agree to the use of their EHR data for research and those who tend to refuse or not respond. Moreover, some could say that by limiting the integration of data that was envisaged as part of the pan-Canadian info-structure, the informed consent model defies the significant advantages that EHRs could potentially offer to enhance research capacity and improve the quality of health and health services in Canada.

While in our view “informed” consent is most consistent with established and fundamental legal principles, we recognize that there are other plausible policy choices which we, as a society, can make in respect of consent requirements for access to EHR data for different types of health research. This is particularly so if we recognize that privacy is not absolute and if we value—as we clearly do—the important public benefits health research can contribute to our health and the future sustainability and continued improvement in the quality of our health care services. Hence, we may certainly choose to deviate from specific, informed consent as the “gold standard,”⁶¹ but in doing so, we must remain ever mindful of the fundamental values which we have come to recognize at common law and under our *Charter*; we must remember the level of sensitivity of EHR data and the reasonable expectation people have that it will be kept private and confidential; we must deviate from specific, informed consent *only* to the extent necessary to allow for those public health purposes which we clearly and universally cherish as a society; and, we must proceed in a manner that is honest and transparent, and accords with the principles of a free and democratic society. We now turn to discuss alternatives to specific informed consent.

B. Seeking Broad Consent For Future, Yet Unspecified Research Studies

In a first possible deviation from the existing legal standard, policy-makers could recognize the practical limitations of specific, informed consent for non-clinical research and move towards the concept of broad consent, a more practical, yet lesser form of informed consent.⁶² This policy choice would—at least conceptually—liken the data contained in pan-Canadian interoperable EHR systems to large-scale national data registries or research platforms. Instead of obtaining informed consent for each specific research study, broad or general consent would be sought from each individual to permit their EHR data to be uploaded from the info-structure into interoperable health information data warehouses to support future, yet unspecified research uses. These research data warehouses would be governed by specially designated data custodians through appropriate rules, structures, and processes. As research uses become defined over time, the data custodians would govern the release of the EHR data contained in the data warehouse to health researchers for specific research projects under

⁶¹ We have chosen to benchmark specific, informed consent as our gold standard. In our view, informed consent is most closely aligned with the spirit of individual autonomy, a foundational principle in our free and democratic society. Others, however, have not been so generous. As Chassigneux, Trudel & Knoppers argue:

Though a significant part of the legal community remains attached to the supremacy of consent, it appears poorly adapted to protect rights in the univers [*sic*] of networks. As practiced, consent seems more and more like a decoy since it seems to ensure individuals' control over their own data. The considerable number of exceptions as well as the way data circulate make consent naive at best, and at worst, an inadvisable instrument if we really do want to protect the privacy of participants.

Cynthia Chassigneux, Pierre Trudel & Bartha Maria Knoppers, “The Legal Framing of Computerized Processing of Health Data: A European and Canadian Perspective” (2006) 4:1 *GenEdit* 1 at 3, online: [HumGen International <http://www.humgen.umontreal.ca/int/GE/en/2006-1.pdf>](http://www.humgen.umontreal.ca/int/GE/en/2006-1.pdf).

⁶² Roy & Fournier ask: “With the probable quantitative expansion of secondary uses [of EHRs], for multiple and diverse purposes, is the model of informed, express and project-specific consent doomed to evolve towards a model of ‘broad consent’ where consent is less, rather than more, informed?” Roy & Fournier, *supra* note 11 at 25.

specified conditions, subject to proper research ethics review and oversight, and in accordance with special research agreements.

The broad consent could be obtained from individuals preferably at the same time as EHRs are being created and implemented. This way, at least, individuals could know and understand up front all of the terms, conditions, and potential research uses of their EHR data, *albeit* in a broad, general way. Although researchers would not be able to disclose as much detail to support truly informed consent, they would need to provide enough information to describe the general purpose of the research platform and the terms and conditions for subsequent use:

1. which EHR data elements will be uploaded into the research data warehouse;
2. what entity is responsible for managing the data warehouse, subject to what governance rules, structures and processes, and how the entity can be contacted;
3. what general types of research studies the EHR data will help support and whether or not this might include commercial research;
4. under what conditions will researchers be able to gain access to the EHR data within the terms of the broad consent being given, and to what degree the data will be de-identified before release (including details about the de-identification process);
5. under what conditions the individual will be re-contacted to obtain specific informed consent before data is released to researchers;
6. what safeguards does the data custodian have in place to protect the data against risk of privacy or security breach, and what happens in the event of breach;
7. who else will or may potentially gain access to it (*e.g.* third party auditors, regulators, law enforcement, *etc.*);
8. whether the data in the warehouse will be linked with other datasets, and if so, which;
9. how long the data will be retained and whether certain data elements will eventually be completely anonymized and/or destroyed, and if so, how;
10. how the individual can exercise his or her right to withdraw consent and what the implications of such a withdrawal are;
11. who should be contacted, and where and how to obtain more information at any time; and
12. anything else the individual asks about.

Broad consent obtained up front would allow several transactions to occur without having to re-contact individuals. First, broad consent would permit the roll-up of certain EHR data elements from the health service provider at the local point of service, through what has been conceived of architecturally as “the health information access layer,” into an interoperable research data warehouse. Such a warehouse would be governed by specially designated custodians that would essentially act as gatekeepers to the data. Second, a broad consent policy could permit these specially designated custodians to screen EHR data contained in the warehouse against specific entry criteria upon researchers’ request to select potential participants for a particular project. Third, broad consent would allow the research data custodian to manipulate the EHR data of screened-in participants in order to effectively de-identify them (by a process of anonymization, pseudonymization, aggregation, coding, or double-coding) and release them to researchers for specific research projects under certain conditions and subject to special agreements.

Although broad consent would allow significantly more flexibility than the specific, informed consent model, it should not extend to allow indefinite uses of EHR data. In certain special situations, individuals would need to be re-contacted to obtain their informed consent for participation in specific research studies. This may be the case, for example, if the researchers were requesting access to data that identified individuals, if the research method required the ongoing, active involvement of the individual, or if the research study involved highly sensitive data or a high level of risk above a certain threshold.

In these cases, a process for exceptionally allowing disclosure of identifiable information from the data custodian to the researchers for the purpose of re-contacting individuals to obtain specific consent would need to be established, properly managed, and duly recorded. Moreover, the specific risk conditions and threshold levels would need to be clearly defined, at which point the requirement for re-contact and re-consent would be triggered. Possibly, in the interest of greater openness and transparency, policy-makers might consider the creation of a public research registry to publicize, on an annual basis, specific research studies that are using EHR data contained in the data warehouse, with an appropriate level of detail as they become defined, and a description of the research results to facilitate knowledge transfer and benefit-sharing for all.

The broad consent model would appear to provide greater flexibility than the specific, informed consent model, as well as being more practically feasible. Yet, as we have seen with the creation of national bio-banks or large national research platforms around the world, the adoption of even the broad consent model takes a significant amount of time, resources, public consultation, public trust, and public support.

Interestingly, a recent study on the use of personal information for research purposes found that, while a majority of respondents were supportive of research and willing to consider alternatives to conventional study-by-study consent, they still wished to maintain some level of control over the use of their information:

The Canadian public is supportive of health research and open to alternatives to a conventional project-by-project consent. However, they do not wish to completely relinquish control over use of their personal health information. Given the heterogeneity of consent choices, any long-run solution must take this into account to maintain public confidence in the confidentiality of the information they share with their physicians. Although the EMR may play a role here, the outstanding challenge is how best to elicit and keep up to date the individuals' consent preferences. There are no easy solutions.⁶³

From a legal perspective, some argue that broad consent is too far removed from the true concept of individual autonomy to be valid. Without details about each specific research project, individuals are not in a position to really turn their minds to the situation at hand and make a truly informed, autonomous choice. General, uninformed consent may simply not be a viable or cognizable type of consent under the current law.

Such an approach [broad consent] would undoubtedly make it easier to do longitudinal health research with large cohorts of participants. It would allow researchers to resolve consent issues with a single consent at the time individuals are recruited into the [research platform]. There is, however, little or no *legal* support for the use of blanket consents in Canada. Such consents are, by definition, far too general to have much legal weight.⁶⁴

Others may argue that true autonomous choice includes the right to waive one's right to more specific information and make decisions whenever and on whatever basis one chooses.

⁶³ Donald J. Willison *et al.*, *supra* note 29 at 711-712.

⁶⁴ See Caulfield & Ries, *supra* note 52 at 30 [footnote omitted]. The authors cite Vilhjálmur Árnason, who posits: "There is no such thing as 'general informed consent.' The more general the consent is, the less informed it becomes. It is misleading to use the notion of informed consent for participation in research that is unforeseen and has not been specified in a research protocol." See "Coding and Consent: Moral Challenges of the Database Project in Iceland" (2004) 18:1 *Bioethics* 27 at 42.

This includes the right to waive more specific information so as not to be hassled by researchers' calls and/or the right to selflessly exercise altruism for the public good in the fullest and truest sense, without condition or paternalistic restraint. Still, most commentators recognize that even though broad consent may be a departure from the gold standard of specific, informed consent and the principles of autonomy in the truest sense, this shift is critically necessary to alleviate the costs, burdens, and impediments of reaffirming consent for each individual, for each specific research project. Only by accepting to move away from specific, informed consent, could valuable health research—particular large-scale, longitudinal, population-based research—be allowed to proceed in the public interest.⁶⁵

This latter view is gaining increasing traction internationally, particularly in the evolving area of bio-banks, which provides us with a good analogy for considering interoperable EHR systems that could, once integrated, likewise serve as a significant national research platform.

For example, UNESCO offers the following commentary on research using human genetic databases:

The consent requirements in the research context are more rigorous. A difficult question in this area is that of whether fresh consent has to be obtained if new research of a different nature is to be conducted on samples originally given for another form of research. A system which required fresh consent would be extremely cumbersome and could seriously inhibit research and it is for this reason that a system of "blanket consent" covering all forms of future medical research might be preferable, provided that the consent given in the first instance explicitly recognizes this.⁶⁶

The HUGO Statement on Human Genomic Databases, recognizing the public good of research, recommended that "[i]nformed consent may include notification of uses (actual or future), or opting out, or, in some cases, blanket consent."⁶⁷

In 1997, a World Health Organization (WHO) report recommended that "blanket informed consent that would allow use of a sample for genetic research in general, including future as yet unspecified projects, appears to be the most efficient and economical approach, avoiding costly re-contact before each new research project."⁶⁸ However, the WHO, in a 2003 report titled *Genetic Databases: Assessing the Benefits and Impact on Human and Patient Rights* recommended the following protections and limitations to the concept of broad consent:

In some cases it might be desirable to seek broad, open-ended consent to future research, the purposes, limits or consequences of which are currently unknown. In such cases, blanket future consent is only permissible where anonymity can be guaranteed, and there is no risk that unexpected results will filter back to the subjects concerned. If this guarantee is not possible, or if linking of data is necessary for the research, then specific consent to the specific research must be obtained. The use of sunset clauses, whereby consent will only be valid during a finite period of time, might be considered as a means to ensure adequate protection of individual interests.⁶⁹

⁶⁵ For an in-depth discussion of the different views, perspectives, and rationales underlying the selection of broad consent as a policy choice, see Timothy Caulfield, "Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales" (2007) 18:2 *The King's College Law Journal* 9 [Caulfield, "Biobanks"].

⁶⁶ Sylvia Rumball & Alexander McCall Smith, *Human Genetic Data: Preliminary Study by the IBC on its Collection, Processing, Storage and Use* (Paris: UNESCO, 2002) at 16, online: UNESCO <http://portal.unesco.org/shs/en/files/2138/10563744931Rapfinal_gendata_en.pdf/Rapfinal_gendata_en.pdf>.

⁶⁷ Human Genome Organization (HUGO), *HUGO Ethics Committee: Statement on Human Genomic Databases* (London: HUGO, December 2002), online: Human Genome Organization <http://www.hugo-international.org/img/genomic_2002.pdf>.

⁶⁸ World Health Organization, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services*, Report of a WHO Meeting on Ethical Issues in Medical Genetics, Doc. No. WHO/HGN/GL/ETH/98.1 (Geneva: World Health Organization, 1997) at 13, online: World Health Organization <<http://www.who.int/genomics/publications/en/ethicalguidelines1998.pdf>>.

⁶⁹ Fons Dekkers *et al.*, *Genetic Databases: Assessing the Benefits and Impact on Human and Patient Rights*, Report of the Working Group of the World Health Organization's European Partnership on Patients' Rights and Citizens' Empowerment (Geneva: World Health Organization, 2003) at 14, online: World Health Organization <<http://www.law.ed.ac.uk/ahrb/publications/online/whofinalreport.pdf>>.

Many might contend that this broad consent model would allow greater integration of data between health care and health research so as to maximize the broader public benefits that were originally envisaged of the expansive purposes of the pan-Canadian health info-structure. Researchers could gain access to more comprehensive data, with greater ease and reduced potential for biased results in order to ultimately improve the quality of health care services. Individuals, too, could participate more fully in the research enterprise knowing that they are doing good for others, and future generations, without the need to provide specific consent in every case. Were this policy option adopted for observational health research, relevant laws would need to be amended accordingly. Arguably, to reflect this policy in law, the requirement for *informed* consent would perhaps have to be re-framed more accurately as prior authorization for future, yet unspecified research uses of personal data.⁷⁰ In the context of biobanks, Professor Bartha Knoppers has sounded the clarion call for the adoption of broad consent, with the appropriate protections, as the preferred policy option to enable longitudinal research studies in the public interest:

[T]he increasing complexity of choices and issues, and the legalistic nature of informed "choice" and the consent "process" could undermine the very act of communication and consensualism so necessary to ethically sound research. Moreover, in the future, can truly public resources and infrastructures such as population biobanks, be built to gird a universal health care system—one that promotes open access where the applicable norms are extrapolated only from personal data or health information legislation? The latter presumes that personal privacy is inimical to participating as a citizen in the public interest. In revisiting consent, researchers should ... consider ... the challenges they pose to mindsets forged by the polarization of setting up consent and confidentiality barriers for individuals that impede their participation as citizens in society for the benefit of others, including future "others" without an explicit consent in every case.⁷¹

Others, however, are more reticent to embrace such a policy shift too quickly, lest we be swayed by persuasive rationales for which we have much sympathy, while omitting to reflect carefully on the core legal and ethical principles at stake. Professor Caulfield cautions as follows:

These are, no doubt, challenging issues, and reasonable people can disagree over how they might best be resolved. However, we should be careful not to succumb to arguments that are not grounded in (or, at least, not reconciled with) foundational principles. It is easy to call for the protection of a principle when the threat to it is blatantly nefarious; it is less so when the incursion is supposedly being made for the greater good. But it is in this latter situation that a careful understanding and scrutiny of the principle – here, respect for autonomy – seems most crucial. This is particularly the case when the principle at stake flows from universally accepted, fundamental human rights. The ad hoc modification of standard consent principles in favour of a blanket consent model undertaken in the name of near-future scientific goals, no matter how worthwhile, seems a dangerous path.⁷²

We should not mistake such policy debates simplistically as pitting the ideal of personal autonomy underlying an individual's right to control the collection, use, and disclosure of her personal health information against utilitarian arguments about society's interests in health research and the collective right to share in its benefits. In the current context, such a clean dichotomy between the individual and the collective would not be possible. On the one hand, the protection of privacy is as much a collective interest as it is an individual one. The concept of public interest in the protection of privacy is finding increasing support in third generation privacy laws.⁷³ On the other hand, the individual's opportunity to participate in research may serve as an expression of her individual right to participate meaningfully in society as a contributing citizen, as has been suggested above. Moreover, with such rapid advances in science, health research is increasingly of immediate and direct benefit to individuals, and not merely to future generations.

⁷⁰ Timothy Caulfield, Ross E.G. Upshur & Abdallah Daar, "DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model" (2003) 4 BMC Medical Ethics E1.

⁷¹ Bartha Maria Knoppers, "Consent Revisited: Points to Consider" (2005) 13:2&3 Health Law Review 33 at 36.

⁷² Caulfield, "Biobanks", *supra* note 65 at 24.

⁷³ See e.g. PHIPA, *supra* note 58, s. 44(3)(c); HIA, *supra* note 58, s. 50(1)(b)(i).

C. Using De-Identification as a Means of Carving Out Research Activities Altogether

To the extent that it is possible to completely de-identify personal information in EHRs, de-identification of personal information required for health research purposes may provide a partial solution. Where personal information is genuinely rendered de-identified, that information will fall outside the scope of existing privacy regimes altogether.

Early proponents of EHRs who foresaw their usefulness for health research purposes viewed de-identification as a means of making EHRs readily available to researchers. Roy Romanow, for one, suggested that researchers could have ready access to data “extracted generically for health research purposes, without being linked to any individual electronic health record.”⁷⁴

Canada Health Infoway appears to favour this approach. It has developed a conceptual architecture that articulates an overview of the necessary component parts of a pan-Canadian electronic health info-structure, one of which is an anonymization service.⁷⁵ The anonymization service it contemplates as a necessary component of Canada’s health info-structure would enable both the use of pseudonyms and the removal of all personal identifiers from an EHR to enable use of the data for secondary analysis and research purposes.⁷⁶

A recent EKOS Research Associates Inc. survey commissioned by Canada Health Infoway, Health Canada, and the Office of the Privacy Commissioner of Canada indicates that a strong majority of Canadians are also comfortable with the use of de-identified EHRs for secondary health research purposes. This survey revealed that 84 per cent of Canadians support the use of EHRs for secondary health research purposes, provided that personally identifying information is not disclosed to researchers.⁷⁷ This is consistent with earlier findings resulting from studies conducted on this similar question.⁷⁸

De-identification of data for research use is strongly encouraged as a crucial and practical form of protection.⁷⁹ However, to render EHR data truly de-identifiable for research purposes is, from a technological and organizational standpoint, an elusive, relative, and ever-shifting objective.

First, the specifications required of EHR systems must be clear and consistent to preserve their interoperability and their potential value for health research purposes. Whether the goal will be to de-identify data or to render the data truly de-identifiable has very different implications for privacy protection. For example, will the data be coded or double-coded? Will the code be reversible or irreversible, on a temporary or permanent basis? Will the data remain linkable or un-linkable and will individuals’ identities be ultimately traceable or untraceable? All of these specific choices will have significant impact on privacy protection. The

⁷⁴ *Romanow Report*, *supra* note 6 at 79.

⁷⁵ Canada Health Infoway, *An Overview of the Electronic Health Record Privacy and Security Conceptual Architecture* (2006) at 7, online: Canada Health Infoway <<http://knowledge.infoway-inforoute.ca/EHRSRA/doc/EHR-Privacy-Security-Overview.pdf>>.

⁷⁶ *Ibid.*

⁷⁷ EKOS Research Associates Inc., *Canadians and the Privacy Landscape* (Ottawa: EKOS Research Associates Inc., 2007) at 6, online: Office of the Privacy Commissioner of Canada <http://www.privcom.gc.ca/information/survey/2007/ekos_2007_02_e.asp>.

⁷⁸ Kalpana Nair *et al.*, “Patients’ consent preferences regarding the use of their health information for research purposes: a qualitative study” (2004) 9:1 *Journal of Health Services Research & Policy* 22; Nandini Saxena *et al.*, *Understanding Canadians’ Attitudes and Expectations: Citizens’ Dialogue on Privacy and the Use of Personal Information for Health Research in Canada* (Ottawa: Canadian Policy Research Networks, 2006), online: Canadian Policy Research Networks <<http://www.cprn.com/doc.cfm?doc=1428&l=en>>; Donald J. Willison *et al.*, “Patients’ consent preferences for research uses of information in electronic medical records: interview and survey data” (2003) 326 *B.M.J.* 373.

⁷⁹ William W. Lowrance & Francis S. Collins, “Ethics: Identifiability in Genomic Research” (2007) 317 *Science* 600.

nomenclature around de-identification in the literature is inherently confusing,⁸⁰ and several attempts have been made to clarify these concepts for Canadian researchers through research ethics guidelines and best practices.⁸¹ Despite the current confusion, definitions themselves are not an insurmountable problem if what they refer to substantively is commonly understood by all those who use and apply them. System requirements and specifications must be made very clear and explicit from the outset, lest this policy option become an obtuse way of providing misleading assurances to Canadians who believe they are meaningfully contributing to research in the false confidence that there is little or no technical risk to their privacy.

Second, de-identification is a relative concept in that data may be completely de-identifiable in the hands of one person or entity, and yet remain readily re-identifiable in the hands of another person or institution holding the key to re-linkage. Resorting to de-identification as a solution requires a sophisticated governance structure to determine which entity or entities will carry out the de-identification, who will be the key-holder, and who will retain the potential to re-identify EHR data and/or link it to other personal data at the request of researchers. While systems could be configured to disclose only de-identifiable data—however defined—to individual researchers for specific research projects, many researchers might eventually need to re-identify individuals in order to fulfill the verification requirements of regulators, sponsors, or publishers; link the data with other datasets in order to examine the influence of other health, socio-economic, and environmental determinants; track changes in data over time in longitudinal-type research; and/or possibly contact individuals down the road to seek consent to collect physical measures and/or carry out a subsequent qualitative arm of the research, such as a quality of life survey, for example. Who will bear responsibility for de-identifying the data, and then retaining the ability to re-identify it as needed? Will this responsibility remain with health information custodians on the front line? Will it be transferred to specially designated research data custodians charged with maintaining interoperable research data warehouses? Or will it be entrusted to a recognized, independent third party trustee? Who will be the key-holder? These are critical decisions that will have major implications for accountability, capacity, and resources.

Third, the difficulty inherent in ensuring a sufficient degree of de-identification is exacerbated by the fact that an adequate standard of de-identifiability will inevitably be a moving target. That is, as more and more personal information is collected about individuals and disseminated in various public sources and fora, there is an increasing likelihood that the information could be aggregated, cross-referenced, and linked in order to re-identify previously de-identified records.⁸² The fiasco surrounding the release of de-identified search query records by AOL aptly demonstrates why this is so.⁸³ Even where obvious or common personal

⁸⁰ Bartha Maria Knoppers & Madelaine Saginur, "The Babel of Genetic Data Terminology" (2005) 23 *Nature Biotechnology* 925.

⁸¹ See e.g. Canadian Institutes of Health Research, *CIHR Best Practices for Protecting Privacy in Health Research* (Ottawa: Public Works and Government Services Canada, 2005) at 33, online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf> [*CIHR Best Practices*]; see also Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 1998 (with 2000, 2002, 2005 amendments) (Ottawa: 2005), art. 3.2, online: Interagency Advisory Panel on Research Ethics <http://pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf>.

⁸² See Khaled El Emam *et al.*, "Evaluating Common De-Identification Heuristics for Personal Health Information" (2006) 8 *Journal of Medical Internet Research*, online: *Journal of Medical Internet Research* <<http://www.jmir.org/2006/4/e28>>.

⁸³ "Just how personally revealing such data can be became evident last year, when AOL released records of the searches conducted by 657,000 Americans for the benefit of researchers. While AOL did not identify the people behind the searches, reporters from The New York Times were able to track down some of them quickly through their search requests": Miguel Helft, "Google Adds a Safeguard on Privacy for Searchers" *The New York Times* (15 March 2007) C4, online: *New York Times Online* <<http://www.nytimes.com/2007/03/15/technology/15googles.html>>.

identifiers are stripped from the data, information may in some cases be linked back to the individual in question, particularly where sub-optimal de-identification techniques were used.⁸⁴ Hence, from a technological perspective, the effectiveness of de-identification features must be measured by the residual risk for data to be re-linked at the individual level through external re-identification attacks, and not merely by the extent to which direct and/or quasi-personal identifiers have been removed.⁸⁵ The complexity and variability of existing standards, which already recognize a spectrum of acceptable degrees of de-identification, will only be augmented by the fact that the potential for re-identification continues to increase as more and more personal information is made publicly available. This does not lead necessarily to the conclusion that de-identification can never be effective, but rather that de-identification techniques and practices must be continually upgraded to keep pace with the rising potential for re-identifiability.

Under existing statutory privacy regimes in Canada, personal information must be de-identified, with no serious possibility of re-identification, before it would fall completely outside the scope of legislated privacy protections, including the requirement to obtain consent for its use. This is necessarily implied from the fact that most, if not all, data protection regimes apply to *identifiable* data. Legislative definitions that would place health information outside of legal regimes are, however, inconsistent or non-existent and thus extremely difficult to apply in practice.

For example, section 3(2) of Saskatchewan's *Health Information Protection Act* defines "de-identified health information" as "personal health information from which any information that may *reasonably be expected* to identify an individual has been removed".⁸⁶ Compare this to Alberta's *Health Information Act*, in which the term "non-identifying," in reference to health information, "means that the identity of the individual who is the subject of the information *cannot be readily ascertained* from the information".⁸⁷ Under Ontario's *Personal Health Information Protection Act*, "identifying information means information that identifies an individual or for which it is *reasonably foreseeable* in the circumstances that it could be utilized, either alone or with other information, to identify an individual."⁸⁸ Section 1(3) of the New Brunswick *Protection of Personal Information Act* stipulates that personal information will be considered identifiable for the purposes of that *Act* if it includes a name, makes an individual's identity obvious, or does not itself include the name of an individual or make his or her identity obvious but is likely in the circumstances to be combined with other information that does. New Brunswick exempts de-identified data from its data protection regime without articulating any test for what constitutes de-identification.⁸⁹

A 1997 European data protection directive provides that an "individual shall not be regarded as identifiable if identification requires an unreasonable amount of time and manpower".⁹⁰ More recently, the Article 29 Data Protection Working Party has expressed the

⁸⁴ Latanya Sweeney, "k-Anonymity: A Model for Protecting Privacy" (2002) 10 *International Journal of Uncertainty, Fuzziness and Knowledge-Based Systems* 557; Salvador Ochoa *et al.*, *Reidentification of Individuals in Chicago's Homicide Database: A Technical and Legal Study* (2001) [unpublished, archived online: Massachusetts Institute of Technology <<http://web.mit.edu/msalib/www/writings/classes/6.805/reid.pdf>>].

⁸⁵ See El Emam *et al.*, "Pan-Canadian", *supra* note 29 to determine the risks, in the Canadian context, of re-identification of anonymized data based on publicly available information.

⁸⁶ *Health Information Protection Act*, S.S. 1999, c. H-0.021, s. 3(2) [*HIPA*] [emphasis added].

⁸⁷ *HIA*, *supra* note 58, s. 1(1)(r) [emphasis added].

⁸⁸ *PHIPA*, *supra* note 58, s. 4(2) [emphasis added].

⁸⁹ See *Protection of Personal Information Act*, S.N.B. 1998, c. P-19.1, s. 1(2), which states: "information that relates to an identifiable individual but is collected, used or disclosed in a form in which the individual is not identifiable is not personal information when so collected, used or disclosed."

⁹⁰ Council of Europe, Committee of Ministers, Recommendation No. R (97) 5 (1997), online: Council of Europe—Human Rights and Legal Affairs <[http://www.coe.int/t/e/legal_affairs/legal_co-operation/data_protection/documents/international_legal_instruments/Rec\(97\)5_EN.pdf](http://www.coe.int/t/e/legal_affairs/legal_co-operation/data_protection/documents/international_legal_instruments/Rec(97)5_EN.pdf)>.

view that a mere hypothetical possibility of singling out an identifiable individual from a larger data set is not enough to consider that person “identifiable” for the purpose of data protection regimes. One must consider “all the means likely reasonably to be used” and if, taking into account “all the means likely reasonably to be used”, the possibility for re-identification “does not exist or is negligible, the person should not be considered as “identifiable,” and the information would not be considered as “personal data” subject to data protection regimes.⁹¹

The United States has rejected, in large measure, a speculative approach to assessing the likelihood of re-identification in favour of an explicit de-identification protocol. Under the *Health Insurance Portability and Accountability Act*,⁹² data may be considered de-identified when it does not contain any of eighteen specified data elements and there is no knowledge that the remaining information could, on its own or in combination with other information, be used to identify the subject of the information. However, *HIPAA* also permits data to be considered de-identified if an individual with knowledge and expertise in de-identification has certified that there is a “very small risk” of re-identification.

Canadian courts are just beginning to struggle with the question of when data may legally be said to be adequately de-identified so as not to constitute personal information caught by access to information and data protection regimes. The Federal Court of Appeal has found that data will constitute personal information “if it is ‘about’ an individual and if it permits or leads to the possible identification of the individual.”⁹³ More recently, the Federal Court has further specified that “[i]nformation will be about an identifiable individual where there is a serious possibility that an individual could be identified through the use of that information, alone or in combination with other available information.”⁹⁴

Given that the legal test turns on possibilities that are difficult to ascertain in practice, it is not clear that removal of personal identifiers alone will constitute an adequate substitute for consent. In order for de-identification to provide workable and effective protection, clear standards and protocols may be required in order to meet or surpass the applicable threshold of risk.

Quite apart from the legal complexity inherent in ascertaining what constitutes de-identifiable data for the purposes of interpreting a given statute, it is not clear that individuals’ legal and moral interests in their personal information dissipate simply because it is de-identified and falls outside the scope of data protection regimes. Though it may be premature to base public policy decisions on this controversial line of argument, at least one author has tentatively argued that an individual may have a continuing privacy interest in his or her personal health information under Canadian common law, even if it has been de-identified.⁹⁵ This continuing interest, to the extent it exists, would no doubt be enhanced if one or more parties retained the capacity to re-identify personal information somewhere along the chain of transactions involving the data.

In *Re Source Informatics Ltd.*,⁹⁶ the English Court of Appeal determined that an action for breach of confidence was not available to restrict the non-consensual sale of de-identified prescription data from pharmacists to Source Informatics Ltd., since there was no significant

⁹¹ Article 29 Data Protection Working Party, *Opinion 4/2007 on the concept of personal data* (20 June 2007) at 15, online: European Commission—Justice and Home Affairs <http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp136_en.pdf>.

⁹² *Health Insurance Portability and Accountability Act of 1996*, Pub. L. No. 104-191, 110 Stat. 1936 [HIPAA].

⁹³ *Information Commissioner v. Canada (Transportation Accident Investigation and Safety Board)*, 2006 FCA 157 ¶ 43, [2007] 1 F.C.R. 203.

⁹⁴ *Gordon v. Canada (Health)*, 2008 FC 258 at para 34.

⁹⁵ See Elaine Gibson, “Is There a Privacy Interest in Anonymized Personal Health Information?” (2003) Health L.J. 97 for an interesting discussion of this issue.

⁹⁶ [1999], E.W.J. No. 6880 (C.A.) (QL).

risk of re-identifying individual patients from the prescription data in question. The Court of Appeal looked to equity and held that an individual does not maintain a privacy interest in personal information that has been anonymized. The Court acknowledged that pharmacists owe patients a duty of confidentiality in respect of their personal health data, but reasoned that “pharmacists’ consciences ought not reasonably to be troubled”⁹⁷ by the disclosure of their patients’ data once de-identified. In Canada, however, liberty, autonomy, and *prima facie* control over personal information have been recognized as the fundamental underpinnings of privacy rights. The constitutional nature of these rights suggests that if interests implicating section 7 of the *Charter* are engaged, a different result could obtain in Canada. An assessment of the machinations of the data custodian’s conscience, therefore, is not necessarily an appropriate proxy for the principles of fundamental justice.⁹⁸

It seems clear then that de-identification, while often heralded as the answer to the consent dilemma, cannot provide a universal solution for many forms of valuable health research. While de-identification may, in some cases, provide an effective means of managing privacy risks, it cannot be relied upon as the only viable policy option. It will likely be necessary to refocus the debate away from technological solutions like de-identification toward first legal and ethical principles in order to find complementary forms of protection.

D. Relying on Implied Consent by Re-Conceptualizing Research as a Necessary Adjunct to the Primary Purpose of Health Care

In existing legal regimes, transfers of electronic health information for health care purposes depend largely on implied or deemed consent. Once consent for the initial collection, use, and disclosure of personal health information for primary health purposes has been sought and obtained, health care providers within what is colloquially known as an individual’s “circle of care”⁹⁹ are typically able to use and disclose that individual’s personal information as necessary for treatment and other primary health purposes. Even within the circle of care, however, personal information remains subject to the specific access rights depending on the health care provider’s role, as well as to possible exceptions in those jurisdictions in which masking, lock-box, or other opt-out mechanisms exist.

Consent issues usually arise more acutely where transfers of personal information outside a circle of care are contemplated. Within a circle of care, consent is deemed or implied. Outside a circle of care, there is no deemed or implied consent for secondary uses of personal information unrelated to the purposes for which consent was originally provided, typically health care.

Traditionally, health care was understood as having as its sole purpose the provision of *direct* benefits to the individual patient. By contrast, health research was understood as having as its purpose *future* benefits that would accrue, not to the individual, but to society as a whole. The use of personal information for health research has therefore been conceptualized as a secondary use.

First principles of research ethics, which developed at the time of the *Nuremberg Code* of 1949¹⁰⁰ and the *Declaration of Helsinki* of 1964,¹⁰¹ have contributed to codifying this conceptual distinction. These seminal ethical codes developed as a means of protecting the individual against the encroachment of utilitarian interests seeking to advance collective

⁹⁷ *Ibid.* at 35.

⁹⁸ *Supra* note 95.

⁹⁹ The “circle of care” is a core concept defined as the individuals and activities directly related to the health care and treatment of an individual.

¹⁰⁰ *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, vol. 2 (Washington D.C.: U.S. Government Printing Office, 1949) at 181-182.

¹⁰¹ *Declaration of Helsinki*, *supra* note 41.

interests in health research at the expense of fundamental rights to autonomy, bodily integrity, and human dignity.

More recent developments in the Canadian context have come to challenge the notion that the purposes motivating health care and publicly funded health research are so diametrically opposed.

For several decades now, we have seen a sustained commitment to maintaining Canada's system of universal, publicly funded health care. Though an increased role for the private sector within our publicly funded health care system has been contemplated and permitted in recent years,¹⁰² the fundamental commitment to ensuring a baseline level of access to publicly funded health care for all has not been questioned. Access to health care data, prescription data, billing information, and other personal data has been indispensable for the purpose of administering a publicly funded health care system. Health system managers and health services researchers must be able to rely on these data in order to plan the appropriate allocation of public resources and work to improve the quality of, and access to, health care services. Canadians benefit directly from enabling publicly-funded research which operates to ensure the economic viability of their health care system for the universal benefit of all. Over time, this uniquely Canadian reality has necessarily blurred the philosophical divide between publicly funded health care and publicly funded health research.

The gap between the role of health care provider and health researcher has also begun to close on both ends. Health care providers are increasingly being encouraged to make treatment decisions based on all available and accessible research evidence, which we see being incorporated into relevant professional standards of care.¹⁰³ Health researchers, for their part, are being encouraged through funding requirements and knowledge transfer incentives to translate their research results into effective practice through improved policies and/or clinical care for the direct benefit of Canadians.¹⁰⁴

Moreover, progress in the fields of information technology, genomics, and nanotechnology has resulted in such rapid advances in health care that the traditional assumption that health research will not likely result in any direct benefit for research participants or their families within their lifetimes may be outdated. Indeed, it is increasingly likely that individuals will see benefits from their participation in research accrue to themselves and their genetically related next of kin.

¹⁰² *Chaoulli v. Quebec (A.G.)*, 2005 SCC 35, [2005] 1 S.C.R. 791.

¹⁰³ “[I]nformation, evidence and ideas have the potential to unlock the cures to many of today’s illnesses, identify the genetic source of chronic illnesses, give health care providers access to the latest and best information on new treatments or drugs, improve the quality and safety of care within the health care system, and most importantly, empower patients to manage and maintain their own health With a complete system of electronic health records in place ... [h]ealth care providers would have access to clinical decision support tools to assist them in making decisions based on the best available evidence. Health care providers would be able to access patient records at the point of a clinical encounter. It would help manage the massive amounts of complex health information and ensure that health care providers have complete and accurate information about patients’ health and health care histories. It also would improve physicians’ ability to access the latest information, select the best course of action, and use evidence to guide their decisions.” *Romanow Report*, *supra* note 6 at 75 and 78-9.

¹⁰⁴ The *Canadian Institutes of Health Research Act*, S.C. 2000, c. 6, which created the Canadian Institutes of Health Research (CIHR), Canada’s leading federal health research agency, clearly states at s. 4: “The objective of the CIHR is to excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system ...” [emphasis added]. For example, in one of its many initiatives aimed at meeting this objective, CIHR is investing significant resources to ensure that knowledge gained from its clinical research efforts is translated into health innovations that are applied in practice and for which Canadians themselves will be the immediate beneficiaries of improved health. See also Canadian Institutes of Health Research, *A Partnership for Clinical Research*, online: Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/22113.html>>.

In light of this evolving reality, Dr. Khaled El Emam, Canada Research Chair in Electronic Health Information at the University of Ottawa, contends that “research and clinical applications are merging and researchers are increasingly turning to EHRs as a source of clinically relevant data.”¹⁰⁵ Canada Health Infoway has also implicitly espoused similar reasoning. While it recognizes that patient-centric access to EHRs by caregivers and other types of end-users is the primary goal of the EHR Info-Structure, Infoway has noted that a lot can be said for the health care value derived from being able to use this information for research, analysis, and health prevention initiatives.¹⁰⁶

Elsewhere, the UK Clinical Research Collaboration argued before the British House of Commons Health Committee that “[f]acilitating access by the research and public health communities to electronic patient records has substantial benefits for patients and the health service. Since research shares a mission of improving patient care and patient safety it is integral to patient benefit. Access to patient data for this purpose should be considered a primary and not a secondary use.”¹⁰⁷ In the U.S., Henry Lowe, Chief Information Officer at Stanford University School of Medicine, has argued that, “[i]f we want to improve outcomes and develop an evidence-based model of healthcare, we have to eliminate the dichotomy between patient care and research. EMR systems”, he said, “provide a tremendous opportunity to bridge that gap.”¹⁰⁸

What then would be the implications of formally re-conceptualizing publicly funded health research as a necessary adjunct to health care as the primary use of EHRs? Could health researchers realistically be brought together with providers into that trusted circle of care within which we have come to accept an implied consent model for data sharing?

This policy option depends on re-conceptualizing not only health research, but health researchers too, as a class of professionals that requires comprehensive, coherent, and effective regulation, with proper training and certification, ethical codes of conduct, accountability mechanisms, and appropriate disciplinary sanctions. As a profession, health researchers are currently not regulated as closely or rigorously as health care providers. If health researchers are allowed to enter the circle of trusted health professionals, they too would require an appropriate level of scrutiny over their work.

A complex system of user-based privileges for health researchers, running parallel to those currently being developed for health care providers, would be required. These user-based privileges would be required to tailor degrees of access commensurate with area of specialization, research method, and role-based variables, among other factors. A shift from the current disclosure-based regime to an access-based model for research purposes would no doubt also be required. That is, this policy option would necessitate a move away from existing privacy protection models which seek to limit the uses and disclosures of personal data vis-à-vis outside third parties, including health researchers, towards the adoption of new “security perimeter models”¹⁰⁹ which would allow health researchers to come within the permissible zone of role-based access rights.

¹⁰⁵ El Emam *et al.*, “Pan-Canadian”, *supra* note 29 at 3.

¹⁰⁶ Canada Health Infoway Inc., *EHRs Blueprint, version 2*, *supra* note 20 at 5.

¹⁰⁷ U.K., H.C. Select Committee on Health, “Evidence submitted by the UK Clinical Research Collaboration (EPR 52)” (25 April 2007), online: House of Commons - Health - Written Evidence <<http://www.publications.parliament.uk/pa/cm200607/cmselect/cmhealth/422/422we47.htm>>, cited in Roy & Fournier, *supra* note 11 at 7.

¹⁰⁸ FasterCures, *Think Research: Using Electronic Medical Records to Bridge Patient Care and Research* (Washington D.C.: FasterCures, 2005) at 12, online: FasterCures <http://www.fastercures.org/pdf/emr_whitepaper.pdf>.

¹⁰⁹ For an in-depth discussion of the security perimeter of EHRs and the policy implications of making such technological choices, see E. Brown *et al.*, *Technology Choices and Privacy Policy in Health Care* (2007), online: Memorial University of Newfoundland <<http://cpig.cs.mun.ca/TechnologyChoices.pdf>>.

This policy option would add to the organizational complexity of a pan-Canadian interoperable EHR system and the management challenges already associated with its adoption by health care providers. Re-conceptualizing health research as a necessary adjunct to the primary purpose of the collection, use, and disclosure of personal health information also has the potential to affect the current dynamic between patients and their physicians. Privacy guidelines with a clear basis in health ethics promulgated by the Canadian Medical Association recognize that a patient's "ability to decide with whom he or she will share information is crucial for the protection of the right of privacy and for the preservation of trust in the therapeutic context."¹¹⁰ If the proposed re-conceptualization of health research as an integral part of the health care circle is not closely aligned with the views of Canadians, distrust and unintended schisms between health care providers and their patients could result, threatening the traditional underpinnings of that confidential relationship:

Fidelity of health care professionals, of health care institutions, and of the health care system itself to patients will be brought into question if patients believe they have been deceived by multiple secondary uses of their PHI [personal health information], particularly if these uses occur without their knowledge. Patients, whatever their degree of vulnerability may be, may rightfully expect that effective measures exist to protect their privacy, and the confidentiality of their health information, particularly when that information is circulating in identifiable form.¹¹¹

The Canadian Medical Association has expressed the view that "[m]any laws, practices and initiatives may not withstand the kind of scrutiny deemed necessary and reasonable for the protection of privacy and the trust and integrity of the therapeutic relationship."¹¹² Re-conceptualizing health research as an integral part of the primary purpose of the collection, use, and disclosure of personal health information may be one such initiative that would no doubt be met with some notable resistance.

Nevertheless, evidence of a willingness to collapse health research and health care purposes is extant in some Canadian legal regimes. For example, Manitoba's *The Personal Health Information Act* permits an information trustee to disclose, without an individual's consent, personal health information to specified public bodies for "research and planning that *relates to the provision of health care or payment for health care by the trustee*".¹¹³ The requirement that research and planning "relate to" the provision of health care or payment for health care is sufficiently broad in scope that it can authorize the disclosure of personal health information for research purposes unlikely to result in direct care or treatment benefits to individuals affected. Indeed, such a provision would appear to catch a wide range of secondary research purposes including quality control, audit and financial planning that, while related to the provision of health care, may not directly improve quality of care.

Similarly, in Ontario's *Personal Health Information Protection Act*, a health information custodian may disclose personal information to a prescribed person or entity "who compiles or maintains a registry of personal health information for purposes of facilitating or improving the provision of health care"¹¹⁴ or "for the purpose of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services".¹¹⁵ Such prescribed persons or entities must have in place practices and procedures to protect the privacy of the individuals whose personal health information they receive and to maintain the

¹¹⁰ Canadian Medical Association, *CMA Health Information Privacy Code* (Ottawa: Canadian Medical Association, 1998), Principle 5, online: Canadian Medical Association <http://www.cma.ca/index.cfm/ci_id/3216/la_id/1.htm>.

¹¹¹ Roy & Fournier, *supra* note 11 at 5.

¹¹² *Supra* note 110.

¹¹³ S.M. 1997, c. 51, C.C.S.M. c. P33.5, s. 22(2)(g)(ii).

¹¹⁴ *PHIPA*, *supra* note 58, s. 39(1)(c).

¹¹⁵ *Ibid.*, s. 45(1).

confidentiality of the information. Moreover, those practices and procedures must be approved by the Privacy Commissioner. Interestingly, once prescribed and approved, these entities are permitted under the terms of the *Act* and its accompanying regulations to use personal health information for research purposes as *though they were a health information custodian* under the *Act*, effectively assimilating them to other health care providers within the “inner circle,” and therefore subjecting them to the same rules regarding research use.¹¹⁶

What these existing legislative regimes appear to effectively do is allow prescribed entities to be regarded as equivalent to health providers for the purpose of permitting access to data, subject to the same rules and conditions. However, they do not go as far as assimilating health research to health care purposes within the permissible circle of care uses based on implied consent.

Though controversial, this policy option for addressing the consent requirements for research access to EHR data may gradually gain traction as a viable alternative to specific, informed consent. The reasons surveyed above that would seem to support a re-conceptualization of health research and health researchers within the “inner circle,” however, are clearly limited to publicly funded research carried out for the common good. In the current context, the common good, as we conjecture, is increasingly likely to result in good for the individual as well, in his or her lifetime, or that of the immediate next of kin. An attempt to argue that commercial research should also be included within that same circle is nowhere nearly as clear or likely to be persuasive. Hence, the viability of any policy option that would recognize health research as a primary purpose would depend on a sophisticated ability to distinguish between non-commercial, academic, publicly sponsored health research which benefits all, from commercially sponsored research that is primarily profit-driven. It is questionable whether such a distinction could ever be realistically delineated today, given the high degree of public-private research integration:

Furthermore, the activities of health researchers themselves will be difficult to categorize as either commercial or noncommercial in nature. Increasingly, academia, private sector, voluntary charitable organizations and government are joining forces to engage in innovative research partnerships and to transform this new knowledge into forms which are beneficial to the population. In an era where such partnerships are actively encouraged, a whole spectrum of public-private arrangements have begun to emerge. More and more often, university researchers receive salary support and/or funding from various sponsors. In some cases, the support is provided to conduct research that may directly or indirectly enhance the competitiveness of Canadian businesses; in other cases, it is provided to support peer-reviewed, academic research to advance general knowledge about the health and/or health system of Canadians; more commonly, support is intended to sustain both these objectives.¹¹⁷

E. Resorting to Existing Statutory Consent Exemptions for Research

The departure from informed consent and the foundational principle of individual autonomy is significantly marked in the case of consent exemptions. In this policy option, the design and development of EHRs would continue to focus strictly on health care purposes, with no up front discussion of potential research uses of the data. Later, when EHR systems are eventually made available for use in support of research purposes, resort would be had to existing legislative exemptions that exceptionally allow disclosure of personal information for research purposes without consent.

¹¹⁶ O. Reg. 329/04, ss. 13(4) and 18(3).

¹¹⁷ Canadian Institutes of Health Research & Canadian Institute of Health Information, *Personal Information Protection and Electronic Documents Act: Questions and Answers for Health Researchers* (Ottawa: Public Works and Government Services Canada, 2001), online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/pdf_14391.htm>.

Most data protection statutes contain research exceptions for the collection, use, or disclosure of personal information without the consent of the individuals that the information pertains to, subject to several, any, or all of the following conditions:

- the research plan must outline the nature, objectives, and anticipated benefit of the research, as well as the qualifications and affiliations of the researchers;
- the objectives of the research cannot otherwise be reasonably accomplished without the data being requested, at some necessary level of identifiability;
- obtaining the consent of each individual must be shown to be impracticable;
- the research must meet some public interest test or pass some harm/benefit analysis;
- there must be review and approval by a research ethics board, and in some cases, notification and/or approval by a data protection authority;
- the research must be conducted with adequate safeguards in place to protect the privacy and confidentiality of the data, with additional safeguards and protections in the case of data matching or data linkage;
- there must be in place procedures to remove all identifying information at the earliest opportunity consistent with the purposes of the research;
- the researcher must use the personal information only for the purposes set out in the research plan, and not use or disclose the data for any other purpose, unless required by law;
- the researcher must not contact or attempt to contact the individuals, unless the data custodian obtains prior consent from the individuals for such contact to occur;
- the researcher must not publish the research results in a way that may identify individuals;
- the researcher must notify the custodian immediately in the event of a privacy or security breach; and,
- the researchers must enter into a research agreement with the data custodian, wherein the researcher expressly agrees to a number of the above conditions, as well as other conditions imposed by the data custodian, including requirements for security, return, retention, or disposal of the data, and requirements to submit to on-site audits to ensure compliance with the agreement.¹¹⁸

While many, if not all, data protection statutes in Canada exceptionally allow non-consensual research use of personal information subject to a number of conditions listed above, these conditions are by no means the same—let alone similar—across different jurisdictions. In fact, there are significant differences, both in their formulation and combination, which may impede the interoperability of systems and inter-jurisdictional research.

In view of this variability, reliance on legislated exemptions after the fact to allow disclosure of personal information to researchers without consent may prove to be difficult to reconcile from one jurisdiction to another. This was similarly the case for consent rules in respect of the collection, use, and disclosure of personal information for health care purposes—particularly in electronic form—until policy-makers undertook concerted efforts to reduce the gap by harmonizing and consolidating legislative solutions. The Federal/Provincial/Territorial

¹¹⁸ For an overview of relevant statutory conditions for allowing access to personal information for research purposes without consent, see Kosseim, Kardash & Penta, *supra* note 31 at 60-128.

(FPT) Conference of Deputy Ministers of Health mandated its Advisory Committee on Information and Emerging Technologies to develop a *Pan-Canadian Health Information Privacy and Confidentiality Framework*.¹¹⁹ The objective of the *Framework* was:

... to respond to Canadians' privacy and confidentiality expectations and to suggest a harmonized set of core provisions for the collection, use and disclosure of personal health information in both the publicly and privately funded sectors. Consistent, or at least more consistent, privacy regimes among jurisdictions would facilitate health care renewal, including the development of electronic health record systems and primary health care reform.

The *Framework*, endorsed by a majority of members of the FPT Conference of Deputy Ministers of Health in January 2005,¹²⁰ recommended, as part of its core provisions, harmonized rules for *both* health care treatment and health research. However, jurisdictions, during and since the development of the *Framework*, appear to have focused primarily—if not exclusively—on developing and/or revamping legal rules around an implied knowledgeable consent model for the collection, use, and disclosure of personal health information within the circle of care.¹²¹ These efforts have been motivated by a common objective to facilitate the rapid development and deployment of EHRs for treatment purposes,¹²² but unless sustained legislative efforts are similarly undertaken now to harmonize the disparity of existing conditions for research purposes, this “wait and see” policy option may not turn out to be the panacea it is hoped to be. Several examples of critical disparity illustrate the point.

For one, the harm-benefit analysis and public interest test are fundamentally different, both legally and philosophically, in different statutes. In several jurisdictions, the analysis of whether the consent exception applies to the proposed research turns on weighing the potential harm to an individual's privacy with the anticipated public benefit of the research. That is, the analysis in some jurisdictions requires consideration of the individual's private interest in protecting his or her privacy versus the public interest in conducting the research.¹²³ Other jurisdictions have devised different tests. For example, Ontario's health information protection regime requires consideration of two competing public interests, “the public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed”.¹²⁴ Similarly, Alberta law requires that “the proposed research is of sufficient importance that the public interest in the proposed research outweighs to a substantial degree the public interest in protecting the privacy of the individuals who are the subjects of the health information to be used in the research”.¹²⁵

Another significant difference in the conditions required for non-consensual research use of personal information across jurisdictions is the level of oversight required. Some jurisdictions expressly provide for the role of the research ethics board,¹²⁶ while others also require notification and/or review and approval of the relevant data protection authority in

¹¹⁹ Health Canada, *Pan-Canadian Health Information Privacy and Confidentiality Framework* (Ottawa: 2005), online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pubs/ehealth-esante/2005-pancanad-priv/index_e.html>.

¹²⁰ Quebec and Saskatchewan did not endorse the *Framework*.

¹²¹ For example, Ontario developed and adopted its health information law in 2004 consistent with the emerging consensus at the time around an implied consent model within the circle of care, whereas Saskatchewan and Alberta had to amend their respective health information laws to better harmonize themselves in accordance with this consolidated legal rule.

¹²² Nola M. Ries, “Patient Privacy in a Wired (and Wireless) World: Approaches to Consent in the Context of Electronic Health Records” (2006) 43 Alta. L. Rev. 681.

¹²³ See e.g. *Freedom of Information and Protection of Privacy Act*, R.S.B.C. 1996, c. 165, s. 35(b); *HIPA*, *supra* note 86, s. 29(2)(c); *Personal Health Information Act*, C.C.S.M., c. P-33.5, s. 24(3)(a) [*PHIA*].

¹²⁴ *PHIPA*, *supra* note 121, s. 44(3)(c).

¹²⁵ *HIA*, *supra* note 58, s. 50(1)(b)(i).

¹²⁶ See e.g. *PHIA*, *supra* note 123, s. 24(2)(b); *HIA*, *supra* note 58, ss. 49 and 64(2); *HIPA*, *supra* note 86, s. 29(1)(b); *PHIPA*, *supra* note 58, s. 44, and accompanying regulations, O. Reg 329/04, s. 15.

that jurisdiction.¹²⁷ Still others envisage some degree of oversight by the health data custodian who releases the data to the researcher without consent under conditions which must be specified in a research data agreement to varying degrees of specificity.¹²⁸

Yet a further example of the significant differences between laws is the requirement that consent be impracticable to obtain. In some jurisdictions, the requirement is stated differently in terms of being impracticable, impractical, or impossible.¹²⁹ For present purposes, this condition is critical. An attempt to concretely flesh out what is meant by “impracticable” has been made in best practice guidelines for health researchers. It demonstrates a range of factors that lie somewhere between sheer impossibility and mere inconvenience.¹³⁰

The term “impracticable” has been interpreted in a recent decision of the Ontario Superior Court of Justice. Having considered various dictionary meanings of the term “impracticable,” as distinguished from the terms “impractical” and “impossible,” Molloy J. concluded as follows:

In my view, the word “impracticable” ... should be given its plain and ordinary meaning. Based on the standard dictionary definitions of the word, I conclude that the word “impracticable” is not synonymous with “impossible”, although it may be closely related. Neither is it synonymous with the word “impractical”. Rather, “impracticable” should be interpreted as meaning “practically impossible” or “not feasible”. In my opinion, this imports a measure of reasonableness and proportionality ...¹³¹

If consent exemptions for research are going to be resorted to as the preferred policy choice, it will be somewhat disingenuous to wait until 2015—after an incremental roll-out of these massive, interoperable EHR systems covering the entire Canadian population for purposes of care and treatment, and after billions of dollars will have been invested—to argue then that it is impracticable to go back to each individual to obtain consent for research.

Moreover, it is conceivable—but not a certainty—that in 2015 it will be impracticable to re-contact every individual in Canada to obtain his or her consent for the use of their EHR data for research. To proceed now to develop EHR systems prospectively, while knowingly deferring the research issues and ignoring the present consent opportunities, is neither valid nor justifiable as a public policy option. Surely, the spirit and intent of the existing consent exemptions was not to avoid the legal obligation to obtain consent for anticipated research uses by postponing its execution until such time as it has *become* impracticable.

EHR systems are presently being designed and developed prospectively to take into account patients’ consent preferences for the use of their EHR data for health care purposes, including the creation of consent registries and the implementation of masking features, lock-boxes, and the like. In addition to the obvious direct and immediate benefits accruing to health care, the use of EHRs to facilitate health research and support evidence-based health care has been envisaged as an integral component and key justification for the creation of a pan-Canadian interoperable health info-structure since 1999. Yet, as complex consent directives for health care purposes are presently being introduced by system developers, it is not clear why the consent directives would not also, at the same time, inquire into patients’ consent preferences for the use of their EHR data for research purposes that are eminently foreseeable, if not inevitable.

¹²⁷ See e.g. *Personal Health Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, s. 7(3)(f); *HIA*, *supra* note 58, s. 50(4); *PHIPA*, *supra* note 58, s. 47(4); *An Act respecting Access to documents held by public bodies and the Protection of personal information*, R.S.Q., c. A-2.1, s. 125.

¹²⁸ See e.g. *HIA*, *supra* note 58, s. 54; *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25, s. 42(d) and accompanying regulations, Alta. Reg. 200/95 s. 8; s. 35; *PHIPA*, *supra* note 58, s. 44(5); *Freedom of Information and Protection of Privacy Act*, R.S.O. 1990, c. F.31, s. 21(1)(e), and accompanying regulations, R.R.O. 1990, Reg. 460, s. 10.

¹²⁹ For a review of different formulations across relevant statutory provisions see Kosseim, Kardash & Penta, *supra* note 31, c. 4.

¹³⁰ See *CIHR Best Practices*, *supra* note 81 at 40.

¹³¹ *Kinglip Holdings Inc. v. Novak Graphics Inc.*, [2000] 100 A.C.W.S. (3d) 148 at para. 9.

Nor is it necessarily clear that the existing research exemptions would constitute a sufficiently clear source of authority to disclose identifiable EHRs in circumstances where consent could have been sought prospectively, but was not. Notwithstanding the social utility associated with valuable health research, it may be difficult to legally sustain a claim that it would be “impracticable” to obtain consent in these circumstances, especially if *Charter* values are invoked to help interpret and resolve any ambiguity in the term.

The Supreme Court of Canada has confirmed that in the absence of specific legal authorization that would, itself, be subject to *Charter* scrutiny, physicians ought not to collect personal medical information from individuals seeking treatment and disclose that information to third parties for unrelated purposes.¹³² While it arose in the context of a *Charter* challenge in the course of a criminal prosecution under section 8, this finding echoed the Court’s earlier indication that “the patient has the right to require that the secret shall not be divulged; and that right is absolute, unless there is some paramount reason which overrides it.”¹³³ The view that personal information to which a reasonable expectation of privacy attaches should not be disclosed without consent has found further support in evolving jurisprudence under section 7, which has expanded the application of this principle beyond the criminal context and, indeed, elevated it to the level of a principle of fundamental justice.¹³⁴

From a public interest perspective, the benefits of resorting to consent exemptions for research are obvious. Epidemiological or population-based researchers could gain access to even more comprehensive, valuable sources of data, unimpeded by potential bias concerns. The knowledge gained by such research efforts could be translated and directly re-invested into improved health care services for Canadians.

Notwithstanding these clear public benefits, the negative impact on privacy protection and public trust in the health care system could be significant. Users’ confidence in their health care providers could be eroded if and when it came to their attention that their EHR data will be or has been released for research purposes without their knowledge and consent in a manner that completely undermines their autonomous control over the use and disclosure of sensitive personal information. The impact on public trust is not to be underestimated, according to some studies. Canadians’ concern about how widely their personal health information is shared or how it is used may reduce the quantity and accuracy of the data they give their health care provider, which, in turn, can result in treatment errors, patient safety issues, under-reporting of disease prevalence, and underestimation of compliance statistics.¹³⁵

F. Retroactively Deeming Consent by Legislative Amendment

Rather than require researchers, ethics review boards, and health custodians to undertake a case-by-case analysis of whether it is impracticable (or impractical or impossible) to obtain consent, legislators could choose, as a matter of general public policy, to retroactively deem consent to have existed or remove the legislative requirement for consent altogether. Effectively, this would open up access to certain designated data elements of EHR records for health research purposes after the fact. In such a model, legislators would be replacing consent obtained from each user of the health system on an individual basis, with a public, retroactive, and omnibus “consent” obtained from the Canadian population through a legislative process. Such deemed consent would fill in where no consent ever existed, or might even go so far as to override express objections that the individual may have expressed at the time.

¹³² *Dyment, supra* note 46.

¹³³ *Halls v. Mitchell, supra* note 43 at 136.

¹³⁴ *Cheskes v. Ontario (Attorney General)*, [2007] 87 O.R. (3d) 581, O.J. No. 3515 (Ont. Sup. Ct.) [*Cheskes*].

¹³⁵ El Emam *et al.*, “Pan-Canadian”, *supra* note 29 at 5-6.

While a retroactive legislative solution of this type may seem far-fetched, it is not entirely without precedent. In a recent decision of the Ontario Superior Court of Justice, *Cheskes v. Ontario (Attorney General)*,¹³⁶ Mr. Justice Belobaba considered amendments to the *Vital Statistics Act*.¹³⁷ The impugned provisions would have had the retroactive effect of allowing the Ontario government to disclose birth and adoption records without the consent of the birth parents or adult adoptees involved, contrary to the promise of confidentiality that had been originally made in respect of those records when they were sealed.

Belobaba J. found (with “no difficulty”) that these amendments violated the applicants’ right to liberty pursuant to section 7 of the *Charter*. Belobaba J. held that the non-consensual disclosure of private records violated a privacy interest that extended beyond the actual documents themselves and inhered in the very dignity and self-worth of the individuals:

In this case, to track the language of the Supreme Court ... , the disclosure of the birth and adoption records under the new law, in circumstances where a reasonable expectation of privacy has been created ... constitutes an invasion of the dignity and self-worth of each of the individual applicants, and their right to privacy as an essential aspect of their right to liberty in a free and democratic society has been violated.¹³⁸

Belobaba J. further found that the decision made by the applicants to keep the birth and adoption records confidential and not have their identity revealed came within what the Supreme Court of Canada has referred to as an “irreducible sphere of personal autonomy wherein individuals may make inherently private choices free from state interference.”¹³⁹ By its very nature, this implicated a basic choice “going to the core of what it means to enjoy individual dignity and independence”.¹⁴⁰

Having found that the applicants’ right to liberty within the meaning of section 7 of the *Charter* was engaged, Belobaba J. went on to decide that the infringement of the applicants’ right to liberty was in violation of a principle of fundamental justice. In so doing, the right to control disclosure of one’s confidential personal information was elevated to the level of a principle of fundamental justice, which was crystallized in the following terms: “Where an individual has a reasonable expectation of privacy in personal and confidential information that information may not be disclosed to third parties without his or her consent.”¹⁴¹

Of particular interest for present purposes was Belobaba J.’s consideration of the two safeguards that had been built into the legislation. One was the no-contact provision. Where an individual affected by the *Act* filed a “no contact notice,” the retroactive amendments would have only permitted disclosure of the birth and adoption records if the individual or entity requesting the records undertook in writing *not* to contact the biological kin who filed the “no contact notice.” The other safeguard, the non-disclosure procedure, would have allowed individuals to apply to the Child and Family Services Review Board for a non-disclosure order. However, a mere objection to disclosure on the part of birth parents or adult adoptees would not suffice. According to the legislative scheme, the Board could only grant such an order in exceptional circumstances if it were satisfied that “the order is appropriate to prevent sexual harm or significant physical or emotional harm to [the adopted person or birth parent].”¹⁴² The Court held that these so-called safeguards were insufficient to temper the privacy breach and save the impugned provisions.

¹³⁶ *Cheskes, supra* note 134.

¹³⁷ R.S.O. 1990, c. V.4.

¹³⁸ *Cheskes, supra* note 134 at para. 83.

¹³⁹ *Malmo-Levine, supra* note 55 at para. 85, quoting *Godbout, supra* note 55 at para. 66.

¹⁴⁰ *Ibid.*

¹⁴¹ *Ibid.* at para. 127.

¹⁴² *Cheskes, supra* note 134 at para. 23.

Transposed to the health research context, this case seems to suggest that any legislative amendment that would retroactively open up confidential EHR records for research purposes could remain vulnerable under a section 7 *Charter* analysis, even if the researcher undertook in writing not to contact individual patients, and even if a special procedure were built in (equivalent to a lock-box or other mechanism) to permit individuals to object to disclosure if the threshold for such a procedure were set too high.

We have seen another relevant example of the retroactive, legislative approach when Parliament amended the *Statistics Act* in 2005 to retroactively remove a legislative guarantee of confidentiality that had applied to census records collected after 1918.¹⁴³ This legislative promise of confidentiality served to codify prior assurances of confidentiality set out in historical census manuals of instructions.¹⁴⁴ The 2005 amendments now permit census records collected between 1911 and 2001 to be released in their entirety to the public via Library and Archives Canada after ninety-two years. Interestingly, the *Statistics Act* was also amended to provide that census records collected prospectively after 2001 would not be released to the public after ninety-two years unless the individual to whom the information related consented to such a release.

Proponents of the 2005 amendments to the *Statistics Act* argued that the public benefits of genealogical research outweighed the privacy interests individuals maintained in census records collected ninety-two years earlier. They argued that critical information about the history of Canada and individual families' ancestors would be lost if census records were not made available to the public. The research community expressed the view that information collected through the census is not particularly sensitive and that any personal information that could be construed as sensitive was considerably less so ninety-two years after its collection. Historical guarantees of confidentiality were read narrowly. It was argued that these assurances of confidentiality did not and were not intended to provide a perpetual guarantee of confidentiality. It was felt that evidence of the intent to preserve census records for the use of future generations, namely the fact census records were stored at National Library and Archives Canada, rebutted such an interpretation.

Detractors of the 2005 amendments disagreed. Citing the highly sensitive and intrusive nature of many census questions, those who opposed the 2005 amendments to the *Statistics Act* felt that the needs and interests of historical and genealogical researchers ought not be permitted to trump assurances of confidentiality that were made, particularly after these informal assurances were codified in statute in 1918. In their view, privacy rights did not end with death. Also troubling to those who opposed the 2005 amendments to the *Statistics Act* was the fact that Canadians had a legal obligation to participate in the census. The amendments eliminated the assurance of confidentiality that census respondents had received in return for their coerced participation. Stakeholders were particularly concerned that retroactively eliminating a legislative promise of confidentiality to previous generations of Canadians would undermine Canadians' willingness to be honest and forthright in the future.

¹⁴³ R.S.C. 1985, c. S-19, s. 18.1, as am. by *An Act to amend the Statistics Act*, S.C. 2005, c. 31.

¹⁴⁴ In 1871, census takers were advised that "[p]ersons having apprehensions, or showing hesitation in giving their answers, must be assured that no information they may give, and that nothing taken down in the schedules, can possibly injure, or in any way affect their standing or their business." In 1918, sub-section 15(1) of the *Statistics Act*, S.C. 1918, c. 43 provided: "No individual return, and no part of an individual return made, and no answer to any question put, for the purposes of the Act, except as hereinafter set forth, shall without the previous consent in writing of the person or of the owner for the time being of the undertaking in relation to which the return or answer was made or given, be published, nor, except for the purposes of a prosecution under this Act, shall any person not engaged in connection with the census be permitted to see any such individual return or any part of any individual return." See Statistics Canada, *Final Report of the Expert Panel on Access to Historical Census Records*, online: Statistics Canada <<http://www.statcan.ca/english/census96/finalrep.htm>>.

The 2005 amendments to the *Statistics Act* have not been constitutionally challenged to date. Whether a *Charter* challenge would succeed as in the *Cheskes* case is debatable given several distinguishing features that might play into the analysis. For example, it could be argued that information contained in census records is relatively less personal and sensitive than that contained in birth and adoption records. The passage of time before the census records could be opened up (ninety-two years) lends support to this view as does the fact that the real impact of disclosure on people's lives may be relatively less serious and profound. Finally, the *Statistics Act* amendments are more limited in scope in that they apply only to existing census records, and continue to require informed consent for eventual release of any prospectively collected census information after 2001.

Arguably, however, the reasoning employed in *Cheskes* could find more direct and relevant application to a legislative amendment that would purport to retroactively open up EHRs for health research purposes without consent. It is possible that such an amendment could run afoul of section 7 of the *Charter*.

First, Canadians confide sensitive personal health information to health providers in the confines of a therapeutic relationship that gives rise to a legitimate and strong expectation of confidentiality. This expectation of trust and confidence is widely affirmed in existing legal and ethical frameworks governing relationships between health care providers and patients. Personal health information is imparted to health providers for inclusion in EHRs on the clear understanding that it will not be disclosed to third parties without consent, particularly since research purposes are not being integrated or even discussed in the current design and architecture processes.

Second, EHRs reflect not only a passive, static picture about an individual's *de facto* health status as he or she may have inherited or developed it, but more fundamentally, may contain highly personal information about the most intimate and fundamental decisions individuals may actively choose to make as a result of their health condition. These decisions, including decisions about reproductive and family planning, lifestyle choices, drug prescriptions, genetic tests, psychological therapies, elective surgeries, medical use of marijuana, and enrollment in controversial clinical trials, may reflect one's personal philosophy and moral values about private affairs which extend far beyond one's physiological state.

Third, because EHRs may potentially contain personal information about individuals from "cradle to grave," they provide an evolving and continually relevant window into people's lives. Opening up these records may have a serious and profound impact on individuals at any point in their lifetimes. Because these records are continuously updated with each encounter between an individual and the health system, the passage of time and evolution of one's personal circumstances will not necessarily nullify or dampen the enormous implications that disclosure may have or the psychological stress individuals may feel as a result.

In view of the significance the judiciary has attached to the right to control disclosures of one's personal information, a retroactive, legislative amendment mandating non-consensual disclosure for research could interfere with the liberty interest protected under s. 7 of the *Charter*. If the principle of fundamental justice, as articulated by Belobaba J. in the *Cheskes* case stands,¹⁴⁵ it is difficult to see how any such interference could be construed as either in accordance with the principles of fundamental justice or demonstrably justified in a free and

¹⁴⁵ *Cheskes*, *supra* note 134 at para. 107: "In my view, the principle being suggested by the applicants can be stated more directly as follows: *where a reasonable expectation of privacy has been established in the collection and storage of one's personal and confidential information, one should have the ability to control the dissemination of this information.* Or, to put it even more plainly:

Where an individual has a reasonable expectation of privacy in personal and confidential information, that information may not be disclosed to third parties without his or her consent ... "

democratic society. Much would turn on the express rationale, means, limitations, and protections that would accompany such an amendment.

From a public interest perspective, the advantages of retroactively mandating disclosure of EHR data for research purposes are obvious. Researchers will no doubt point out that retroactivity is necessary and desirable to enable many types of valuable health research that require access to EHR data. For example, the integrity of longitudinal population health studies depends on seamless and consistent sources of data over time. This type of research would be severely compromised, if not precluded, if the data are subject to large temporal holes occasioned by a failure to obtain appropriate consent when the data were first collected, and by the sheer practical difficulty of re-contacting individuals to obtain consent for the secondary use of their data.

However, for the same reasons as discussed in the fifth policy option above, the public interest in privacy, trust, and confidence in the health care system could be seriously compromised by such a solution. Retroactive, legislative amendments that allow disclosure of personal information for research purposes despite promises of confidentiality would suffer from the same type of flaws affecting the application of existing consent exemptions discussed in the fifth policy option above.

On the one hand, it is arguable that the negative impact on privacy, public trust, and confidence could be considered worse in the case of a retroactive legislative amendment than in the application of existing consent exemptions. This is particularly so if the retroactive legislative amendment were allowed to override the clear objection expressed by individuals, and if such an amendment were only introduced after a deliberate and avoidable omission to seek people's consent upon the prospective creation of EHRs in a manner which respects their personal autonomy.

On the other hand, retroactive legislative amendment allowing access to EHRs for research purposes, if subject to a truly comprehensive, consultative, and democratic decision-making process, would necessitate a more inclusive and transparent public policy debate. Rather than distort the application of existing research exemptions subject to little or spotty and opaque oversight, a conscious legislative amendment would publicly highlight the relevant issues and cause them to be openly acknowledged and specifically confronted. The need for such open debate is particularly strong in a public policy dilemma such as this, where policy makers and legislators would be seeking to strike an appropriate balance between the public interest in protecting the individual right to control how personal information is used, and the public interest in facilitating health research to improve the quality of Canadian's health and their health care system.

CONCLUSION

More than fifteen years ago, the Supreme Court recognized the burgeoning size and complexity of the health care field:

The twentieth century has seen a vast expansion of the health care services. Rather than relying on one individual, a physician, the patient now looks directly and indirectly to dozens and sometimes hundreds of individuals to provide him with the services he requires. He is cared for not simply by his own physician but by a veritable army of nurses, numerous consulting physicians, technologists and technicians, other allied health personnel and administrative personnel.¹⁴⁶

The increasing complexity of health care in the world of paper records foreshadowed the exponential changes that EHRs would bring to the confidential doctor-patient relationship:

¹⁴⁶ *McInerney v. MacDonald*, *supra* note 44 at 146, citing L.E. Rozovsky & F.A. Rozovsky, *The Canadian Law of Patient Records* (Toronto: Butterworths, 1984) at 73-74.

Recent trends in health care exacerbate the problems relating to privacy in the medical context, particularly in light of the health-team approach in an institutional setting and modern health information systems. If the health-team approach gives a patient easy access to a wide range of medical services, it inevitably results in the fragmentation of the classical doctor-patient relationship among a team of medical and para-medical personnel.¹⁴⁷

A move toward electronic records to modernize, maximize, and integrate information-sharing in this increasingly complex health care context seems both inevitable and overdue. This evolution is not *per se* concerning. It is the subtle consequences of the manner in which EHRs have been developed and deployed in Canada that have been our focus.

EHRs in Canada represent much more than the simple transformation of paper records into electronic form. In addition to their role in the modernization of information systems in the health care system, EHRs seem—as a result of the manner in which they have been deployed and the vast potential they hold—to be fundamentally redefining an individual's right to control the use and dissemination of his or her personal information in the health context.

Specifically, the deployment of EHRs in Canada for health care purposes, in advance of addressing issues of secondary uses such as research, may effectively preclude the maintenance of well-established standards of consent. Current legislative regimes require express and informed consent to anticipated uses before or at the time personal information is collected. The incremental deployment of EHRs for health care purposes, without any contemplation of research uses, has ensured that this requirement will simply not be met at the time of collection as EHR systems are being built. Moreover, it seems that it will be technologically and organizationally impracticable, if not impossible, to re-contact all patients, after the initial creation of EHR systems, to seek their consent to use EHRs for health research and to record and manage the resultant responses in electronic consent management directives. Deployment in advance of addressing research uses is effectively undermining the likelihood that express and informed consent will be the selected policy choice, and thereby pre-determining a forced departure from that standard.

The fact that the current, accepted standard of express and informed consent in advance of collection will apparently be impossible to maintain will not cause research using EHRs to grind to a halt. Rather, the compelling public benefits associated with the use of EHRs for research purposes will serve as a catalyst for altering the standard of consent or, even more significantly, shifting away from consent as the default access control. There is already a growing consensus in the academic literature that some type of shift away from the existing standard of express and informed consent will be necessary to overcome inherent practical and technological difficulties and to facilitate the use of EHRs (or equivalent vast stores of valuable personal information) for health research purposes.¹⁴⁸

To avoid “succumbing to a technological imperative”¹⁴⁹ and letting practical expedience further determine, by default, critical public policy choices that implicate human rights and human dignity, public debate is required about what viable alternatives exist to replace specific, informed consent. In this paper we have outlined what some of those policy alternatives might be, together with a range of possible implications, in order to stimulate such a debate. We have outlined options that began with specific, informed consent, and moved towards broad consent, implied consent, no need for consent, consent waiver, and retroactive override of previous consent regimes. Through this spectrum of options we have attempted to demonstrate

¹⁴⁷ *Dyment, supra* note 46 at 433.

¹⁴⁸ See e.g. J.V. Tu *et al.*, “Impracticability of Informed Consent in the Registry of the Canadian Stroke Network” (2004) 350 N. Eng. J. Med. 1414; Caulfield, Upshur & Daar, *supra* note 70; Peter Singleton & Michael Wadsworth, “Confidentiality and consent in medical research: Consent for the use of personal medical data in research” 333 B.M.J. (2006) 255; Ries, *supra* note 122.

¹⁴⁹ Glenn Griener, “Electronic Health Records as a Threat to Privacy” (2005) 1 Health Law Review 14 at 15.

that legal and policy ideals require early reflection and up-front integration into systems as they are being designed, since we can anticipate that technological and organizational aspects will become impossible to retrofit after the fact. Conversely, we have attempted to show that where policy options appear to be attractive from a practical perspective of ease and convenience, the underlying legal and policy implications show cause for concern and require further reflection and public debate before we gravitate too quickly to these proposed solutions.

Deploying EHRs in advance of addressing consent to secondary research uses of personal information has effectively stacked the deck against the maintenance of the *status quo*, which is express, informed, and specific consent. We must be mindful of this artificially created policy context *when* (as opposed to *if*) the time comes to determine whether an alternative to the existing standard of express and informed consent can be justified and what it would look like. Driven by the incremental deployment of EHRs designed exclusively for health care purposes, the case for moving away from the need to obtain express and informed consent presently rests on arguments that invoke speculative technological and pragmatic hurdles. The pragmatic hurdles, though speculative, are evident. The technological issues, doubtlessly made more complicated by the incremental deployment of EHRs designed to address only health care purposes, are, however, more difficult to accept, particularly when the opportunity is present *now* to avoid policy procrastination and effectively address some of these issues.

The legal, ethical, and policy difficulties inherent in the alternatives to express and informed consent that we have surveyed suggest that there is no easy or ready substitute for express and informed consent, despite their appearance as panaceas to difficult practical problems. It is not clear that when policy-makers eventually do turn their minds to research uses of EHRs, Canadians would be willing to cede all meaningful and ongoing control over their personal health information, even in support of researchers' pursuit of important public benefits. The case for why Canadians should be required to do so is even less clear and compelling, especially if they are not part of an open and inclusive policy debate over the available choices.

The policy options we have highlighted are not mutually exclusive. Their viability and appropriateness will vary by the type of research undertaken. For example, it would be difficult to cogently argue that anything less than specific and express informed consent could adequately authorize clinical trials involving human subjects. The same may not be true of retrospective epidemiological research that relies exclusively on pre-existing health records or prospective population-based studies using personal information contained in research registries or platforms originally created for that general purpose.

Moreover, none of the proposed policy options obviate the need to apply research ethics guidelines and seek review and approval from research ethics boards. Quite the contrary, all of the policy options we have canvassed reveal the need for strong and effective ethical governance regimes, particularly as policy-makers contemplate moving away from informed consent as the governing principle for some types of research.

The need for strong public and stakeholder approval is also equally pronounced in each of the policy options we have surveyed. It may be difficult to see how some of the policy options canvassed—especially the options of resorting to existing legislative exemptions or enacting new, retroactive legislation—are consistent with the critical need to maintain users' trust in their health care providers and in the system itself. Yet, public trust, which sits at the foundation of these critical relationships, must be continually nurtured and facilitated as a core component of any policy option that would permit researchers access to EHR data for secondary health research purposes, particularly in the absence of express and informed consent.

LA VALEUR DE L'IMPUTABILITÉ DANS L'ALLOCATION DES RESSOURCES AU CANADA : UNE PERSPECTIVE DE POLITIQUES PUBLIQUES

*Catherine Régis**

L'auteur explore le rôle qu'occupe le principe d'imputabilité au sein des processus d'allocation des ressources publiques en santé au Canada. Pour se faire, une approche de politiques publiques, laquelle s'écarte d'une vision juridique traditionnelle, est employée. L'auteur constate que ce principe requiert la possibilité de demander des justifications et d'imposer des conséquences aux décideurs dans le système de santé. L'imputabilité demeure peu reflétée présentement dans les processus décisionnels d'allocation des ressources. Or, ce principe joue un rôle clé dans l'amélioration de ces processus et, conséquemment, de la qualité des soins et services. Qui plus est, l'imputabilité contribue à améliorer la confiance des citoyens envers leur système de santé. L'auteur termine en explorant des pistes de solution possibles afin d'augmenter la présence de cette valeur dans ce secteur névralgique d'activités et discute du rôle des mécanismes de résolution des conflits à cet égard, et de celui des tribunaux spécifiquement. Elle note que les tribunaux, bien qu'ils offrent un potentiel intéressant, n'ont pas joué un rôle prédominant en ce sens jusqu'à présent. L'affaire Auton de la Cour suprême du Canada illustre ce point. Enfin, la voie de l'ombudsman spécialisé dans le secteur de la santé représente une option à considérer pour améliorer la présence de la l'imputabilité dans les processus décisionnels d'allocation des ressources en santé.

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INTRODUCTION

La santé—source d'intérêt et de préoccupation plurielle et transfrontalière — rassemble les patients, les familles, et les citoyens face à l'inéluctable réalité que représente la survenance de la maladie et de la mort¹. La majorité des systèmes de santé dans le monde entérine une composante importante de gestion et de financement publics, ce qui témoigne de l'ampleur de cette préoccupation au sein des sociétés. Mais comment s'assurer que les priorités des systèmes de santé rejoignent adéquatement les besoins des individus qui les financent (via leurs taxes ou à même leurs finances personnelles) et en utilisent les services ? Nous proposons que l'imputabilité, un principe clé associé à la bonne gouvernance, est nécessaire pour répondre à cette question.

La valeur d'imputabilité, un standard en émergence dans la gestion des systèmes de santé et en lien avec la montée du discours économique dans ce secteur, favorise une plus grande exploration des rôles, responsabilités, et interactions entre les différents acteurs de ces systèmes. Cette valeur s'intéresse à plusieurs questions : comment les décisions sont-elles prises ? par qui ? et pourquoi ? Elle met de plus l'emphase sur les processus décisionnels — partageant ici une préoccupation similaire à la justice procédurale avec toutefois un fondement, une portée, et un but différents. Elle propose complémentaires d'offrir une réponse à la question de savoir face à qui, ou encore vers quelle institution, un individu peut-il se tourner en cas d'insatisfaction ? En outre, l'imputabilité requiert que les personnes bénéficiant de pouvoirs discrétionnaires soient aussi transparentes que possible dans leurs décisions.

Considérant que le système de santé est au cœur des préoccupations des citoyens et des gouvernements, l'imputabilité dans les systèmes de santé devient une valeur à implanter pour faire le pont entre ces deux acteurs et assurer la pérennité des systèmes financés par les fonds publics, lesquels font face à des pressions financières et privatistes grandissantes en raison, notamment, de l'escalade des coûts liés aux médicaments. Qui plus est, certains pays dont le Canada doivent composer avec une crise de légitimité envers les institutions gouvernantes². Le système de santé canadien étant en grande partie administré (sur le plan macro) et financé par le gouvernement, notamment pour la portion ayant trait aux services *médicaux* et *hospitaliers*, cette crise de légitimité affecte directement le système³.

Or, tel que nous le verrons dans cet article, le manque d'imputabilité dans le domaine de l'allocation des ressources en santé au Canada est une problématique réelle et préoccupante qui mérite une attention particulière.

Cet article propose une réflexion sur, d'abord, l'importance de la valeur d'imputabilité dans la gestion des systèmes de santé et, ensuite, sur le rôle de l'institution judiciaire dans l'atteinte d'objectifs d'imputabilité. Nous étudions ces problématiques à la lumière d'une approche de politiques publiques, ce qui se distingue d'une analyse juridique stricte. Cet article est divisé en

¹ Bien que le concept de santé ne doive pas être limité au sens restreint de «l'absence de maladie». L'Organisation mondiale de la santé définit la santé comme suit : «La santé est un état de complet bien-être physique, mental et social, et ne consiste pas seulement en une absence de maladie ou d'infirmité.» Constitution de l'Organisation mondiale de la santé, préambule, en ligne : <http://www.who.int/governance/eb/who_constitution_fr.pdf>.

² Canada, Commission sur l'avenir des soins de santé au Canada, *Comment faire participer vraiment le public à l'élaboration et au maintien d'une vision globale du système de santé correspondant à ses valeurs et à ses principes ?* (Étude n° 33 par Harley D. Dickinson), Saskatoon, Commission sur l'avenir des soins de santé au Canada, 2002.

³ Cette crise de confiance a été mentionnée à l'occasion du rapport final de la Commission sur l'avenir des soins de santé au Canada ainsi que dans la décision *Chaoulli c. Québec (P. G.)*, [2005] 1 R.C.S. 791 [*Chaoulli*]. Pour la première référence, voir : Canada, Commission sur l'avenir des soins de santé au Canada, *Guidé par nos valeurs : l'avenir des soins de santé au Canada* — Rapport Final, Saskatoon, 2002 (Commissaire : Roy J. Romanow) [Commission Romanow].

trois parties. Dans la première, nous expliquons brièvement les grands principes du processus d'allocation des ressources dans le système de santé public au Canada. Dans la deuxième partie, nous définissons plus précisément ce en quoi consiste la dynamique d'imputabilité ainsi que son rôle, cette étape étant nécessaire pour aborder par la suite la problématique du manque d'imputabilité face au processus d'allocation. Enfin, dans la dernière partie, nous discutons du rôle des tribunaux face à cette problématique : représentent-ils une partie de la solution ? En d'autres mots, les tribunaux ont-ils un rôle à jouer dans l'injection d'une dynamique d'imputabilité auprès des acteurs clés du système de santé ? Nous verrons que si l'institution judiciaire offre un potentiel unique en ce sens, l'histoire nous a démontré à ce jour qu'elle a été peu disposée à jouer pleinement ce rôle pour la détermination des soins financés par les fonds publics au Canada.

I

LES GRANDS PRINCIPES DE L'ALLOCATION DES RESSOURCES AU CANADA

Avant de discuter du processus d'allocation des ressources en santé au Canada, il convient d'abord de démystifier les bases sur lesquelles le système de santé est fondé. Il ne s'agit pas ici d'exposer les subtilités financières et organisationnelles qui peuvent varier à l'échelle du pays mais de donner une perspective générale afin de mieux situer le lecteur face aux enjeux discutés dans cet article. En fait, il n'existe pas de système de santé «canadien» comme tel, mais autant de systèmes qu'il y a de provinces et de territoires au Canada puisque la santé est principalement un domaine de compétence provinciale/territoriale (et non fédérale) en vertu de la Constitution canadienne⁴. En d'autres mots, chaque province et territoire est libre d'établir les règles de financement, d'allocation, et de gestion des soins de santé qui lui semblent appropriées eu égard à sa population et ses besoins. Les systèmes provinciaux et territoriaux partagent néanmoins des caractéristiques communes qui établissent une certaine uniformité pancanadienne dans le secteur des soins de santé, et ce, en raison de l'existence de la *Loi canadienne sur la santé (LCS)*⁵. C'est donc cette loi, dont les principes ont été repris au sein de la législation provinciale/territoriale, qui a contribué à ancrer les bases fondatrices des systèmes actuels et qui permet incidemment la référence à un système de santé «canadien» en raison de l'homogénéité qu'elle crée. Pour les Canadiens, plus qu'un simple instrument juridique, cette loi a une valeur symbolique et identitaire importante⁶.

Or, comment expliquer l'existence d'une loi canadienne dans un domaine de compétence provinciale ? Le gouvernement fédéral a utilisé, comme il le fait dans d'autres secteurs d'activité provinciale, son «pouvoir de dépenser»⁷ afin de s'immiscer dans le domaine de la santé. Le but de la *LCS* consiste à mentionner les critères à respecter par les provinces et territoires dans la gestion et le financement de leur système de santé afin de recevoir une portion de financement fédéral — lequel peut être retenu ou réduit en cas de non-respect de ces critères. Les cinq conditions principales sont les suivantes : la gestion publique, l'intégralité, l'universalité, la transférabilité, et l'accessibilité⁸. Le critère de l'intégralité est particulièrement pertinent à la détermination de la liste des soins et services financés par les fonds publics (article 9). Celui-ci requiert que les régimes provinciaux d'assurance-maladie couvrent les

⁴ *Loi constitutionnelle de 1867* (R.-U.), 30 & 31 Vict., c.3, art. 92, al. 7, reproduit dans L.R.C. 1985, app. II, n° 5 [*Loi constitutionnelle de 1867*].

⁵ R.S.C. 1985, c. C-6 [*LCS*].

⁶ Ceci a été mentionné à plusieurs reprises à l'occasion de diverses commissions sur les soins de santé, notamment la Commission Romanow, *supra* note 3, ainsi que l'arrêt *Chaoulli*, *supra* note 3.

⁷ Voir Commission sur l'avenir des soins de santé au Canada, *Rôles et responsabilités en matière de politique des soins de santé* (Étude n° 34) par Antonia Maioni, Saskatoon, Commission sur l'avenir des soins de santé au Canada, 2002. Le pouvoir de dépenser s'infère des articles 91(1)(A), 91(3) et 106 de la *Loi constitutionnelle de 1867*, *supra* note 4.

⁸ *LCS*, *supra* note 5, art. 7.

services de santé fournis par les hôpitaux, les médecins ou les dentistes. Nous y reviendrons dans le paragraphe suivant. Pour les fins du présent article, il n'est pas pertinent de définir plus amplement ces critères. Il suffit de retenir que l'homogénéité des soins de santé au Canada tient principalement à un outil de transfert fiscal entre le gouvernement fédéral et les gouvernements provinciaux et territoriaux. Jusqu'à présent, les provinces n'ont pas eu le luxe de pouvoir se passer de ces transferts, considérant les pressions financières croissantes exercées par l'industrie des soins de santé sur les gouvernements et les contribuables.

Les soins de santé qui doivent être assurés, en vertu du critère d'intégralité, par les provinces/territoires au sens de la *LCS*, englobent principalement les services «hospitaliers» et «médicaux». Les premiers sont définis comme étant les services offerts dans un hôpital ainsi que «médicalement nécessaires» et les seconds étant évasivement et circulairement définis comme étant les «services médicalement nécessaires fournis par un médecin». La *LCS* ne fournit aucune définition de ce qui est «médicalement nécessaire». Cette tâche revient aux provinces et territoires.

Outre les cinq conditions mentionnées précédemment, la *LCS* précise deux interdictions importantes à respecter par les provinces et territoires afin de ne pas être pénalisés à l'occasion des transferts fédéraux. Les gouvernements ne peuvent permettre la surfacturation⁹ et les frais modérateurs¹⁰. La première interdiction empêche les médecins de demander aux patients un montant plus élevé pour leurs services que ce qui est autrement autorisé par le régime public. La deuxième interdiction requiert que tous les services couverts par le régime d'assurance santé provincial ou territorial soient fournis sans aucune contribution directe des usagers. En d'autres mots, il n'est pas possible d'imposer un «ticket modérateur». La présence du secteur public dans les soins de santé au Canada est donc principalement sectorielle et non populationnelle, c'est-à-dire qu'elle vise des domaines précis du système de santé (surtout les soins médicaux et hospitaliers) et non des groupes de population (riches versus pauvres)¹¹.

Une première conséquence liée à l'existence de la *LCS* est que pour les services médicaux et hospitaliers médicalement nécessaires, il n'est pas possible, en pratique, d'acheter une assurance privée afin d'obtenir un passage permettant d'éviter la file d'attente du secteur public. Le seul critère de discrimination permis afin d'avoir accès à de tels soins au Canada est, en principe, celui basé sur les besoins des individus : «À chacun suivant ses besoins socialement reconnus»¹². C'est sur la base de ce principe de solidarité que s'est bâti le système de santé au Canada¹³. La Cour suprême du Canada est toutefois venue dire en 2005 dans l'arrêt *Chaoulli* que le gouvernement du Québec ne peut interdire la possibilité d'acheter une assurance privée pour des soins médicalement requis dans la mesure où il ne remplit pas adéquatement ses obligations dans le système public. Notamment, il se doit d'offrir des soins dans un délai raisonnable.

⁹ *Ibid.*, art. 18.

¹⁰ *Ibid.*, art. 19.

¹¹ Voir Colleen M. Flood, Mark Stabile et Sasha Kontic, «Finding Health Policy 'Arbitrary': The Evidence on Waiting, Dying, and Two-Tier Systems» dans Colleen M. Flood, Kent Roach et Lorne Sossin, dir., *Access to Care, Access to Justice: The Legal Debate Over Private Health Insurance in Canada*, Toronto, University of Toronto Press, 2005 à la p. 296 [*Access to Care, Access to Justice*].

¹² Michael Walzer, *Spheres of Justice: A Defense of Pluralism and Equality*, New York, Basic Books, 1983 à la p. 91. La traduction est celle de l'auteure. L'original se lit comme suit : «[T]o each according to his socially recognized needs.»

¹³ L'affaire *Chaoulli*, *supra* note 3, rendue en 2005 par la Cour suprême du Canada constitue une brèche importante à ce principe mais nous ne discuterons pas des détails de cet arrêt dans le présent article. Voir les nombreux articles écrits sur le sujet, notamment : Marie-Claude Prémont, «L'affaire *Chaoulli* et le système de santé du Québec : cherchez l'erreur, cherchez la raison» (2006) 51 R.D. McGill 167. Voir aussi Flood, Roach et Sossin, *Access to Care, Access to Justice*, *supra* note 11.

Une deuxième conséquence est que les conditions de la LCS liées au financement fédéral ont fait que la liste des services assurés par les régimes publics d'assurance maladie provinciaux et territoriaux (le « panier de soins ») s'est concentrée autour des soins médicaux et hospitaliers. Par conséquent, cela laisse une multitude de soins et services non couverts par cette loi face à une possibilité de financement privé, dont les médicaments¹⁴, les soins de longue durée et à domicile, les services de psychologie, *etc.* D'ailleurs les régimes publics à travers le Canada couvrent à divers degrés (parfois aucunement) ces autres composantes des services de santé. La nature et l'étendue exactes du partenariat privé/public sont régulièrement méconnues auprès des Canadiens. La participation du privé représente environ 30 % du total des services fournis en santé au Canada¹⁵ et 52 % des dépenses liées aux médicaments prescrits¹⁶. L'intervention du privé consiste en un marché florissant qui évolue parallèlement à la diversification et le développement de la médecine et de l'industrie des soins de santé ; l'expression « privatisation passive » du système de santé canadien est d'ailleurs souvent employée pour décrire cette réalité. En effet, alors que la dispensation des soins de santé se concentrait principalement autour des hôpitaux et des médecins il y a une trentaine d'années, une panoplie de nouveaux services professionnels, technologiques, et produits pharmaceutiques ont émergé depuis, les médicaments représentant maintenant la deuxième plus importante dépense dans le système de santé et celle qui a augmenté le plus rapidement depuis les dernières années¹⁷.

En ce qui a trait à l'allocation des ressources médicales à l'échelle provinciale/territoriale, la portion des soins et services médicalement nécessaires — et donc le contenu de la liste des services financés par les gouvernements — est en partie déterminée à l'occasion des négociations salariales effectuées entre les associations médicales et les délégués du gouvernement provincial/territorial. Les associations médicales discutent en compagnie des délégués de la liste des services et soins médicaux assurés (ou potentiellement assurés) tout en déterminant la rémunération des médecins associée aux actes médicaux requis pour les effectuer, ce qui inclut les demandes d'augmentation salariale¹⁸. Au Canada, la rémunération des médecins est principalement basée sur le mode du paiement à l'acte, c'est-à-dire que les médecins facturent le gouvernement pour les actes cliniques effectués suivant une tarification définie, par opposition à la réception d'un salaire fixe qui demeure exceptionnel. Le résultat de ce processus de négociation est que la liste des tarifs négociés devient la liste des soins et services financés par le gouvernement et, par conséquent, de ce qui est « médicalement nécessaire »¹⁹. Les dépenses qui seront accordées aux nouveaux services de santé et aux technologies émergentes sont déterminées en fonction de la portion du « budget santé » restant une fois l'augmentation des tarifs allouée²⁰.

¹⁴ Il s'agit ici des médicaments fournis en dehors du centre hospitalier.

¹⁵ Institut canadien d'information sur la santé, *Tendances des dépenses nationales de santé, 1975 à 2007*, (Ottawa : ICIS, 2007) à la p. 10 [*Tendances*]. Ce pourcentage peut toutefois varier de province en province.

¹⁶ *Ibid.* aux pp. 21-22.

¹⁷ La première dépense demeure celle des hôpitaux qui représentent environ 28,4 % du total des dépenses en santé en 2007. *Ibid.* à la p. xiii.

¹⁸ Voir Colleen M. Flood, «The Anatomy of Medicare» dans Jocelyn Downie, Timothy Caulfield et Colleen M. Flood, dir., *Canadian Health Law and Policy*, 2^e éd., Ontario, Butterworths, 2002, 1 à la p. 1 ; Joan Gilmour, «Creeping Privatization in Health Care : Implications for Women as the State Redraws Its Role», dans B. Cossman et J. Fudge, dir., *Privatization, Law and the Challenge to Feminism*, Toronto, University of Toronto Press, 2002, 267 aux pp. 277, 281.

¹⁹ Colleen M. Flood, Carolyn Tuohy et Mark Stabile, *What is In and Out of Medicare ? Who Decides ?*, document de travail N° 5, Projet de recherche CHSRF-MOHLTC «Defining the Medicare Basket», 2004, en ligne : University of Toronto Health Law & Policy Group <http://www.law.utoronto.ca/healthlaw/basket/docs/working5_inandout.pdf> ; Colleen M. Flood, «Just Medicare : The Role of Canadian Courts in Determining Health Care Rights and Access» (2005) 33 J.L. Med. & Ethics 669 à la p. 675 [Flood, «Just Medicare»].

²⁰ Flood, Tuohy et Stabile, *ibid.*

Le processus de détermination de ce qui est financé par les fonds publics à l'échelle provinciale/territoriale ainsi que de ce qui est «médicalement nécessaire» a soulevé des préoccupations au fil des années. Certains auteurs ont plaidé en faveur d'une procédure davantage transparente et démocratique²¹. Nous sommes convaincue que le processus actuel devrait être plus ouvert à l'évaluation et la participation publiques, sans pour autant dire que chaque soin et service devrait être discuté publiquement. Il est présentement très difficile, voire impossible, d'obtenir de l'information sur qui est impliqué plus précisément dans ce processus d'allocation, de quelle façon ainsi que sur la base de quels critères les choix des soins financés par le réseau public sont effectués. À titre d'illustration, un groupe de chercheurs de l'Université de Toronto s'est vu opposer un refus des gouvernements provinciaux face à sa demande d'avoir accès aux procès-verbaux des rencontres durant lesquelles le choix des services à ajouter ou retirer du panier de soins est discuté²². Les gouvernements ont justifié ces refus en invoquant le motif que l'accès aux informations contenues dans ces procès-verbaux pourrait miner les relations entre les gouvernements fédéral et provinciaux et révélerait des informations confidentielles²³. Au Québec, il est très ardu, voire impossible, d'avoir accès à l'information utile relativement au processus, qu'il s'agisse de passer via les associations médicales, le Collège des médecins du Québec ou le Ministère de la Santé et des Services Sociaux. Personne ne semble savoir comment les décisions sont prises précisément. Si le processus demeure obscur pour les gens impliqués dans le réseau de la santé, on peut aisément imaginer l'opacité de celui-ci pour les citoyens ordinaires.

Outre cette opacité afférente à une partie centrale du processus décisionnel de l'allocation des ressources en santé au Canada, le processus est teinté d'une apparence de conflits d'intérêts entre les besoins d'un acteur clé du système de santé, le médecin, et ceux des citoyens. Les associations médicales peuvent avoir intérêt à préserver certains services plus lucratifs pour leurs membres au sein de la liste des services assurés, même si ceux-ci mériteraient d'être remplacés par de nouveaux services ou technologies davantage efficaces. Aucune donnée n'indique que cette situation prévaut présentement mais l'apparence de conflits est problématique en soi pour le maintien de la confiance publique. Pour les décideurs politiques, le sujet est délicat (ceux-ci souhaitant rarement entrer en conflit avec les médecins) et peu payant sur le plan politique considérant le manque de connaissance de ces enjeux par les citoyens.

Cette situation, (soit un processus d'allocation des ressources en partie lié aux négociations salariales des médecins) combinée à un financement fédéral axé sur les soins médicaux et hospitaliers, peut mener à un manque de flexibilité afin d'adapter la liste des services assurés face à l'émergence de nouveaux traitements, technologies, ou produits plus efficaces et susceptibles d'offrir aux Canadiens un meilleur rapport coûts/bénéfices. Ces nouvelles options de soins, en effet, pourraient ne pas impliquer des soins administrés par des médecins ou au sein d'un centre hospitalier. Cette conjoncture favorise possiblement le maintien d'un *statu quo* dans les choix d'allocation de ressources qui contraste avec l'évolution rapide et constante de l'industrie des soins de santé.

D'ailleurs, les retraits du panier de soins sont rares et la liste des soins assurés a plutôt tendance à s'allonger sans pour autant être réaménagée. Au meilleur de notre connaissance, le

²¹ Voir par ex. l'exposé de Daniel Weinstock dans Canada, Commission sur l'avenir des soins de santé au Canada, *Médicalement nécessaire : de quoi s'agit-il et qui décide ?* (Dialogue sur les politiques n° 7) (Montréal, 2002), en ligne : Santé Canada <http://www.hc-sc.gc.ca/francais/pdf/romanow/Dialogue_7_Medically_F.pdf> ; Mona Awad, Julia Abelson et Colleen M. Flood, *The Boundaries of Canadian Medicare : The Role of Medical Directors and Public Participation in Decision-Making*, document de travail N° 2, Projet de recherche CHSRF-MOHLTC, «Defining the Medicare Basket», 2004, en ligne : University of Toronto Health Law & Policy Group <<http://www.law.utoronto.ca/healthlaw/basket/index.html>> ; Commission Romanow, *supra* note 3 aux pp. 49, 53, 55.

²² Awad, Abelson et Flood, *ibid.*

²³ *Ibid.*

panier de soins au Québec — et ailleurs au Canada²⁴ — n'a jamais fait l'objet d'une révision significative ou systématique. Ce fait est d'autant plus inquiétant qu'entre 30 et 40 % des services de santé recommandés par les médecins auraient peu ou pas de preuve d'un apport bénéfique sur la santé²⁵.

Par conséquent, le panier de soins, par souci de transparence et d'efficacité, gagnerait à être révisé périodiquement par un comité d'experts neutres ayant les moyens de procéder à une analyse de son contenu et de proposer des modifications en se basant sur les données scientifiques à jour et solides. Les critères d'analyse et la composition de ce comité devraient être des informations accessibles au public. À cet égard, la récente proposition émise dans le rapport *En avoir pour notre argent*²⁶ sorti en 2008 afin de rendre le processus de décision plus transparent en y associant la participation du public et des experts est intéressante.

Soulignons que le rationnement des ressources dans le secteur de la santé est une réalité avec laquelle la plupart des systèmes de santé doivent composer dans la mesure où ils tendent à être financièrement viables. Des compromis d'allocation sont inévitables considérant la croissance exponentielle de la demande de soins et le caractère fort onéreux de ceux-ci, particulièrement dans les secteurs des technologies de pointe et pharmaceutique. Le rationnement des ressources peut s'avérer un moyen de contrôler les coûts et de favoriser, dans certains cas, le choix de services qui offrent un bon rapport coûts/bénéfices.

Au Canada, le rationnement pose possiblement un problème sur le plan juridique en raison de l'interdiction (directe ou indirecte) d'obtenir une couverture d'assurance privée²⁷ pour les soins couverts par le régime public. Tel que souligné précédemment, la décision *Chaoulli* est venue affirmer que le gouvernement du Québec ne peut interdire l'accès aux citoyens à une couverture d'assurance privée s'il ne remplit pas ses obligations dans le réseau public. Or, en principe, un accès raisonnable aux soins médicalement nécessaires doit être fourni. De ce fait, un rationnement qui exclurait clairement certains soins médicalement requis serait-il une pression suffisante pour donner ouverture à l'établissement d'un régime parallèle privé dans la province ? Une conséquence possible à ce phénomène est la survenance d'un rationnement implicite²⁸. Le Canada joue plutôt sur la conception vague de ce qui est «médicalement nécessaire» pour inclure ou exclure certains services²⁹. Par ailleurs, sur le terrain, les médecins convertissent les décisions politiques en jugements cliniques, ce qui internalise la limite des ressources et classe des priorités parmi les patients et l'accès aux soins³⁰.

Tous les gouvernements, dans la mesure où les soins de santé comportent une portion de financement public, souhaitent garder un certain contrôle sur les coûts des soins de santé, ce qui est compréhensible. Aucun gouvernement ne consent à signer un chèque en blanc quant à ce secteur d'activité, ce qui aurait d'ailleurs pour effet de remettre un pouvoir considérable entre les mains des médecins dans un programme social clé, sans contrepois démocratique.

²⁴ Pour le Canada, voir Flood, Tuohy et Stabile, *supra* note 19.

²⁵ Voir G.L. Stoddart *et al.*, *Why Not User Charges ? The Real Issues*, Ontario, The Premier's Council on Health, Well-being and Social Justice, 1993 à la p. 5.

²⁶ Québec, Groupe de travail sur le financement du système de santé, *En avoir pour notre argent*, Québec, Bibliothèque et Archives nationales du Québec, 2008 à la p. 66 (Président : Claude Castonguay, Vice-Présidents : Joanne Marcotte et Michel Venne), en ligne : Groupe de travail sur le financement du système de santé <<http://www.financementsante.gouv.qc.ca/>>.

²⁷ Cette interdiction se concrétise de différentes façons au sein des législations provinciales et territoriales.

²⁸ Il faut toutefois admettre pour cela que les systèmes de santé au Canada effectuent un minimum de rationnement pour ce type de soins et services. Cela nous apparaît être un truisme de penser que tous les services médicalement requis sont offerts dans le régime public au Canada.

²⁹ Voir Timothy A. Caulfield, «Wishful Thinking : Defining 'Medically Necessary' [*sic*] in Canada» (1996) 4 *Health L.J.* 63.

³⁰ Keith Syrett, «Impotence or Importance ? Judicial Review in an Era of Explicit NHS Rationing» (2004) 67 *Modern Law Review Limited* 289.

Le rationnement implicite peut être jugé plus facile à assumer politiquement car il est davantage aisé et moins compromettant d'effectuer des choix délicats derrière des portes fermées que sur la place publique. Toutefois, ce choix implique trop souvent un compromis important, celui de l'imputabilité des décideurs et, incidemment, une possibilité de réviser les décisions prises par ceux-ci.

II

L'IMPUTABILITÉ FACE À L'ALLOCATION DES RESSOURCES

Avant de discuter des problématiques liées à l'imputabilité dans le processus d'allocation des ressources au Canada, il est tout d'abord utile de préciser davantage le rôle et l'importance de ce concept, ici dans le contexte d'un système de santé ayant une composante majeure de financement public.

Nous avons vu au début de cet article que l'imputabilité est un standard qui s'intéresse aux processus décisionnels et intègre un souci de transparence à cet égard. Ce standard permet ultimement de mieux explorer les rôles, responsabilités, et interactions entre les différents acteurs du système de santé, et ce, tant au niveau politique, professionnel qu'administratif³¹. La notion d'imputabilité a beaucoup évolué au cours des dernières années. Espérons-le, elle s'est éloignée d'une vision réductrice consistant à identifier le concept comme le simple fait de suivre la trace de l'argent, des dépenses des décideurs bénéficiant de pouvoirs discrétionnaires. La vision en est maintenant une plus holistique, certes plus complexe, à l'image de l'évolution des systèmes de santé.

Au plan politique, l'imputabilité est une valeur associée aux principes de bonne gouvernance et requiert des gouvernements qu'ils soient responsables de leurs décisions, à l'écoute de leurs citoyens, et qu'ils respectent leurs engagements. En d'autres mots, l'imputabilité vise à augmenter la cohésion entre les priorités politiques, qui se concrétisent dans l'action gouvernementale, et les besoins des citoyens afin de créer une société qui reflète les préoccupations de l'électorat. Ultimement, ce standard cherche à établir un pont communicationnel d'une extrémité à l'autre des pôles démocratiques. Dans le secteur de la santé, ces besoins, pour l'essentiel, incluent l'accès à des soins de qualité dans un délai raisonnable.

Deux éléments sont nécessaires pour que l'imputabilité dépasse le stade de valeur certes louable pour en arriver à un standard susceptible d'application. Il s'agit de la présence d'un devoir de *justification* des décideurs et l'imposition de *conséquences* si cette justification est insatisfaisante³². Ces éléments définissent ce qui est nécessaire pour qu'une véritable dynamique d'imputabilité se mette en place dans une organisation ou un système, ici dans les systèmes de santé au Canada. En ce qui a trait au premier élément, les individus réellement imputables peuvent s'attendre à répondre à des questions ayant trait aux motifs de leurs décisions et à donner des explications claires à cet égard. Ce devoir de justification est susceptible d'exister en vertu d'une obligation formelle (lorsque qu'elle est prévue dans la loi,

³¹ Chacun de ces niveaux correspond en fait à un modèle d'imputabilité : le modèle politique, professionnel, et administratif. Pour les fins du présent article, nous discutons uniquement du modèle politique.

³² Jennifer S. Lerner et Philip E. Tetlock, «Accounting for the Effects of Accountability» (1999) 125 *Psychological Bulletin* 255 ; Julia Abelson et François-Pierre Gauvin, *Engaging Citizens : One Route to Health Care Accountability*, Health Care Accountability Papers N° 2, Ottawa, Canadian Policy Research Networks, 2004 à la p. 13 ; Andreas Schedler, «Conceptualizing Accountability» dans A. Schedler, L. Diamond et M.F. Plattner, dir., *The Self-Restraining State : Power and Accountability in New Democracies*, London, Lynne Rienner, 1999 à la p. 13. Certains auteurs utilisent les expressions «answerability» et «responsibility» plutôt que «justification» et «conséquences». Emmanuel et Emmanuel résumant ces deux éléments lorsqu'ils mentionnent : «accountability entails the procedures and processes by which one party justifies and takes responsibility for its activities». Ezekiel J. Emanuel et Linda L. Emanuel, «What Is Accountability in Health Care?» (1996) 124 *Annals of Internal Medicine* 229, en ligne : <http://www.annals.org/cgi/content/full/124/2/229>.

par exemple³³) ou informelle (en vertu d'une attente politique légitime, par exemple³⁴). En ce qui a trait aux conséquences, elles peuvent inclure une perte de pouvoir dans une organisation, une perte de privilèges ou de droits, l'imposition de sanctions financières, *etc.* À l'opposé, si les justifications fournies sont suffisantes, les conséquences peuvent être positives et, à titre d'illustrations, mener à une promotion ou à un gain de pouvoir. S'il n'est pas possible de demander aux décideurs clés d'un système de santé de fournir un certain degré de justification pour leurs décisions et de subir les conséquences de celles-ci, l'impact en sera une réelle difficulté d'évaluer la qualité des décisions — et donc de les améliorer — tant via les gouvernements (et leurs institutions) que les tribunaux et l'évaluation publique des citoyens.

Pourquoi devrions-nous mettre l'emphase sur la valeur d'imputabilité dans l'administration des programmes publics, incluant dans les systèmes de santé au Canada ? Cette valeur est importante pour plusieurs raisons. Premièrement, elle représente maintenant une composante essentielle des attentes des Canadiens face à leurs gouvernements et à la gestion publique ; elle est partie intégrante du nouveau contrat social que forment les attentes des citoyens envers les institutions gouvernementales³⁵. Dans le système de santé, ce constat s'applique avec particulièrement d'acuité tel qu'il a été confirmé par des commissions d'étude d'envergure dans ce secteur³⁶.

Deuxièmement, la demande pour une imputabilité accrue est liée à la crise de légitimité dans les institutions gouvernementales et le manque de confiance envers les médecins³⁷, ainsi que les revendications pour une plus grande participation citoyenne dans les choix d'orientations d'un programme social au cœur des préoccupations de l'électorat. Ces divers éléments ont suscité un intérêt grandissant envers l'implantation de mécanismes de surveillance indépendants des institutions gouvernementales afin de permettre une meilleure représentation des intérêts des citoyens/patients. C'est notamment pour cette raison que les mécanismes de résolution de conflits (dans leur sens libéral, soit englobant les tribunaux, les tribunaux administratifs et les ombudsmans) peuvent jouer un rôle important dans l'amélioration de l'imputabilité au sein des systèmes de santé, aspect sur lequel nous reviendrons dans la troisième partie de cet article.

Enfin, l'imputabilité est une valeur à implanter pour assurer la pérennité du système de santé public. Les travaux menés par Abelson et Gauvin indiquent que les Canadiens veulent davantage d'information sur l'endroit où va leur argent et sur comment les décisions sont prises dans le système de santé³⁸. Jusqu'à ce qu'ils aient de meilleures preuves d'une gestion

³³ À titre d'exemple, voir l'article 182.7 de la *Loi sur les services de santé et les services sociaux*, L.R.Q. c. S-4.2, qui indique :

Un établissement [de santé] doit préparer un rapport annuel de gestion.

Ce rapport doit notamment comprendre :

1° une présentation des résultats obtenus par rapport aux objectifs prévus par l'entente de gestion et d'imputabilité ;

2° une déclaration du directeur général de l'établissement attestant la fiabilité des données contenues au rapport et des contrôles afférents ;

3° tout autre élément ou renseignement déterminé par le ministre. Un établissement transmet à l'agence son rapport annuel de gestion et celle-ci le communique au ministre.

³⁴ Par exemple, les Québécois peuvent s'attendre à une explication de la part du ministre de la Santé advenant son choix de contracter avec un regroupement d'hôpitaux de Buffalo pour le transfert de certains patients québécois.

³⁵ Cathy Fooks et Lisa Maslove, *Rhetoric, Fallacy or Dream ? Examining the Accountability of Canadian Health Care to Citizens*, Health Care Accountability Papers N° 1, Ottawa, Canadian Policy Research Networks, 2004 ; Mary Pat MacKinnon *et al.*, *Citizens' Dialogue on Canada's Future : A 21st Century Social Contract*, Ottawa, Canadian Policy Research Networks, 2003.

³⁶ Notamment, il s'agit d'un des constats de la Commission Romanow, *supra* note 3.

³⁷ Voir Dickinson, *supra* note 2.

³⁸ Julia Abelson et François-Pierre Gauvin, *Transparency, Trust and Citizen Engagement : What Canadians Are Saying About Accountability* (en collaboration avec Mary Pat MacKinnon et Judy Watling), rapport de recherche

efficace des ressources — ce dont ils doutent présentement — ils demeureront peu enclins à avaliser de plus amples investissements publics dans ce secteur³⁹. Éventuellement, leur support envers le système s'amenuisera, un processus déjà entamé⁴⁰. En d'autres mots, si les gouvernements souhaitent convaincre les Canadiens de maintenir le financement et même d'investir davantage dans un système qui consume une portion aussi importante des finances publiques, ils se doivent de démontrer leur capacité de bonne gestion et d'en être imputables.

Or malgré l'importance et le rôle de l'imputabilité, cette valeur demeure peu reflétée dans le système de santé au Québec ainsi qu'ailleurs au Canada.

III

UNE PROBLÉMATIQUE DANS LE SYSTÈME DE SANTÉ

Considérant le processus décisionnel provincial/territorial d'allocation des ressources en santé au Canada et ce qu'implique le concept d'imputabilité tel que défini précédemment, il est possible d'identifier certains problèmes qui limitent l'atteinte d'un tel objectif dans le système de santé. Ces problèmes correspondent principalement à la présence d'un nœud décisionnel peu transparent et donc difficilement susceptible de révision — soit pour lequel il est ardu de demander des justifications et d'imposer des conséquences.

Tout d'abord, le nœud décisionnel en matière d'allocation des ressources est enfoui au sein de l'organisation que représente le ministère de la santé. Nous avons souligné précédemment qu'il est difficile, si l'information n'est pas carrément inaccessible, de savoir qui sont les acteurs officiellement responsables des choix d'allocation de ressources. Par exemple, pour le choix des services médicaux financés par les fonds publics, nous constatons qu'il s'agit d'un processus conjoint entre les associations médicales et le gouvernement, mais il demeure difficile de savoir qui est impliqué plus précisément dans ce processus au sein des ministères de la santé⁴¹. L'équipe de chercheurs de l'Université de Toronto a toutefois réussi à identifier un fonctionnaire clé dans le processus d'élaboration du panier de soins, méconnu au sein du réseau de la santé et des citoyens, soit le «directeur médical». Cependant, nous en savons encore très peu sur les responsabilités réelles et les critères décisionnels de cet acteur. Aussi, le nœud décisionnel relatif au processus d'allocation des ressources en santé demeure nébuleux.

Ensuite, nous avons souligné plus haut que le nœud décisionnel lié à l'allocation des ressources se matérialise souvent, en pratique, via le jugement clinique au Canada. Les médecins effectuent plusieurs décisions d'allocation à l'échelle individuelle, lorsqu'ils décident des choix de traitements et soins à donner à leurs patients. Notamment, les médecins gèrent régulièrement les listes d'attente en attribuant des priorités de besoin à leurs patients, modifiant ainsi leur classement sur les listes⁴². Ces décisions d'allocation sont politiquement et

N° 5, Ottawa, Canadian Policy Research Networks, 2004 (basé sur quatre expériences de dialogue ayant impliqué plus de 1600 Canadiens).

³⁹ *Ibid.* à la p. 11. En outre, Abelson et Gauvin mentionnent, à la p. 15, que l'inclusion de participants citoyens dans le processus délibératif tend à rendre ceux-ci plus sensibles à la complexité des décisions dans le secteur de la santé et, incidemment, plus respectueux face aux décideurs actuels.

⁴⁰ L'affaire *Chaoulli*, *supra* note 3, témoigne de cette diminution de confiance dans la capacité du gouvernement du Québec à bien gérer le système de santé.

⁴¹ Lorsque j'ai demandé cette information, on m'a référé à plusieurs intervenants du secteur de la santé (au sein du ministère, des associations médicales, du Collège des médecins, *etc.*) qui, ultimement, n'ont jamais pu répondre à ma question.

⁴² À la suite de la décision *Chaoulli*, *supra* note 3, le Gouvernement du Québec a néanmoins décidé de proposer un mécanisme de gestion centralisé des listes d'attente pour certains soins spécialisés et surspécialisés (article 185.1 de la *Loi sur les services de santé et les services sociaux*, *supra* note 33). Ce système pourrait, en partie, améliorer l'imputabilité des décisions corrélatives aux listes d'attente. Ce mécanisme doit préciser, entre autres, les règles à suivre pour inscrire un usager sur la liste d'attente, les modalités de détermination, et de communication de la date prévisible de l'obtention de ces services à l'utilisateur. Ce mécanisme est trop récent pour en évaluer l'impact réel. Il demeure toutefois, et ce pour l'ensemble du pays, que les médecins gèrent en premier lieu les listes d'attente.

juridiquement invisibles car elles sont fragmentées à travers le temps et l'espace à l'occasion de transactions individuelles entre les médecins et les patients⁴³. Selon Harrison, cette situation peut mener à l'illusion que le système de santé est en mesure de rencontrer les besoins de tous⁴⁴. Il est, de ce fait, difficile de rendre les médecins imputables face à ce type de décisions, lesquelles incluent pourtant un volet de gestion des ressources.

Finalement, le nœud décisionnel correspondant au processus de sélection des soins médicalement nécessaires (et donc assurés) est empreint d'une apparence de conflits d'intérêts tel que discuté plus haut. Il nous semble impératif de rendre le processus de sélection et les critères liés aux choix des services assurés davantage transparents ainsi que neutres, et de rendre accessibles les critères sur lesquels se fondent les choix d'allocation de ressources (efficacité ? ; rapport coûts/bénéfices ? ; standard international ou national ?). Cette transparence et cette neutralité permettraient notamment d'améliorer les processus décisionnels au cœur du système en les rendant plus stables. En effet, les processus au sein desquels les critères décisionnels sont ambigus demeurent vulnérables aux pressions momentanées et à plus long terme, qu'elles soient financières, corporatistes, ou politiques. Sans processus solide et transparent, il y a davantage d'espace pour diverses sources d'intérêts d'influencer le processus décisionnel. Conséquemment, les décisions peuvent devenir instables et représentatives, non pas des besoins à long terme des citoyens et patients, mais de certains mouvements ou groupes d'intérêts plus influents dans le secteur des soins de santé ; par exemple, des associations de médecins ou d'infirmières ou des intérêts politiques à court terme. Les choix dans le système de santé devraient plutôt changer de manière cohérente avec l'évolution des besoins et valeurs de la société. Mais la transparence — ou minimalement le fait de tendre vers celle-ci — posera nécessairement un choc de cultures et de pratiques puisqu'elle n'a pas été un réflexe jusqu'à présent.

En résumé, il découle du processus d'allocation des ressources en santé au Canada une difficulté 1) d'accéder aux critères sur la base desquels les décisions sont prises et 2) d'évaluer et de contester la qualité des décisions. La deuxième difficulté découle de la première. Deux questions se posent alors : Comment savoir si les critères décisionnels qui prévalent présentement respectent les intérêts des citoyens (et non les intérêts politiques, corporatistes, ou autres) ? Comment s'assurer que les fournisseurs de soins utilisent les meilleures informations, preuves, et options disponibles lorsqu'ils dépensent l'argent investi par les contribuables en santé ? Ces deux questions nous conduisent à la dernière section de cet article dans laquelle nous nous demandons si les tribunaux peuvent pallier ces problèmes d'imputabilité. Autrement dit, l'institution judiciaire est-elle en mesure de créer un pont entre les instances décisionnelles en matière d'allocation des ressources en santé et les citoyens afin d'infuser le système de santé d'une dynamique d'imputabilité, d'une plus grande transparence décisionnelle, et d'une représentation adéquate des intérêts de ces derniers ?

IV

L'INTERVENTION DES TRIBUNAUX : UNE PARTIE DE LA SOLUTION ?

La question à savoir si les tribunaux représentent des outils adéquats pour injecter une plus grande dynamique d'imputabilité dans le système de santé s'inscrit, à notre avis, à l'intérieur d'une interrogation plus large, soit : quels sont les rôles du droit et des institutions juridiques dans l'atteinte d'objectifs d'imputabilité au sein de la société, incluant dans les systèmes de santé ? Le présent article n'a pas pour but de fournir une réponse définitive et exhaustive à

⁴³ S. Harrison, «The Politics of Evidence-Based Medicine in the United Kingdom» (1998) 26 *Policy and Politics* 15 à la p. 18 : "They therefore render the process of rationing as it were politically invisible, by fragmenting it across space and time into individualised and private transactions between doctors and individual patients."

⁴⁴ *Ibid.* : "The result was that the NHS was able to maintain the fiction of meeting everyone's needs ..."

cette importante mais vaste question sur laquelle nous aurons l'occasion de nous pencher à l'occasion d'autres travaux⁴⁵.

Une partie de la solution face au manque d'imputabilité et de transparence dans le processus d'allocation des ressources réside en notre capacité à augmenter la participation citoyenne dans le système de santé⁴⁶. Cette participation, ou cette aptitude à exprimer la «voix citoyenne», exercera un contrepoids face aux intérêts des autres acteurs du système⁴⁷ et se traduira en l'exigence d'une plus grande disponibilité d'information face aux enjeux et aux décisions prises dans le système de santé. Il est nécessaire de veiller à ce que les patients et les citoyens bénéficient d'avenues pour exprimer leurs préoccupations face à ce programme social clé, et ce pour des raisons démocratiques et afin de s'assurer que les autorités gouvernementales bâtissent un système en lien avec ces préoccupations. Les Canadiens seront davantage enclins à supporter un système qui s'adapte à leurs valeurs et leurs besoins, lesquels sont évolutifs. Cette solution consistant à intensifier la participation citoyenne répond ainsi, certainement en partie, à plusieurs des problèmes soulevés précédemment dans cet article.

Cependant, le souci d'accroître cette participation n'est pas nouveau et il y a eu plusieurs tentatives au fil des années pour y pallier⁴⁸. Elles ont inclus l'exigence d'impliquer des représentants de la population au sein des conseils d'administration des établissements de santé, des consultations publiques à travers le Canada, la création de comité des usagers chargés de représenter les droits et intérêts des patients dans des établissements au Québec, *etc.* Malgré ces efforts, nous devons néanmoins conclure à un succès fort mitigé de ces tentatives car, en pratique, des barrières significatives limitent la possibilité d'une diffusion effective et représentative de la voix citoyenne dans les systèmes de santé⁴⁹. Parmi ces obstacles, on compte celle d'une difficulté réelle à intéresser les citoyens sans liens particuliers dans le système de santé à s'investir dans un rôle de conseiller dans l'orientation du système. Ce rôle implique un investissement personnel direct (d'abord en temps) pour un retour qui se mesure en une influence généralement diffuse et indirecte dans le système de santé⁵⁰. Cette situation est peu attrayante pour les individus. Le résultat est que les personnes impliquées dans ces divers rôles de représentation sont souvent affiliées, de près ou de loin, à des groupes ayant des intérêts précis — par exemple, des syndicats ou des groupes d'usagers ayant une

⁴⁵ Nous avons eu l'occasion d'étudier cette question en lien avec les systèmes de santé à l'occasion de nos travaux de doctorat. Ceux-ci feront l'objet de publications ultérieures.

⁴⁶ En outre, James Morone indique que la voix du patient/citoyen a fait des changements durables dans la planification des soins de santé : James A. Morone, *The Democratic Wish : Popular Participation and the Limits of American Government*, New Haven, Yale University Press, 1990 aux pp. 253-321. À son plein potentiel, la participation peut impliquer le contrôle par les citoyens : voir Sherry R. Arnstein, «A Ladder of Citizen Participation» (1969) 35 *Journal of the American Institute of Planners* 216 ; Eugene Feingold, «Citizen Participation: A Review of the Issues» in Harry Rosen, Jonathan M. Metsch et Samuel Levey, dir., *The Consumer and the Health Care System : Social and Managerial Perspectives*, New York, Spectrum Publications, 1977 ; Cathy Charles et Suzanne DeMaio, «Lay Participation in Health Care Decision Making: A Conceptual Framework» (1993) 18 *J. Health Pol.* 881.

⁴⁷ La voix citoyenne est celle qui peut changer l'agenda politique ainsi que reprendre une partie de l'autorité autrement donnée à la profession médicale en la remplaçant davantage entre les mains du public. Voir Morone, *ibid.*

⁴⁸ Voir Joseph Facal, *Volonté politique et pouvoir médical : La naissance de l'assurance-maladie au Québec et aux États-Unis*, Montréal, Boréal, 2006.

⁴⁹ Professeur Pivik mentionne plusieurs barrières qui limitent une participation significative des citoyens dans le système de santé dont la limite des ressources, une mauvaise communication, des définitions divergentes de la notion de participation, des conflits d'intérêts, une incongruité entre les buts mentionnés et la pratique, le manque de représentativité, une difficulté à rejoindre les populations marginalisées, les limites de temps ainsi que le manque de connaissance et de formation. Voir Commission sur l'avenir des soins de santé au Canada, *Stratégies pratiques afin de faciliter la participation réelle du public à la planification des services de santé* (Étude n° 23) par Jayne Renee Pivik, Saskatoon, Commission sur l'avenir des soins de santé au Canada, 2002 à la p. 4.

⁵⁰ Voir par ex. Facal, *supra* note 48.

cause particulière à défendre — et donc non représentatives de l'intérêt du «citoyen ordinaire»⁵¹.

Or, nous proposons⁵² que les mécanismes de résolution de conflits (MRCs) représentent un des outils les plus efficaces, et relativement aisés à implanter, pour outrepasser ces barrières et favoriser la participation des patients et citoyens dans le système de santé⁵³. Les MRCs offrent à l'ensemble des citoyens l'opportunité d'intervenir dans le système au moment où ils en ont besoin — soit une voie de participation basée sur une problématique spécifique («*issue-based participation*»)⁵⁴ — et ce, via des institutions neutres. Plus le MRC est accessible, plus il sera possible d'obtenir une avenue représentative des divers intérêts des citoyens car un plus vaste éventail de la population pourra ainsi transmettre ses préoccupations. Qui plus est, les MRCs possèdent généralement une capacité unique de mettre en branle la dynamique d'imputabilité (soit de demander des justifications aux décideurs et d'imposer des conséquences si nécessaires). Les tribunaux représentent indubitablement une option, mais pas la seule. D'autres avenues de résolution des conflits peuvent (et doivent) être utilisées en parallèle pour contribuer à atteindre cet objectif. Nous nous limitons toutefois pour les fins du présent article à explorer brièvement, et nécessairement partiellement, le rôle des tribunaux à cet égard, à savoir si ils peuvent contribuer à rendre le gouvernement davantage imputable face à l'allocation des ressources en santé. Nous verrons que l'institution judiciaire offre un potentiel intéressant à cet égard, mais, qu'en pratique, elle fait face à des limites notables (qu'elle a parfois choisi de s'imposer). Nous émettrons quelques recommandations sur les pistes à explorer pour atténuer ce problème.

En se basant sur la définition émise plus haut de l'imputabilité, quel potentiel offrent les tribunaux de nourrir la dynamique d'imputabilité dans le système de santé ? Rappelons que nous tentons de répondre à cette question à travers une perspective de politiques publiques.

Les tribunaux ont l'avantage de représenter des mécanismes puissants et légitimes pour favoriser l'imputabilité des décideurs publics car ils sont en mesure, à travers leur rôle d'interprétation et d'application des lois (et le processus qui y conduit), de requérir des justifications et d'imposer des conséquences aux autorités et institutions gouvernementales dans une société de droit. Ils peuvent requérir des gouvernements, des autorités déléguées par ceux-ci, et de l'ensemble des citoyens des justifications sur des actions et décisions qui enfreignent, possiblement, des règles de droit. Aussi, en principe, les tribunaux peuvent imposer une obligation formelle de la part des autorités gouvernementales à fournir une explication pour certains choix d'allocation de ressources, ce que le citoyen seul peut difficilement faire. Dans la mesure où la Constitution ainsi que la loi le permettent, les tribunaux peuvent donc forcer le gouvernement à expliquer (ce qui ne veut pas nécessairement dire modifier) son processus décisionnel en matière d'allocation de ressources et ainsi favoriser la transparence des décisions en les rendant plus ouvertes à l'évaluation et à la compréhension publique. Ceci afin de contribuer à améliorer la justice interne de ce processus (tant sur le fond que sur l'aspect procédural) et, ultimement, améliorer le fonctionnement du système de santé par une possible évaluation des procédures décisionnelles clés.

En outre, dans la mesure où les institutions gouvernementales ne fournissent pas une explication adéquate aux choix qu'elles font et qu'elles enfreignent une règle de droit, les tribunaux sont en mesure d'imposer des conséquences liant le gouvernement — par exemple,

⁵¹ *Ibid.*

⁵² Nous avons soutenu ce point de manière plus élaborée à l'occasion de nos travaux de doctorat à la Faculté de droit de l'Université de Toronto. Ce sujet fera l'objet de publications à l'occasion des années 2008 et 2009.

⁵³ Bien que les divers types de MRCs (des modes amiables aux plus adversatifs) influencent de différentes façons et peuvent être utilisés en combinaison.

⁵⁴ Selon le professeur Pivik, le «*issue-based participation*» serait une des avenues de participation les plus efficaces. Voir Pivik, *supra* note 49.

en annulant une loi ou en octroyant une indemnité aux citoyens. Il s'agit du deuxième élément essentiel afin qu'une réelle dynamique d'imputabilité puisse s'implanter. Peu d'institutions ou d'outils (économiques, politiques, administratifs, et même juridiques) dans notre société sont ainsi en mesure de susciter une dynamique d'imputabilité au sein des autorités gouvernementales. Voilà pourquoi les tribunaux offrent un potentiel unique et significatif, en étant de surcroît neutres, de favoriser l'imputabilité dans le système public de santé au Canada.

Certes, les élections peuvent fournir une autre avenue aux citoyens afin de demander des explications au gouvernement face à sa gestion des ressources et imposer par la suite la conséquence de voter suivant leur satisfaction face aux explications et résultats donnés. L'imputabilité démocratique demeure néanmoins limitée en ce qui a trait à la gestion du système de santé car les citoyens votent principalement sur les grandes orientations du système et non sur des questions précises ayant trait à la gestion des ressources — la détermination des soins financés par les fonds publics appartenant davantage à cette deuxième catégorie. Le choix d'introduire un partenariat privé/public pour les soins médicalement requis serait davantage susceptible de faire l'objet d'un dialogue démocratique direct entre les gouvernements et les citoyens considérant qu'il s'agit d'un débat majeur pour les Canadiens et d'un enjeu politique primordial pendant les campagnes électorales, comme les dernières élections au Québec l'ont démontré.

Si les tribunaux offrent un potentiel significatif, ils demeurent néanmoins confinés dans leur capacité de rendre imputables les décideurs politiques en ce qu'ils n'ont pas la fonction de substituer leur jugement à ceux-ci en ce qui a trait aux choix politiques difficiles qui doivent être faits. Il y a une distinction à émettre entre la décision politique et la décision judiciaire. Il demeure que les tribunaux ont le mandat légitime de s'assurer de la justice de telles décisions.

L'historique des décisions rendues par la plus haute cour du Canada laisse toutefois planer le doute sur le fait que l'institution judiciaire assumera, pleinement, ce rôle de contrôler la justice des décisions gouvernementales en matière d'allocation des ressources en santé ainsi que son potentiel d'institution favorisant l'imputabilité des institutions gouvernantes dans ce domaine. Force est d'en arriver à ce constat, malgré le fait que les Canadiens se soient davantage tournés vers les tribunaux pour résoudre leurs problèmes d'accès aux soins au cours des dernières années⁵⁵. Cette augmentation de recours s'explique possiblement en raison des limites imposées par le gouvernement au sein du financement public — celui-ci tentant de contrôler les coûts d'un programme social qui consomme près de 10,6 % (en 2007) de son produit intérieur brut⁵⁶ —, de l'augmentation des attentes des individus envers la médecine et le développement des technologies, ainsi que l'impossibilité, en pratique, pour les Canadiens d'obtenir une couverture d'assurance privée pour des soins «médicalement nécessaires».

Parmi les cas ayant fait l'objet d'une évaluation par les tribunaux, ceux qui ont retenu le plus d'attention se sont basés sur la *Charte canadienne des droits et libertés*, laquelle fait partie de la Constitution et constitue la loi suprême du pays⁵⁷. Les gouvernements y sont soumis. De 1985 à 2002, il a eu trente-trois cas de contestation de politiques publiques liées aux coûts des soins de santé dans le secteur santé⁵⁸. En 2005, il y a aussi eu l'affaire *Chaoulli* mentionnée précédemment. De ces cas, un seul requérant du financement public pour certains soins et

⁵⁵ Notamment, il y a eu une augmentation des demandes de recours basés sur l'article 15(1) de la *Charte*. Voir Flood, «Just Medicare», *supra* note 19 à la p. 672.

⁵⁶ *Tendances*, *supra* note 15 à la p. 7.

⁵⁷ *Charte canadienne des droits et libertés*, partie I de la *Loi constitutionnelle de 1982*, constituant l'annexe B de la *Loi de 1982 sur le Canada* (R.-U.), 1982, c.11.

⁵⁸ Donna Greschner, «How Will the Charter of Rights and Freedoms and Evolving Jurisprudence Affect Health Care Costs?» dans T. McIntosh, P.G. Forest et G.P. Marchildon, dir., *The Governance of Health Care in Canada : The Romanow Papers Volume 3*, Toronto, University of Toronto Press, 2004, 83 à l'app. 2.

services a été décidé en faveur des plaignants, soit l'arrêt *Eldridge*⁵⁹. Dans cette affaire, un couple de gens ayant une déficience auditive a contesté l'absence de financement public pour les services d'un interprète dans les hôpitaux de la province de la Colombie-Britannique. La Cour a considéré que les plaignants avaient été victimes de discrimination en vertu de l'article 15 de la *Charte*⁶⁰ et a demandé au gouvernement de fournir lesdits services.

Outre ce cas exceptionnel, on se doit de faire le constat d'une Cour très déférente face aux décisions du gouvernement en matière d'allocation des ressources et qui hésite à créer de nouvelles attentes de la part des citoyens envers le contenu du «panier de soins». En d'autres mots, spécifiquement dans le contexte des recours basés sur la *Charte*, la Cour hésite à intervenir lorsqu'il en résulterait une obligation positive pour le gouvernement de reconsidérer son financement pour certains soins et services. En outre, la Cour a régulièrement imposé un fardeau de preuve fortement élevé aux plaignants, dans la mesure où il est presque impossible à rencontrer considérant la réalité d'un processus décisionnel peu transparent dans le secteur de l'allocation des ressources en santé au Canada⁶¹.

L'affaire *Auton*⁶² rendue en 2004 est un exemple éloquent de cette situation⁶³. Ce cas impliquait la demande de parents d'avoir accès au financement public pour un traitement controversé pour le bénéfice de leur enfant autiste (la thérapie de Lovaas). Dans ce recours, basé à nouveau sur l'article 15 de la *Charte* et alléguant que la décision du gouvernement de ne pas fournir ces services était discriminatoire, la Cour a indiqué que les plaignants auraient dû prouver que des traitements ayant le même niveau d'incertitude sur le plan de l'efficacité clinique étaient financés pour d'autres groupes de la population. Alors, les plaignants auraient pu démontrer la présence d'un comportement discriminatoire de la part du gouvernement. La question qui se pose est la suivante : Comment arriver à prouver cette «discrimination par comparaison» considérant que le processus décisionnel lié à l'allocation des ressources est enfoui au sein des ministères de la santé et que les critères qui guident ce processus demeurent occultes⁶⁴ ? Établir une telle preuve devient en pratique insurmontable pour les citoyens.

Pourtant, tel que le souligne le professeur Flood, l'affaire *Auton* fournissait une occasion en or pour la Cour d'envoyer un signal aux décideurs politiques de la nécessité d'articuler des principes clairs et justes lorsqu'ils effectuent des choix relatifs aux soins et services financés par le réseau public⁶⁵. Cette intervention aurait contribué à améliorer la justice interne du système de santé, laquelle est essentielle afin de maintenir la confiance des Canadiens dans celui-ci. Le système de santé au Canada ne survivra que si les citoyens le perçoivent comme étant juste⁶⁶.

Est-ce à dire que les tribunaux sont stériles prosaïquement comme outil juridique favorisant l'imputabilité des décideurs politiques dans le secteur de la santé ? À notre avis, tel que mentionné plus tôt, le constat est davantage que ceux-ci ne jouent pas pleinement leur rôle à l'heure actuelle à cet égard, spécifiquement lorsque les recours se fondent sur la *Charte*, alors qu'ils pourraient significativement contribuer à améliorer la justice du processus d'allocation

⁵⁹ *Eldridge c. Colombie-Britannique (P. G.)*, [1997] 3 R.C.S. 624.

⁶⁰ L'article se lit comme suit : 15. (1) *La loi ne fait exception de personne et s'applique également à tous, et tous ont droit à la même protection et au même bénéfice de la loi, indépendamment de toute discrimination, notamment des discriminations fondées sur la race, l'origine nationale ou ethnique, la couleur, la religion, le sexe, l'âge ou les déficiences mentales ou physiques.*

⁶¹ En ce qui a trait au processus d'allocation des ressources, voir mes propos émis précédemment. Voir aussi Flood, «Just Medicare», *supra* note 19.

⁶² *Auton (Tutrice à l'instance de) c. Colombie-Britannique (Procureur général)*, [2004] 3 R.C.S. 657.

⁶³ Flood, «Just Medicare», *supra* note 19.

⁶⁴ *Ibid.*

⁶⁵ *Ibid.* à la p. 675.

⁶⁶ Je remercie le professeur Sujit Choudhry, professeur à la Faculté de droit de l'Université de Toronto, pour ce point.

des ressources en santé au Canada. Chose certaine, il n'est pas à craindre un effondrement financier du système de santé en raison de l'intervention des tribunaux dans ce secteur⁶⁷.

En outre, le difficile accès aux tribunaux fait que ce MRC demeurera toujours limité dans sa capacité à intervenir dans le secteur de la santé sur une base suffisamment régulière pour favoriser une imputabilité effective et soutenue. Pour la même raison, les tribunaux sont aussi limités dans leur aptitude à créer un dialogue démocratique entre les deux pôles de notre société qui soit pleinement représentatif des besoins évolutifs et pluriels des Canadiens en santé.

En somme, puisque les tribunaux se montrent déférents face aux décisions gouvernementales qui impliquent la détermination de ce qui est inclus et exclu du panier de soins et sont limités en pratique dans leur capacité de créer un pont entre les besoins des citoyens et les décideurs du système, y a-t-il d'autres options pour pallier cette résistance et favoriser une plus grande imputabilité des décideurs clés du système de santé ? La réponse, comme nous l'avons soulignée plus haut, se trouve en partie dans l'exploration d'autres MRCs à utiliser en combinaison avec les tribunaux.

À notre avis, une piste de solution se trouve dans la mise en place d'un ombudsman affecté au domaine de la santé afin de fournir un interlocuteur crédible et indépendant pour représenter les intérêts des citoyens dans le système de santé. Qui plus est, considérant la plus-value des MRCs tel que mentionné antérieurement, l'ombudsman devrait idéalement combiner un processus de résolution de doléances eu égard à l'administration du système de santé. L'exemple du Protecteur du citoyen, lequel s'est adjoint un vice-protecteur dédié plus spécifiquement au secteur de la santé⁶⁸ (ce dernier pourrait donc être qualifié d'«ombudsman santé»), illustre bien cette possibilité de combiner les deux rôles, via une institution aisément accessible pour les citoyens du Québec⁶⁹. Cette organisation possède une voix directe auprès des institutions gouvernementales afin d'émettre des recommandations relatives à la gestion et à l'organisation du système de santé. Le Protecteur du citoyen doit notamment transmettre un rapport annuel faisant état de ses constats devant l'Assemblée nationale du Québec. Il peut entendre, et ce suivant une procédure de résolution des conflits structurée, des doléances en provenance des usagers du système de santé, de leur famille et d'organismes représentant les patients. Il peut également agir de sa propre initiative pour investiguer les problèmes qui lui semblent nécessiter une intervention. Les pouvoirs de cet ombudsman sont néanmoins confinés à ceux d'émettre des recommandations et avis — et possiblement d'avoir recours à la pression publique en cas de refus de l'établissement ou la personne visée par la plainte de suivre une recommandation. De fait, si le Protecteur du citoyen possède différents leviers pour obtenir des justifications des divers acteurs du domaine de la santé⁷⁰, il s'en remet essentiellement à des conséquences informelles pour susciter la dynamique d'imputabilité, ce qui réduit en partie son potentiel à cet égard.

Nous pensons que l'absence de pouvoir contraignant de l'ombudsman représente une faiblesse et une force à la fois. Alors que l'ombudsman ne peut forcer légalement les décideurs

⁶⁷ Divers auteurs ont fait ce constat. Le professeur Flood mentionne que la Cour suprême du Canada semble davantage décidée à intervenir dans la balance privée/publique des soins de santé que dans l'amélioration du fonctionnement actuel du système public. Voir Flood, «Just Medicare», *supra* note 19.

⁶⁸ Le Vice-protecteur attiré au domaine de la santé se retrouve depuis quelques années sous l'égide du Protecteur du citoyen, soit l'Ombudsman général de la province du Québec. Ce vice-protecteur était auparavant une institution indépendante du Protecteur du citoyen et portait le nom de «Protecteur des usagers».

⁶⁹ Pour une description plus détaillée du rôle et des limites de l'Ombudsman santé au Québec, voir : Catherine Régis, «Enhancing Patients' Confidence in Access to Health Care : The Ontario or Québec Way ?» (2004) 12 Health L.J. 243.

⁷⁰ Il a l'avantage d'avoir une saisine beaucoup plus étendue que les cours et les tribunaux administratifs à cet égard. Il peut aussi utiliser son pouvoir d'enquête pour convoquer certains individus et obtenir des documents utiles à son enquête.

réfractaires à modifier leurs décisions ou actions, il possède toutefois un large champ d'action, probablement corrélatif de ce pouvoir limité, qui lui permet d'évaluer les décisions d'un éventail très large de décideurs impliqués dans le réseau de santé public. Aussi, il est en mesure d'intervenir sur une base régulière, surtout comparativement aux tribunaux pour lesquels l'accès demeure ardu et qui doivent attendre la survenance d'un cas judiciairisé pour intervenir⁷¹. Peut-être le pouvoir limité de l'ombudsman représente-t-il le prix à payer pour un champ d'intervention aussi étendu ? Ces considérations en lien à l'ombudsman en font donc un outil utile à combiner avec un processus plus adversatif de résolution des conflits et contraignant tels que les tribunaux.

En terminant, il est utile de mentionner l'existence depuis l'année 2006 d'un Commissaire à la santé et au bien-être au sein du réseau de la santé québécois. Cette institution a pour mandat d'apporter un éclairage au débat public et à la prise de décision gouvernementale dans le secteur de la santé, en évaluant, entre autres, la performance du système de santé⁷². Bien qu'il ne s'agisse pas d'une organisation combinant une procédure de résolution des conflits comme le Protecteur du citoyen, et donc moins susceptible de mettre en branle les deux conditions de la dynamique d'imputabilité mentionnées précédemment, elle est tout de même en mesure de favoriser la création d'attentes légitimes de justification auprès des décideurs publics. En raison de sa mission consistant à transmettre de l'information aux citoyens, le Commissaire contribue également à nourrir le lien communicationnel entre les deux pôles démocratiques. Dans la même veine, le Commissaire favorise la participation citoyenne (davantage à l'échelle sociétale qu'individuelle) via l'existence de son Forum de consultation, une instance délibérative constituée de membres du public et d'experts. L'impact réel de cette voix citoyenne sur l'orientation des politiques publiques reste à suivre bien que le processus de consultation a une valeur démocratique inhérente en lui-même. Il sera intéressant de surveiller le rôle et la place que prendra ce nouvel acteur au sein du système de santé et dans l'évaluation du processus d'allocation des ressources.

CONCLUSION

Nous avons vu dans cet article que bien que le système de santé soit le programme social au Canada requérant le plus de ressources financières prélevées à même les fonds publics, nous en savons très peu sur les processus décisionnels, à l'échelle provinciale/territoriale, qui mènent à l'allocation des ressources y afférentes. La valeur de l'imputabilité favorise une plus grande exploration des rôles, responsabilités, et interactions entre les différents acteurs du système de santé et milite en faveur d'une plus grande transparence décisionnelle. Il s'agit d'une valeur primordiale pour les Canadiens, laquelle demeure peu reflétée dans le système de santé actuel. Or en raison de ce manque d'imputabilité, il est difficile d'évaluer la qualité des décisions dans ce secteur névralgique de la société.

Malgré des opportunités en or à cet égard, les tribunaux ont peu contribué à améliorer ce manque de transparence. Ils ont ainsi significativement circonscrit une avenue possible pour améliorer la justice interne de la procédure d'allocation des ressources dans le domaine public et encourager l'imputabilité des décideurs bénéficiant de pouvoirs discrétionnaires, notamment les gouvernements. Cela dit, malgré le potentiel unique — mais sous-utilisé — que les tribunaux offrent afin de rendre imputables les acteurs clés de la société, ils demeureront néanmoins toujours limités dans leur capacité de le faire sur une base suffisamment régulière en raison de leur difficile accès et de leur incapacité à intervenir de leur propre chef.

⁷¹ Il existe une procédure spéciale d'enquête pour les actes médicaux, dentaires, et pharmaceutiques. Pour plus de détails voir Régis, *supra* note 69.

⁷² Voir la mission du Commissaire sur le site Internet de l'organisation, en ligne : Commissaire à la santé et au bien-être <www.csbe.gouv.qc.ca>.

Nous devons donc explorer d'autres mécanismes de résolution de conflits afin de nourrir cette dynamique d'imputabilité et accompagner le rôle des tribunaux qui doivent demeurer, à notre avis, la dernière voie. La disponibilité d'interlocuteurs neutres et crédibles pour représenter les intérêts des usagers et exercer un contrepoids face aux autres intérêts dominants dans le système de la santé est une solution à considérer. L'exemple du Protecteur du citoyen au Québec, lequel comprend une mission spécifique pour le secteur de la santé, représente un modèle intéressant puisqu'il allie un processus de résolution de doléances à ce rôle d'interlocuteur et est davantage susceptible d'intervenir sur une base régulière dans le domaine de la santé comparativement aux tribunaux.

L'imputabilité est une valeur essentielle qui devrait transcender les processus décisionnels au sein de tout système de santé afin d'assurer leur pérennité, surtout dans la mesure où ils sont financés par des fonds publics et requièrent la confiance des contribuables pour survivre. L'imputabilité, plus qu'une pensée après coup, se doit d'être un réflexe de bonne gouvernance. Les citoyens et les acteurs juridiques ont la possibilité de faire cause commune et requérir des décideurs politiques qu'ils rendent le système de santé plus transparent, une condition pour le rendre plus juste.

HEALTHY START: A POLICY AND LEGAL ANALYSIS OF HEALTH CARE REFORM IN MASSACHUSETTS

*Matthew Kanter**

On April 12, 2006, Massachusetts enacted a comprehensive health care reform package designed to provide near-universal coverage for the state's residents, including 550,000 who were previously uninsured. The first part of this paper describes and analyzes several features of the reform including the first-of-its-kind individual mandate, the employer mandates, and the "Connector." It argues that while the legislation is not perfect—significant questions remain regarding whether it is adequately funded—the legislation goes a long way toward ensuring accessible, high-quality, and portable health care for Massachusetts residents. The second part of the paper analyzes a potential legal hurdle for the new legislation: whether the federal Employee Retirement Income Security Act (ERISA) pre-empts the employer play or pay mandate created by the State. Despite unclear and sometimes conflicting judicial precedent, the author contends that a federal court will likely uphold the employer mandate. The paper concludes by discussing policy implications for states considering similar health care reforms, as well as for federal politicians who want to adopt elements of the Massachusetts reforms into their national health care reform proposals.

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INTRODUCTION

On April 12, 2006, Massachusetts enacted a comprehensive health care reform package designed to provide near-universal coverage for the state's residents, including 550,000 who were previously uninsured.¹ *An Act Providing Access to Affordable, Quality, Accountable Health Care*² (the "Act") is a complex mix of insurance market reforms, subsidized insurance offerings, and individual and employer responsibility provisions. If successful, the Act could serve as an example for health care reform throughout the United States.

The Massachusetts reforms are based on the premise of shared responsibility—that providing health insurance is the combined responsibility of government, individuals, employers, and health care providers. The bi-partisan legislation passed by staggering margins. It was approved 155-2 in the Massachusetts House of Representatives and 37-0 in the State Senate. Furthermore, the legislation has drawn widespread support from across the political spectrum, including from former Republican Governor Mitt Romney, Democratic Senator Ted Kennedy, the Heritage Foundation, and Families USA, a liberal health care advocacy initiative. It has also, of course, drawn widespread criticism from across the same spectrum.

This paper describes several key features of the legislation, including the individual mandate, the employer mandate, and the "Connector." It argues that, from a *policy* perspective, the legislation will go a long way toward ensuring accessible and quality health insurance for Massachusetts residents. The legislation is not perfect, however, and there are significant questions regarding whether health insurance will be affordable and whether the plan is adequately funded. The paper then examines a significant *legal* question surrounding the legislation, namely, whether the federal *Employee Retirement Income Security Act*³ (ERISA) pre-empts the employer mandate to provide health insurance to employees or pay a penalty. While jurisprudence in this area is murky at best, it is argued that a federal court will likely uphold the employer mandate. Finally, the conclusion discusses policy implications of Massachusetts' health plan for other states and potential federal initiatives. During the Democratic primary campaigns, both Hillary Clinton and Barack Obama proposed sweeping health care reforms that drew heavily from the Massachusetts plan. Any significant federal health reforms must draw from the Massachusetts experience with reform and try to avoid the pitfalls learned two years after its implementation.

I

THE LEGISLATION

The ambitious Act has several significant provisions, many of which are creative, novel, and unprecedented. This paper describes the Connector, insurance market reforms, employer responsibility, personal responsibility, and state subsidies for insurance premiums.

A. The Connector

Arguably the most revolutionary aspect of the legislation is the development of an innovative quasi-governmental entity known as the Commonwealth Health Insurance Connector (the "Connector").⁴ The Connector is a state-chartered clearinghouse through which

¹ "Health Care Access and Affordability Conference Committee Report" (April 3, 2006), online: The 185th General Court of the Commonwealth of Massachusetts <<http://www.mass.gov/legis/summary.pdf>> at 1 [Conference Committee Report]. Officially, the Massachusetts Division of Health Care Finance and Policy estimated that there were only 372,000 uninsured Massachusetts residents in April 2006. See Alan G. Raymond, "The 2006 Massachusetts Health Care Reform Law: Progress and Challenges After One Year of Implementation" (May 2007), Blue Cross Blue Shield of Massachusetts Foundation.

² *An Act Providing Access to Affordable, Quality, Accountable Health Care*, c. 58, 2006 Mass. Acts.

³ *Employee Retirement Income Security Act*, Pub. L. No. 93-406, 88 Stat. 829 (1974) [ERISA].

⁴ Robert E. Moffit & Nina Owcharenko, "Understanding Key Parts of the Massachusetts Health Plan" (18 July

individuals and employees in businesses with fifty or fewer employees who designate the Connector as their insurer will be able to purchase insurance from competing private companies, with pre-tax dollars. It will be run by an independent agency, the Commonwealth Health Insurance Connector Authority (the “Connector Authority”), whose eleven-member Connector Board will consist of individuals from both the public and private sectors. Jon Kingsdale, a senior executive at Tufts Health Plan, was appointed as the first Executive Director of the Connector Board in April 2006.

The Heritage Foundation, which developed the idea of a central health insurance exchange originally proposed by Alain Enthoven, refers to the Connector as providing a “Car Max” approach to health insurance:⁵ different (private) health insurance plans are available through a large central dealership (the Connector). It is designed to work like a buying cooperative, generating lower premiums from the purchasing power which results from combining many individuals and smaller employers into a single, state-run insurance pool.⁶ The Connector clearinghouse will pair buyers with sellers efficiently and facilitate the collection and transmission of payments, often from multiple sources. The Connector neither designs plans nor regulates the insurers offering the plans (which will continue to be regulated by the Department of Insurance), who are free to design plans subject to Massachusetts’ existing insurance laws. All plans offered through the Connector, however, must cover all forty-three mandated benefits under Massachusetts law, including mental health, maternity, and chiropractic benefits, and must meet the minimum creditable coverage requirements established by the Connector Board by January 2009.⁷

For individuals with annual incomes above 300 percent of the Federal Poverty Level (FPL), which is currently \$30,630 for an individual or \$61,950 for a family of four, there are no subsidies to purchase “Commonwealth Choice” plans through the Connector. Those individuals can, however, pool their purchasing power and risk to bargain for better rates than insurance companies would ordinarily offer to individuals and small groups. Policies offered through the Connector will be underwritten for a large risk pool (all individuals who obtain coverage through the Connector) rather than for each individual or small group that attempts to obtain insurance.⁸ On average this should lead to larger risk pools, more risk spreading, and lower health insurance costs.

The Connector plans are also portable throughout the state, meaning that individuals can maintain coverage without interruption as they change jobs or experience gaps in employment. In addition, workers with multiple employers (such as seasonal, part-time, or temporary employees) can combine the employers’ contributions to their premiums.

B. Insurance Market Reforms

The legislation also merged small group and non-group (individual and self-employed purchasers) insurance markets in July 2007. The merger was intended to stabilize the non-group market and generate risk-pooling and bargaining power advantages in order to reduce

2006), online: The Heritage Foundation, Web Memo #1045 <www.heritage.org/Research/HealthCare/wm1045.cfm>.

⁵ Edmund F. Haislmaier, “The Significance of Massachusetts Health Reform” (11 April 2006), online: The Heritage Foundation, Web Memo #1035 <www.heritage.org/Research/HealthCare/wm1045.cfm>.

⁶ Edward A. Zelinsky, “The New Massachusetts Health Law: Pre-emption and Experimentation” (2007) 1:49 Wm. & Mary L. Rev. 229 at 237-8.

⁷ See Elizabeth A. Weeks, “Failure to Connect: The Massachusetts Plan for Individual Health Insurance” (2007) 55 Kan L. Rev. 1283 at 1291.

⁸ Zelinsky, *supra* note 6 at 237.

rates. Individual premiums are projected to decrease by 15 percent, while premiums for small employers are only expected to increase by 1 to 1.5 percent.⁹

C. Employer Responsibility

The Massachusetts reform imposes three new requirements on employers. First, employers with more than ten employees must create “cafeteria” plans (under section 125 of the *Internal Revenue Code*) which allows employees to purchase insurance with pre-tax dollars.¹⁰ Second, there will be a “free rider surcharge” levied on employers who do not provide health insurance and whose employees use a threshold amount of uncompensated care.¹¹ The final employer responsibility requirement is the imposition of a “play or pay” mandate. This provision was originally vetoed by Governor Romney, but the Democratic legislature overrode his veto. It requires employers with more than ten employees to provide a “fair and reasonable” contribution to their employees’ health insurance (play) or to pay an annual “fair share contribution” into the state’s Commonwealth Care Trust Fund of no more than \$295 per full-time employee per year.¹² The \$295 assessment represents the estimated private sector share of the average cost (per worker) of free care provided to workers whose employers do not provide health insurance.¹³ If uncompensated care drops, the \$295 assessment will correspondingly decline.

Subsequent regulations from the Division of Health Care Finance and Policy provide that companies meet the “fair and reasonable” requirement if at least 25 percent of the firm’s full-time employees are enrolled in that firm’s health plan and the company is making a contribution towards it, or if the company has offered to pay at least 33 percent of its employees’ health insurance premiums.¹⁴

The assessment was originally expected to affect 8 percent of Massachusetts’ 35,000 companies with more than ten employees and was intended to generate between \$26 million and \$48 million.¹⁵ Democratic Governor Deval Patrick later amended those figures, predicting the employer mandate to generate approximately \$24 million for 2007. However, as of late November 2007, only 518 companies had agreed to pay the penalty, which has generated about \$5 million.¹⁶ Proponents of the health care reform take this low figure as an indication that employers are taking their portion of the shared responsibility seriously, and have begun and continue to provide adequate health insurance to their employees.¹⁷

⁹ Kaiser Family Foundation, “Massachusetts Health Care Reform Plan: An Update” (June 2007), online: Kaiser Family Foundation <<http://www.kff.org/uninsured/upload/7494-02.pdf>> [Kaiser Family Foundation, “Update”].

¹⁰ *An Act Providing Access to Affordable, Quality, Accountable Health Care*, *supra* note 2, §48(2). Cafeteria Plans are regulated by the *Internal Revenue Code*, 26 U.S.C. 125.

¹¹ *Ibid.* The surcharge will be imposed when an employee at a company receives free care more than three times in a year, or a company has five or more instances of employees receiving free care in one year. The free rider surcharge will range from 10 to 100 percent of the state’s costs of free care provided to the employees, with an exemption for the first \$50,000 of free care used.

¹² *Ibid.*, §47(c)(10).

¹³ See John E. McDonough *et al.*, “The Third Wave of Massachusetts Health Care Access Reform” (2006) Health Affairs w420.

¹⁴ For further explanation of these requirements see David A. Hyman, “The Massachusetts Health Plan: The Good, the Bad, and the Ugly” Policy Analysis No. 595 (28 June 2007) at 4, online: The Cato Institute <<http://www.cato.org/pubs/pas/pa-595.pdf>>.

¹⁵ *Ibid.* at 10 note 11 suggests that the amount raised will be \$26 million annually. Weeks, *supra* note 7 at 1287 cites estimates that \$48 million will be raised annually.

¹⁶ Alice Dembner, “Most Firms Complying with Health Law” *The Boston Globe* (22 November 2007), online: The Boston Globe Online <http://www.boston.com/news/health/articles/2007/11/22/most_firms_comply_with_health_law/>.

¹⁷ *Ibid.* State Senate President Therese Murray argued that the \$5 million figure is “unequivocally good news” because “employers are obviously doing their part, and individuals are also taking their responsibility seriously.” Critics of the Massachusetts plan argue that this low figure is an example of how the plan is under-funded, and that a

D. Personal Responsibility

The most controversial and unprecedented aspect of the new legislation is the first-of-its-kind individual mandate. It is also the aspect that has garnered the most media attention. As of July 1, 2007, Massachusetts law *requires* all residents over age eighteen to “obtain and maintain creditable coverage so long as it is deemed affordable under the schedule set by the board of the Connector,” either through their employer, Medicaid, Medicare, or the Connector which facilitates the purchase of private health insurance.¹⁸

There are important exceptions to the individual mandate: those whose “sincerely held religious beliefs” prevent them from obtaining coverage and those for whom there is no coverage deemed “affordable,” are exempted from the mandate.¹⁹ The Connector Authority is responsible for setting the affordability standards and it released an affordability schedule in July 2007. It is also responsible for determining which policies meet the requirements of adequate (*i.e.* creditable) coverage in order to satisfy the individual mandate.

Those who fail to comply with the individual mandate because they do not have documented, creditable coverage, face income tax penalties. In 2007, the penalty for not having health insurance was the loss of the personal income tax exemption (about \$219 for an individual or \$437 for a family).²⁰ In 2008 and thereafter, the penalty for each month without coverage will be half the cost of the cheapest available insurance premiums for creditable coverage within a person’s region. The cheapest plans cost approximately \$150 per month (\$1,800 per year) meaning that the penalty will be roughly \$900 annually, prorated monthly for each month the individual lacks insurance.²¹

E. Subsidies

The legislation also creates mechanisms to help people obtain coverage in order to satisfy the individual mandate. For individuals who cannot afford health insurance, the Massachusetts Plan includes government subsidies through Commonwealth Care. Subsidies are available for low-income uninsured adults below 300 percent of the FPL, allowing them to purchase insurance through the Connector. Eligible individuals below 150 percent of the FPL (an income of \$15,315 for an individual in 2008) will receive subsidized insurance through the Connector with *no premiums or deductibles* and only modest co-payments.²² Individuals who earn between 150 and 300 percent of the FPL will also qualify for premium subsidies based on a sliding fee scale. There will be no deductibles for any Connector-subsidized plans, but the mandatory minimum creditable coverage requirements apply. All plans purchased through the Connector require a Connector Seal of Approval, indicating that they are of “high value and good quality.”²³

tax increase will be required to fund the shortfall.

¹⁸ *An Act Providing Access to Affordable, Quality, Accountable Health Care*, *supra* note 2, §2(a).

¹⁹ *Ibid.*, §2.

²⁰ McDonough *et al.*, *supra* note 13 at w424.

²¹ Commonwealth Health Insurance Connector Authority, Press Release, “Connector Board Endorses Plans from Seven Carriers” (8 March 2007), online: Commonwealth Health Insurance Connector Authority <<http://www.mahealthconnector.org/portal/site/connector/menuitem.4bab485e26865f535734db47e6468a0c/?fiShown=default>>.

²² Originally, the legislation only called for individuals earning below 100 percent of the FPL to receive fully subsidized insurance (no premiums). However, on April 12, 2007, the Connector Board approved new premium subsidies, increasing the threshold for no-premium insurance to individuals who earn up to 150 percent of the FPL. See Raymond, *supra* note 1 at 12.

²³ Conference Committee Report, *supra* note 1 at 1.

II POLICY ANALYSIS

Given the multi-step, multi-year implementation process of the legislation, it is difficult to fully analyze all of the legislation's (positive and negative) consequences. Indeed, it is only after the implementation process is complete that the law's full significance will become clear. That said, the legislation represents a clear step in the right direction for Massachusetts' health care, and has several significant policy benefits.

A. The Benefits of the Legislation

1. *Substantial Increases in Insurance Coverage and a More Efficient Use of Health Care Services*

The first, obvious, benefit of the legislation is that its comprehensive nature will lead to a significant increase in the number of Massachusetts residents with health insurance. According to the Kaiser Family Foundation, the Massachusetts plan will achieve nearly universal health coverage. The Foundation originally estimated that, eventually, of the roughly 550,000 uninsured Massachusetts residents, 92,500 would get coverage through Medicaid expansions, 215,000 would purchase private insurance through the Connector and 207,500 would obtain subsidized insurance.²⁴ That would leave 35,000 residents uninsured, meaning that 99.5 percent of Massachusetts residents will have insurance. This is a significant positive step. Indeed, as McDonough argues, while these predictions may not be completely accurate, "at a minimum, hundreds of thousands of uninsured people will obtain affordable, high quality coverage over the next three years."²⁵ As will be described below, this seems to have occurred in large measure so far, two years after implementation of the Massachusetts reforms.

While it is admittedly difficult to quantify these issues, John Holahan and Linda Blumberg (using methodology developed by the Institute of Medicine) argue that the increase in economic well being from improved health in Massachusetts will total \$1.5 billion.²⁶ This is the estimated value of healthy life years gained as a result of expanding insurance coverage to those who lack it. Holahan and Blumberg further argue that these economic benefits far outweigh any potential new investment of state funds.²⁷ Substantially increasing the percentage of Massachusetts residents with health insurance will have significant health and economic benefits for the state.

The most recent data, from the Connector Board meeting on November 16, 2007, indicate that 216,130 people have become newly insured in Massachusetts. The latest unofficial figures indicate that more than 342,000 people are newly insured, as of March 2008.²⁸ Of the newly

²⁴ Kaiser Family Foundation, "Massachusetts Health Care Reform" (April 2006), online: Kaiser Family Foundation <<http://www.kff.org/uninsured/upload/7494.pdf>>. Interestingly, this "fact sheet" is no longer on the Kaiser Family Foundation website. However, there are no updated estimates as to how many individuals will obtain insurance under the Massachusetts reforms.

²⁵ McDonough *et al.*, *supra* note 13 at w431.

²⁶ John Holahan & Linda Blumberg, "Massachusetts Health Care Reform: A Look at the Issues" (2006) 25 Health Affairs w432 at w442.

²⁷ *Ibid.*

²⁸ Alice Dembner, "Healthcare Cost Increases Dominate Mass. Budget Debate" *The Boston Globe* (26 March 2008), online: The Boston Globe Online <www.boston.com/news/local/articles/2008/03/26/healthcare_cost-increases_dominates_mass_budget_debate/?page=2> [Dembner, "Healthcare Cost Increases Dominate"]. The Connector Authority website indicates that of the roughly 340,000 newly insured, about one third (110,000) are enrolled in private, commercial insurance—85,000 through employer-sponsored insurance and 25,000 in individually purchased non-group insurance plans—and approximately 230,000 have signed up for subsidized or partially subsidized state programs. See Commonwealth Health Insurance Connector, "About Us: Executive Director's Message," (17 April 2008) online: Commonwealth Health Insurance Connector <<http://www.mahealthconnector.org/portal/site/connector/menuitem.dc4d8f38fdd4b4535734db47e6468a0c?fiShown=default>>.

insured, 132,919 people (61 percent) have enrolled in Commonwealth Care, the sliding scale subsidized insurance plans for individuals with incomes below 300 percent of the FPL. The majority of those people have enrolled in plans with fully subsidized premiums.²⁹ A further 73,012 individuals (34 percent) have signed up for MassHealth, the Massachusetts Medicaid program. Interestingly, however, although Commonwealth Choice plans—unsubsidized plans for people earning more than 300 percent of the FPL—have been on the market since July 1, 2007, enrolment has been “sluggish.”³⁰ As of November 2007, only 10,199 people (5 percent) had enrolled in these plans through the Connector.³¹ Indeed, enrolment for individuals in the fully subsidized plans has exceeded estimates, while sign-up for higher income groups has not been as high as expected. Only a small percentage of individuals between 200 and 300 percent of the FPL have enrolled in Commonwealth Care plans, and a smaller percentage of individuals earning more than 300 percent of the FPL have enrolled in Commonwealth Choice. These figures have led some critics of the plan to argue that the premiums for these plans are simply unaffordable.

The enrolment boom of individuals earning below 300 percent of the FPL is an indicator that the health insurance reforms are working because significant numbers of previously uninsured individuals have now obtained health insurance.³² However, since enrolment in the subsidized plans is growing at a higher-than-anticipated pace, the state may face a funding shortfall of as much as \$147 million by the end of the 2008 fiscal year in order to provide sufficient subsidies to low-income residents.³³ The subsidized plans may be a “victim of their own success” as high enrolment has created a budget challenge for the state.³⁴

The significant increase in the number of Massachusetts residents, particularly low-income individuals, obtaining health insurance should lead to a more efficient use of overall health care services. Uninsured residents primarily use emergency rooms as a source of primary care, because American hospitals are required to provide care even if a patient cannot pay for it. This tendency towards emergency room treatment, rather than preventive, primary care is expensive. It represents an inefficient use of health care resources and leads to significantly worse health outcomes for the uninsured.³⁵ Moreover, hospitals are left with unpaid bills and increasing expenses for caring for the uninsured. In Massachusetts, this uncompensated care totaled \$1.3 billion in 2005, with the state picking up \$538.4 million through its Uncompensated Care Pool (UCP).³⁶ This fund, which is unique to Massachusetts, was established in 1985 and reimburses hospitals and community health centers (CHCs) for care provided to lower-income, uninsured and under-insured individuals. It is funded through an

²⁹ Christine Barber & Michael Miller, *Revisiting Massachusetts Health Reform: 18 Months Later* (December 2007) at 7, online: Community Catalyst <www.communitycatalyst.org/doc_store/publications/revisiting_MA_health_reform_dec07.pdf>.

³⁰ *Ibid.* See also Alice Dembner, “Success Could Put Health Plan in the Red” *The Boston Globe* (18 November 2007), online: The Boston Globe Online <http://www.boston.com/news/local/articles/2007/11/18/success_could_put_health_plan_in_the_red/> [Dembner, “Success”].

³¹ A further 8,000 to 30,000 people “... have enrolled in private insurance outside of the Connector, but this is difficult to track among insurers...” Barber & Miller, *supra* note 29 at 7.

³² It should be noted that there are still as many as 200,000 to 400,000 uninsured residents in Massachusetts. See Kevin Sack, “Massachusetts Faces a Test on Health Care” *The New York Times* (25 November 2007), online: The New York Times Online <http://www.nytimes.com/2007/11/25/us/politics/25mass.html?_r=1&oref=slogin>.

³³ Dembner, “Success”, *supra* note 30.

³⁴ *Ibid.* Unlike the federal government, states are required to balance their annual budgets.

³⁵ The Ninth Circuit Court of Appeals in California took judicial notice of these facts. It held that it is “uncontested” that individuals without health insurance are significantly less likely to seek timely medical care than those with health coverage and that this lack of timely access is inefficient and poses serious health risks. See *Golden Gate Restaurant Association v. City and County of San Francisco*, 512 F.3d 1112 (9th Cir. 2008) [*Golden Gate Restaurant Association*, Ninth Circuit Court of Appeals].

³⁶ See Moffit & Owcharenko, *supra* note 4. The Uncompensated Care Pool has been renamed the “Health Care Safety Net Trust Fund.”

assessment of hospitals and a health insurance premium tax (essentially an assessment of those with insurance) and through general revenues and federal matching funds.

The Massachusetts plan leverages these public health care subsidies from institutions that treat the uninsured through the UCP to low-income individuals to assist them in purchasing health insurance. Moreover, according to an econometric model developed by MIT economist Jonathan Gruber, the roughly \$1 billion in the UCP should be able to fully cover the subsidies to the uninsured and allow people to purchase and use their health insurance with no new state spending.³⁷ Using this money to subsidize insurance, rather than pay for emergency room care after the fact, should lead to a greater focus on preventive and primary care, a more efficient use of health care resources, and generally improved health outcomes.

2. *Portable Insurance*

The second major benefit is that the Connector ameliorates one of the biggest problems in the American health insurance market today: people drift in and out of insurance coverage as their employment status changes, often exposing themselves to significant financial risk and impediments to accessing health care during periods without coverage.³⁸ The Connector allows individuals to keep their insurance (purchased with pre-tax dollars) regardless of employment or job status.

In a seminal study of the uninsured population in the United States, Short and Graefe note that there is considerable turnover in the uninsured population; it is not an unchanging group.³⁹ The vast majority of the uninsured experienced gaps and frequent changes in coverage, and between one-half and two-thirds of the uninsured population moved into and out of coverage over the course of a year.⁴⁰ These repeated gaps in health insurance coverage were caused mainly by changes in employment and instability in employer-sponsored health insurance. Short and Graefe argued, therefore, that “to the extent that job turnover undermines coverage stability, designing ways for employers to contribute to the cost of coverage, without directly administering health insurance, could enhance continuity of coverage”, which could improve continuity of care.⁴¹ This is precisely what the Connector is designed to do. It creates stability in coverage because employers contribute financially towards health insurance, but the insurance is purchased through the Connector, rather than through the employer. The Connector empowers individuals to purchase and maintain their own health insurance policies and increases portability by allowing them to keep these policies when they change or lose their jobs.⁴²

3. *Lower Premiums in the Individual and Small-Group Markets*

The third benefit comes from merging individual and small group markets, which took place in July 2007. Prior to the merging of the markets, it was extremely difficult and costly to purchase an individual policy in Massachusetts. Market inequalities, particularly adverse selection and asymmetric information, generally make individual and small group policies “prohibitively expensive.”⁴³ Merging the non-group into the small group market through the

³⁷ Mitt Romney, “Health Care for Everyone? We’ve Found a Way” *The Wall Street Journal* (11 April 2006), online: The Wall Street Journal Online <<http://www.opinionjournal.com/editorial/feature.html?id=110008213>>. <<http://www.opinionjournal.com/editorial/feature.html?id=110008213>>.

³⁸ Pamela Farley Short & Deborah R. Graefe, “Battery-Powered Health Insurance? Stability in Coverage of the Uninsured” (2003) 22 *Health Affairs* 244.

³⁹ *Ibid.*

⁴⁰ *Ibid.* at 253.

⁴¹ *Ibid.*

⁴² Moffit & Owcharenko, *supra* note 4.

⁴³ Weeks, *supra* note 7 at 1286. Adverse selection refers to the phenomenon whereby individuals who demand insurance are likely to use health care services at a higher than average rate. It results from asymmetric information,

Connector is expected to stabilize the market by increasing risk-pooling and bargaining power advantages, particularly for those who were previously priced out of the insurance market. Recent actuarial estimates indicate that individual insurance premiums will decrease by about 15 percent through the merging of the markets, although small group rates are expected to increase by 1 to 1.5 percent.⁴⁴ It should therefore be much more affordable for individuals to purchase insurance, while small groups should only see a minor increase in their premiums.

4. *The Public Supports the Plan*

Public support of such comprehensive health care reform is critical to its success. While an early public survey (taken in September 2006, six months after the plan was announced) found that the public was largely supportive of the legislation, more recent surveys indicate that support is “widespread and has gone up” as more Massachusetts residents learn about and understand the reforms.⁴⁵ 67 percent of residents who had heard of the law in June 2007 approved of it, compared to only 16 percent who opposed it.⁴⁶ In general, Massachusetts residents acknowledge and support the partnership among the public, employers, and government required to meet the goal of substantially increasing health insurance coverage. Furthermore, those most likely to be affected by the individual mandate—the uninsured, younger adults, poorer residents, and minorities—are equally as supportive of the law as other Massachusetts residents.⁴⁷ Interestingly, while over 70 percent of Massachusetts residents were supportive of the parts of the law that require businesses to do more, support was more mixed regarding the individual mandate. Only 57 percent supported the individual mandate, which is a key aspect of the reform.⁴⁸ Indeed, without it, the quest for near-universal coverage may fall short. Moreover, in September 2006, support for the individual mandate varied by income: lower income individuals were least supportive of it (only 43 percent of Massachusetts residents who earned less than \$25,000 per year supported the mandate, even though they are eligible for insurance subsidies).⁴⁹

Blandon *et al.* note that “[t]he public’s views on the individual mandate point to a need for both widespread education about the new requirement and for the new Commonwealth Health Insurance Connector Authority to exercise care when establishing the affordability standards for the individual mandate to ensure that those standards are viewed as fair by the public.”⁵⁰ Politicians, including Democratic Governor Deval Patrick, must fully explain the policy rationale behind the individual mandate—that a high rate of compliance will reduce the number of uninsured, stabilize risk pools by including healthy individuals, and allow the movement of funds from uncompensated care to subsidized insurance—as well as its centrality

the fact that individuals who purchase insurance know more about their health status and their projected demand for health care services than insurers do. The result, of course, is that insurers hedge against the potential for higher than average use of health care services by increasing premiums for individuals and small groups who purchase insurance on their own.

⁴⁴ Kaiser Family Foundation, “Update”, *supra* note 9.

⁴⁵ Kaiser Family Foundation, Press Release, “Poll Finds Most Mass. Residents Support New Health Reform Law, Including Individual Mandate, as Initial Deadline Nears,” (27 June 2007), online: Kaiser Family Foundation <<http://www.kff.org/kaiserpolls/kaiserpolls062707nr.cfm>>, quoting Drew E. Altman, President and CEO of the Kaiser Family Foundation.

⁴⁶ Kaiser Family Foundation, Harvard School of Public Health & Blue Cross Blue Shield of Massachusetts Foundation, “Massachusetts Health Reform Tracking Survey” (27 June 2007), online: Kaiser Family Foundation <<http://www.kff.org/kaiserpolls/upload/7657.pdf>>.

⁴⁷ Robert J. Blandon *et al.*, “The Massachusetts Health Reform Law: Public Opinion and Perception” (2006) at 1, online: Blue Cross/Blue Shield of Massachusetts Foundation <http://bcbsmafoundation.org/foundationroot/en_US/documents/2006HealthReformPollingreport.pdf>.

⁴⁸ Kaiser, Harvard School of Public Health & Blue Cross, *supra* note 46; only 52 percent supported the individual mandate in the September 2006 opinion survey.

⁴⁹ Blandon *et al.*, *supra* note 47 at 9.

⁵⁰ *Ibid.* at 1.

in achieving meaningful reform. Indeed, further outreach, education, and public understanding of the individual mandate are crucial to the program's success.⁵¹ At the same time, however, the Massachusetts health care reform is significantly more popular than other recent health care reforms, including President Bill Clinton's reform package in 1994.⁵² With continuing public education and a fair definition of "affordability," the legislation should continue to garner popular support as long as rising health care costs can be adequately contained.

B. Legitimate Concerns with the Legislation

There are at least three legitimate concerns with the legislation. While these concerns are significant, they should not undermine the overall positive benefits and effects that the new legislation will have on Massachusetts residents or the significant progress that Massachusetts has made towards insuring a substantial number of previously uninsured residents. They should, however, be noted and addressed by other states and federal politicians who want to implement Massachusetts-style health care reform in other jurisdictions.

1. *The Legislation Contains No Cost-Containment Mechanisms*

The lack of significant cost-containment mechanisms may be the most critical concern with the legislation. While the start-up costs of the legislation were funded by re-directing Uncompensated Care Pool funds into private insurance subsidies, the legislation does nothing to contain the *future* skyrocketing costs of health care in Massachusetts, which are already the highest in the world.⁵³

Nationally, health insurance costs increased by 73 percent between 2000 and 2005, compared to a 15 percent increase in wages over that same period,⁵⁴ yet the Massachusetts plan does not address any of the underlying factors that contribute to spending, including the cost of prescription drugs, health care administration, and the reliance on multiple private insurance companies to provide insurance. It has been argued that the overall structure of private health insurance and the payment of medical care will remain intact, leading costs to "relentlessly increase."⁵⁵

Marcia Angell, Steffie Woolhandler and David Himmelstein, three critics of the legislation and supporters of single-payer health insurance, argue that even though the state covered the costs of implementing the reforms at the beginning of the program, at current growth rates the government subsidies will not be able to keep up with the soaring costs of health care.⁵⁶ As a result, Woolhandler and Himmelstein argue that "[t]he program is simply not sustainable over the long—or even medium—term."⁵⁷

⁵¹ Raymond, *supra* note 1 at 3.

⁵² Blandon *et al.*, *supra* note 47 at 19.

⁵³ Holahan & Blumberg, *supra* note 26 at w436. See also Steffie Woolhandler & David Himmelstein, Press Release, "Massachusetts Health Reform Bill: A False Promise of Universal Coverage" (5 April 2006), online: Physicians for a National Health Program <http://www.pnhp.org/news/2006/april/massachusetts_health.php>.

⁵⁴ Weeks, *supra* note 7 at 1305.

⁵⁵ Robert Steinbrook, "Health Reform in Massachusetts—A Work in Progress" (2006) 354:20 *New Eng. J. Med.* 2095 at 2095.

⁵⁶ Marcia Angell, "Health Care Reform Needs Dose of Common Sense" *The Boston Globe* (17 April 2006), online: The Boston Globe Online <http://www.boston.com/news/globe/editorial_opinion/oped/articles/2006/04/17/healthcare_plan_needs_dose_of_common_sense/>; Woolhandler & Himmelstein, *supra* note 53.

⁵⁷ Woolhandler & Himmelstein, *ibid.* The authors argue that the only way to contain costs and expand coverage is to change the system entirely and adopt a single-payer system (as in Canada). They point out that Massachusetts' high health care costs are the result of bloated administrative, marketing, and billing costs in private insurance companies. They argue that if Massachusetts cut bureaucracy to Canada's levels, the state would save \$9.4 billion annually, enough to cover every uninsured resident and improve coverage for the rest. However, while a single payer system may be more administratively efficient and be able to control costs, it is a political non-starter in any U.S.

To the extent that health insurance premiums continue to grow faster than state revenues (or if the number of very low-income uninsured was underestimated), the state may have to increase subsidies and government funding in order to keep health insurance “affordable” and maintain the reach of the mandate. Since substantial increases in government spending may not be politically feasible, if costs are not contained in the near future the state might have to exempt more people from the mandate, cut back on subsidies, or cap enrolment in Commonwealth Care subsidized insurance plans. Reduced subsidies could detrimentally affect the affordability of the individual mandate and could lead individuals to forego insurance if it became unaffordable. These financing issues could grow exponentially over time and could easily be exacerbated by the current recession. As Turnbull argues, “the long-term success and sustainability of the new law will depend on finding successful ways to control costs.”⁵⁸

The lack of any significant cost-containment mechanisms in the legislation is troubling. While a significant percentage of Massachusetts residents now have health coverage, a funding crisis has been brought about by a failure to address costs while focusing exclusively on access.⁵⁹ Indeed, despite former Governor Romney’s assertion that the plan could be adequately funded from existing revenue sources, Massachusetts is already seriously considering a tax increase to pay for the plan, only two years after its implementation. A \$1 per pack cigarette tax is expected, which is projected to raise \$152 million annually to cover the shortfalls in the plan’s budget.⁶⁰

Put simply, the next wave of health care reform in Massachusetts *must* contain cost-containment mechanisms if the legislation is to be viable. Two years of reform have demonstrated quite clearly that “broadening coverage without slowing costs is not a sustainable model” over the long-term.⁶¹ However, the lack of cost containment mechanisms at launch should not overshadow the positive benefits and substantially increased access to health care that the legislation provides.

2. *Minimum Creditable Coverage and the Definition of Affordability*

While the Massachusetts legislation is broad, comprehensive, and detailed, it left a number of potentially contentious decisions to the implementation stage.⁶² In particular, deciding what constitutes “minimum creditable coverage” and “affordable” coverage was left to the Connector Board.

In the legislation, “creditable” coverage must include all forty-three of Massachusetts’ state-mandated benefits, but the definition of “minimum creditable coverage” was left up to the Connector Board. Determining the requirements of minimum creditable coverage is an extremely difficult task. If the minimum coverage required to satisfy the mandate was too comprehensive (too many services had to be covered), then coverage may be too expensive and unaffordable, leaving many residents uninsured. On the other hand, if minimum benefits were set too low, this would create a class of underinsured people who would be forced to purchase

state, even Massachusetts.

⁵⁸ Weeks, *supra* note 7 at 1312 note 146, quoting Turnbull.

⁵⁹ Christopher R. Anderson, “Righting Healthcare Reform,” *The Boston Globe* (31 March 2008), online: The Boston Globe Online <http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2008/03/31/righting_healthcare_reform>.

⁶⁰ Alice Dembner, “Healthcare Cost Increases Dominate Mass. Budget,” *The Boston Globe* (26 March 2008), online: The Boston Globe Online <http://www.boston.com/news/local/articles/2008/03/26/healthcare_cost_increases_dominates_mass_budget_debate/?page=2> [Dembner, “Healthcare Cost Increases Dominate”]. One commentator even called Massachusetts’ health care reform the “Big Dig” of the next generation—an “ambitious and beneficial but deeply flawed public initiative with back-breaking costs to the taxpayer.” See Anderson, *ibid*.

⁶¹ Steve Bailey, “Healthcare Reform II,” *The Boston Globe* (6 February 2008), online: The Boston Globe Online <www.boston.com/business/healthcare/articles/2008/02/06/healthcare_reform_ii/>.

⁶² Raymond, *supra* note 1 at 13.

insurance that may not protect them in cases of medical need. The debate over health coverage illustrates the classic tension between access and comprehensiveness. There was also a significant debate over whether prescription drug coverage should be included in the definition of minimum creditable coverage. Health care advocates like Affordable Care Today! (ACT) argued that prescription drugs are an essential element of adequate coverage both because of their importance to modern medicine, and their ability to drive up consumers' out-of-pocket costs.⁶³ Other commentators argued, however, that the mandatory inclusion of prescription drugs in minimum creditable coverage would drive up costs substantially. Including prescription drugs in the minimum creditable coverage requirements could increase the costs of insurance premiums by 5 to 15 percent.⁶⁴ Moreover, roughly 200,000 individuals who already had health insurance but lacked prescription drug coverage would be forced to buy more costly coverage in order to comply with the mandate and avoid the fines.

In the end, the Connector Board decided on a set of fairly comprehensive standards for the minimum creditable coverage that an individual must have in order to satisfy the individual mandate. The Board defined "minimum creditable coverage" as "comprehensive health plans that include preventive and primary care, emergency services, hospitalization benefits, ambulatory patient services, mental health services *and prescription drugs*."⁶⁵ Creditable coverage must also cap annual deductibles, allow a minimum of three preventive care visits per individual before the deductible kicks in, and have maximum out-of-pocket spending limits of \$5,000 per year per individual or \$10,000 on a family plan.⁶⁶ Any insurance policy that does not contain all of these benefits is not considered adequate to satisfy the individual mandate. The Board has decided to delay the enforcement of the new minimum creditable coverage requirements, including prescription drug coverage, until January 2009 to give employers and consumers time to adjust their coverage in order to meet the minimum standards. Insurers are also trying to develop alternative minimum drug benefits that meet the minimum creditable coverage requirement without substantially increasing premiums.⁶⁷ Such comprehensive minimum benefits protect against individuals purchasing bare bones coverage, but it remains to be seen if the creditable coverage requirements will significantly drive up premium costs. It has been reported that insurers plan on increasing premiums 10 to 12 percent in 2008—more than twice the national average—in order to cover all of the mandated minimum benefits.⁶⁸ However, as Connector Board Executive Director Jon Kingsdale argues, if health insurance premiums continue with double digit inflation, Massachusetts' health care reform will not be sustainable.⁶⁹

Another critical and related implementation decision that engendered significant debate was the Connector Board's definition of "affordability," since individuals only suffer tax penalties if they fail to obtain health insurance that is affordable. Indeed, as Holahan and Blumberg argue, "for an individual mandate to be fair and acceptable, it must make coverage affordable."⁷⁰ A higher affordability standard (such as 15 percent of income) would lead to more coverage (more coverage would be deemed "affordable"), but would produce a greater burden on middle-income individuals, particularly those earning just above 300 percent of the FPL who are unable to obtain government-subsidized policies. Such a high standard might be

⁶³ *Ibid.* at 19.

⁶⁴ Michael D. Tanner, "Whatever Became of RomneyCare?" *The Salt Lake Tribune* (29 January 2008), online: The CATO Institute <http://www.cato.org/pub_display.php?pub_id=9127>.

⁶⁵ Raymond, *supra* note 1 at 19 [emphasis added].

⁶⁶ *Ibid.* at 19-20. Minimum creditable coverage must also include a minimum of six preventive care visits prior to the deductible for family plans.

⁶⁷ *Ibid.* at 19.

⁶⁸ Sack, *supra* note 32.

⁶⁹ *Ibid.*

⁷⁰ Holahan & Blumberg, *supra* note 26 at w436.

considered unreasonable and lead to backlash and decreased compliance with the mandate, which would defeat the purpose of near-universal coverage. Indeed, if the premium levels are seen as imposing an undue hardship on individuals, public support for the legislation could erode, making it difficult to sustain an individual mandate.⁷¹

On the other hand, a low affordability standard (such as 5 percent of income) would ease the individual and family burden of the mandate, but it would also lead to broad exemptions from the mandate and could force more individuals into the subsidized Connector plans, which would increase government spending.⁷² Choosing an appropriate affordability schedule is critical to the overall success and public approval of the legislation. Indeed, as Weeks argues, the “success or failure of the comprehensive state plan may turn in large part on the affordability scale.”⁷³

In July 2007, the Connector Board unanimously approved an “affordability schedule” to determine whether minimum creditable coverage is affordable for most uninsured people in various income brackets (see Appendix A). It also created a waiver and appeals process that allows people to demonstrate that their individual circumstances should exempt them from the mandate even if the schedule says that they should not be exempt.⁷⁴ The affordability schedule deems that individuals who earn between 150 and 200 percent of the FPL can pay up to \$35 per month in insurance premiums, while individuals who make between 251 and 300 percent of the FPL can afford to pay \$105 per month. Individuals, couples, or families who earn more than 600 percent of the FPL (\$50,000 for an individual or \$110,000 for a family) are deemed to be able to afford health insurance at any cost and thus cannot be exempted from the requirement to purchase health insurance on affordability grounds.

The affordability schedule remains controversial. Opponents of the definition point out that some people could be forced to pay up to 9.6 percent of their income on insurance premiums, or pay a fine.⁷⁵ Moreover, out-of-pocket costs are not included in the affordability scale—so individuals or families with high out-of-pocket medical costs may be required to pay premiums and could have additional substantial health care costs that account for a significant portion of their budgets. Indeed, even after the affordability schedule was approved, “concerns remain about requiring people with moderate incomes to spend significant portions of their incomes on health insurance” and health care cost-sharing.⁷⁶ Other commentators argue that the affordability standard is too low, allowing too many individuals to get exemptions from the individual mandate because they will be unable to find “affordable” health insurance. This would defeat the purpose of a mandate—if individuals can easily escape its requirements—and would frustrate the legislation’s goal of achieving universal health insurance. The *New York Times* noted that as many as 60,000 people may not be able to afford premiums and could receive exemptions.⁷⁷ Ultimately, the jury is still out on the impact of the Board’s first affordability schedule.

The affordability schedule is to be updated by the Connector Board every year, so the definition of “affordability” could be a contentious issue each time it is revised. Whenever the Board releases a new schedule, it will have to keep in mind the balance between high

⁷¹ Blandon *et al.*, *supra* note 47 at 19.

⁷² Holahan & Blumberg, *supra* note 26.

⁷³ Weeks, *supra* note 7 at 1288.

⁷⁴ Raymond, *supra* note 1 at 20.

⁷⁵ Sally C. Pipes, “At One Year, Mass. Healthcare Plan Falls Short” *The Boston Globe* (15 May 2007), online: The Boston Globe Online <http://www.boston.com/yourlife/health/other/articles/2007/05/15/at_one_year_mass_healthcare_plan_falls_short/>. For example, couples earning \$90,001 per year are deemed to be able to afford premiums up to \$720 per month (\$8,640 annually), which equals approximately 9.6 percent of their household income.

⁷⁶ Barber & Miller, *supra* note 29 at 6.

⁷⁷ Sack, *supra* note 32.

affordability standards, which force people to spend a significant amount of their money on health insurance, and low affordability standards which make it easy for individuals to exempt themselves from the requirements, hampering the ultimate goal of universal coverage. Indeed, as Raymond argues, “longer-term, the issue of individual affordability will have to be constantly revisited”.⁷⁸

3. Coverage in Name Only

The final concern is that the legislation requires a “minimum level of health insurance, not an optimal level.”⁷⁹ The goal of the (particularly unsubsidized) Connector plans is to make health insurance affordable for individual and small group purchasers in order to facilitate compliance with the individual mandate.⁸⁰ But it is difficult to dictate to private market health insurers that they must provide affordable plans that are low-cost and effective. While the Connector plans could have reduced premiums and cost-sharing requirements by reducing the amount and types of services offered or covered, the Connector Board developed comprehensive requirements for minimum creditable coverage. As mentioned, these mandatory coverage requirements protect against bare bones insurance policies, but they also drive up costs to the insurers.

Since the plans offered through the Connector (with the exception of the Young Adult Plans for individuals between nineteen and twenty-six years of age) must include the minimum creditable coverage requirements, the only way for private insurers to provide affordable insurance and keep costs down is to offer plans that have low premiums (so that individuals can purchase them and satisfy the mandate) but high deductibles, high cost-sharing requirements, and limited provider networks.⁸¹ Indeed, the majority of people who have signed up for unsubsidized plans have chosen to purchase Bronze or Young Adult Plans that have the lowest premiums, highest out-of-pocket costs, and, in the case of the Young Adult Plans, limited benefits.⁸² Most of these Bronze plans have \$2,000 deductibles for individuals or \$4,000 for a family policy (the amount that must be spent by the insured before insurance kicks in) and steep co-payments.⁸³ But these low-premium, high deductible plans have not been very popular in Massachusetts, and individuals may simply prefer to pay the tax (half the cost of a low-premium plan), rather than purchase this type of health insurance.

Woolhandler and Himmelstein argue that the individual mandate requires individuals to spend money they do not have in order to buy “nearly worthless stripped down policies that represent coverage in name only.”⁸⁴ The Bronze plans may be considered “name only coverage” plans because the high deductibles and considerable cost-sharing may lead to insufficient or prohibitively expensive coverage for health care needs.⁸⁵ Indeed, under the mandate, if

⁷⁸ Raymond, *supra* note 1 at 26.

⁷⁹ Steinbrook, *supra* note 55 at 2095.

⁸⁰ For a full analysis see Weeks, *supra* note 7 at 1302.

⁸¹ There are four types of Commonwealth Choice plans (unsubsidized plans purchased through the Connector): (1) Gold (Premium) Plans have the highest premiums, but also have comprehensive benefits, no deductibles and limited cost-sharing; (2) Silver (Value) Plans have mid-level premiums, no deductibles, and some cost-sharing; (3) Bronze (Basic) Plans have low premiums, but high deductibles and high cost-sharing; (4) Young Adult Plans (for individuals aged nineteen to twenty-six) have low premiums, high cost-sharing and limited benefits because they do not need to meet the standards of minimum creditable coverage. Of the 10,199 people who have enrolled in unsubsidized plans, the largest number (40 percent) have enrolled in Bronze Plans, and 28 percent have enrolled in Young Adult Plans. Only 23 percent have enrolled in Silver Plans, while 9 percent have purchased Gold Plans. See Barber & Miller, *supra* note 29 at 7.

⁸² Woolhandler & Himmelstein, *supra* note 53.

⁸³ It should be noted that, as mentioned earlier, under the minimum creditable coverage requirements, plans will have to allow up to three primary care visits (six in a family plan) prior to the deductible.

⁸⁴ Woolhandler & Himmelstein, *supra* note 53.

⁸⁵ Barber & Miller, *supra* note 29 at 5.

individuals get sick, the Bronze plans contain significant gaps (for example, through limited provider networks) and large co-payments that could still lead to an individual's financial ruin. This leads to the worst of both worlds—individuals are forced to pay hundreds (or thousands) of dollars for health insurance, yet they will still not have adequate coverage if they get sick.

The problematic definition of affordability, the lack of cost containment mechanisms, and the potential to force individuals to purchase “name only coverage” are all serious problems that must be addressed by the Massachusetts legislature and the Connector Authority. They must also be acknowledged and addressed by other states and federal politicians considering health care reform initiatives. However, the potential benefits of the legislation—providing at least some health insurance coverage to a substantial number of previously uninsured Massachusetts residents, encouraging the more efficient use of health services, insurance market reforms that take advantage of bargaining power and risk-pooling, and the creation of legitimately portable health insurance all indicate that Massachusetts is going in the right direction. While the legislation may not be perfect, and subsequent health care reforms must address cost-containment issues, the Massachusetts legislation is definitely a step in the right policy direction.

III

IS THE EMPLOYER MANDATE ILLEGAL?

While the amount of the assessment on employers who do not provide a “fair and reasonable” contribution to employees’ health insurance coverage is not financially substantial (up to \$295 per full-time worker per year), it symbolizes the logic of the reforms: both employers and employees should share responsibility for health insurance.⁸⁶ But a landmark ruling in a Federal District Court, which was later upheld in a two-to-one decision at the Fourth Circuit Court of Appeals, struck down a similar Maryland law on the basis that it was pre-empted by the federal *ERISA*.⁸⁷ Maryland had enacted the *Fair Share Health Care Fund Act* (the “*Fair Share Act*”) in January 2006.⁸⁸ That *Act* required for-profit employers with 10,000 or more employees to spend at least 8 percent of payroll on “health insurance costs” (play) or pay the difference between what they spent and 8 percent into a fund supporting the state Medicaid program (pay). In practice, this law only applied to Wal-Mart, because it was the only company that met the criteria (thus it is sometimes called the “Wal-Mart Law”).⁸⁹ This section of the paper will analyze whether Massachusetts’ play or pay employer assessment violates *ERISA*. It will argue that despite the ruling on Maryland’s *Fair Share Act*, the Massachusetts legislation is not likely to be pre-empted by *ERISA*. Ultimately, however, the law is unclear; cases have been decided on their specific facts and a judge may rule either way.⁹⁰

⁸⁶ Steinbrook, *supra* note 55 at 2095.

⁸⁷ *Retail Industry Leaders Association v. Fielder*, 435 F. Supp 2d 481 [*Fielder*, Federal District Court] aff’d in *Retail Industry Leaders Association v. Fielder*, 2007 U.S. App. LEXIS 920 (4th Cir. Md., Jan 17, 2007), 475 3d. 180 [*Fielder*, Fourth Circuit Court of Appeals].

⁸⁸ *Fair Share Health Care Fund Act*, c. 3, 2006 Md. Laws (codified as amended at MD. Code Ann., Health-Gen. Section 15-42; MD. Code Ann., Lab. & Emp. §§ 8.5-101 to 107).

⁸⁹ See Julie Appelby, “Judge Overturns Wal-Mart Law” *USA Today* (19 July 2006), online: The USA Today <http://www.usatoday.com/money/industries/retail/2006-07-19-walmart-healthcare_x.htm>.

⁹⁰ For arguments that, legally, the Massachusetts play or pay mandate should be pre-empted, see *e.g.* Zelinsky, *supra* note 6; Julia Contreras & Orly Lobel, “Wal-Martization and the Fair Share Health Acts” (2006) 19 St. Thomas L. Rev. 105; “Illegal Health Care,” Editorial, *The Wall Street Journal* (23 January 2007), online: The Wall Street Journal Online <<http://online.wsj.com/article/SB116951662631884439.html?mod=opinion&ojcontent=otep>>; William G. Schiffbauer, “Hiding in Plain View: *ERISA* Preempts Provisions of Massachusetts ‘Play or Pay’ Health Care Reform Law,” (2006) 14:37 *Health Care Policy Report* 1; *Retail Industry Leaders Association v. Suffolk County*, 497 F. Supp 2d 403 (E.D.N.Y. 2007). For arguments that the Massachusetts play or pay mandate should not be pre-empted, see *e.g.* Patricia A. Butler, “*ERISA* Implications for State Health Care Access Initiatives: Impact of the Maryland ‘Fair Share Act’ Court Decision” (November 2006) at 8, online: National Academy for State Health Policy

A. ERISA Pre-emption

Federal legislation, *ERISA* “was enacted to remedy fraud and mismanagement in private-sector employer pension plans”.⁹¹ It also applies to employee welfare benefit plans, which include any plan, fund or program which is established or maintained by an employer to the extent that such plan, fund or program provides certain welfare benefits, including medical, surgical or hospital care benefits.⁹² In short, the vast majority of health care benefits that an employer extends to its employees qualify as “employee welfare benefit plans” under *ERISA*. Furthermore, §514(a) contains a broad and explicit pre-emption provision in which *ERISA* “supersedes any and all state laws insofar as they now or hereafter *relate to* any employee benefit plan”.⁹³ In order to define the scope of the pre-emption, the Supreme Court held in *Shaw v. Delta Air Lines Inc.* that a state law “relates to” an *ERISA* plan if the law has a “reference to” or a “connection with” such a plan.⁹⁴

Following *Shaw*, the Supreme Court took an expansive approach to the pre-emption clause, which is “conspicuous in its breadth,” allowing it to pre-empt virtually any state law touching upon an employee benefit plan.⁹⁵ The Court held that several state employer-sponsored plans were pre-empted, such as Hawaii’s mandate that employers provide workers with health coverage.⁹⁶ However, the Supreme Court appeared to narrow the scope of the pre-emption in *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.*⁹⁷ That case concerned a state law that provided for hospital bill surcharges (24 percent of the bill) for patients whose insurance coverage was provided by a commercial insurer other than Blue Cross/Blue Shield. Its purpose was simply to encourage employers to contract with Blue Cross/Blue Shield plans. The Court emphasized that in an area of traditional state regulation, such as health care, federal law should not supersede state laws unless it was the clear and manifest purpose of Congress to do so.⁹⁸

In *Travelers*, the Court held that while the New York law made Blue Cross/Blue Shield more attractive to *ERISA* (employer-sponsored) health plans, it only had an “indirect economic effect” on health insurance choices made by employers, and that such an indirect economic effect should not be pre-empted.⁹⁹ Such an economic incentive did not “bind plan administrators to any particular choice.”¹⁰⁰ More importantly, with respect to the Maryland statute, the Court held in *Travelers* that “there might be a point at which an exorbitant tax leaving consumers with a Hobson’s choice [a free choice with only one option available] would be treated as imposing a substantive mandate” which would clearly be pre-empted.¹⁰¹ Although in that case the surcharges imposed by the New York law were not so prohibitive as to force all health insurance consumers to contract with Blue Cross/Blue Shield.

<<http://www.statecoverage.net/SCINASHP.pdf>>; Amy B. Monahan, “Pay or Play Laws, *ERISA* Preemption, and Potential Lessons from Massachusetts” (2007) 55 Kan. L. Rev. 1203; *Golden Gate Restaurant Association*, Ninth Circuit Court of Appeals, *supra* note 35; see also *Felder*, Federal District Court, *supra* note 87 at 496 note 15.

⁹¹ Butler, *ibid.* at 4.

⁹² *ERISA*, *supra* note 3, §§1002(1), (2)(a).

⁹³ *Ibid.*, §1144(a) [emphasis added].

⁹⁴ *Shaw v. Delta Air Lines Inc.*, 463 U.S. 85 (1983).

⁹⁵ Butler, *supra* note 90 at 4. See also Zelinsky *supra* note 6 at 251.

⁹⁶ Congress later amended *ERISA* to provide an exemption for Hawaii’s employer health insurance mandate, since it was enacted prior to *ERISA*. See *ERISA*, *supra* note 3, §1144(b)(5)(A).

⁹⁷ 514 U.S. 645 (1999) [*Travelers*].

⁹⁸ *Ibid.*

⁹⁹ *Ibid.* at 659.

¹⁰⁰ *Ibid.*

¹⁰¹ *Ibid.* at 664.

B. *Retail Industry Leaders Association v. Fielder*

The Maryland law was challenged by the Retail Industry Leaders Association (RILA) on Wal-Mart's behalf. The case, *RILA v. Fielder*, represented the first time that a court has ruled on a state "play or pay" initiative.¹⁰² After deciding that RILA had standing to pursue the case on Wal-Mart's behalf, Judge Motz examined whether the *Fair Share Act* had an impermissible "connection with" an *ERISA* plan. He held in a footnote that it had a direct and express "reference to" an *ERISA* plan and would have been pre-empted on those grounds as well.¹⁰³

In order to determine whether the law had an impermissible connection with an *ERISA* plan, the court looked at (1) "the objectives of the *ERISA* statute as a guide to the scope of the state law that Congress understood would survive" and (2) "the nature of the effect of the state law on *ERISA* plans."¹⁰⁴ Judge Motz noted that the main objective of the *ERISA* pre-emption clause is "to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans" because national uniformity is impossible if employee benefit plans are subject to different legal obligations in different states or localities.¹⁰⁵ The *Fair Share Act* created spending obligations in one state that were not applicable in other jurisdictions: Wal-Mart had to spend at least 8 percent of its payroll on health care costs in Maryland, but not in other states.¹⁰⁶ Indeed, the *Act* required Wal-Mart to "segregate a separate pool of expenditures for its Maryland employees and structure its contributions (and employee deductibles and co-pays) with an eye to how it would affect the eight percent requirement."¹⁰⁷

The judge then held that the *Fair Share Act* had a "connection with" an *ERISA* plan because it was intended to force Wal-Mart to increase its contributions to its health benefit plan, which was an *ERISA* plan, and that the actual effect would be to force Wal-Mart into doing so.¹⁰⁸ *ERISA* clearly prohibits state laws that directly regulate or mandate that private employers offer or pay for insurance.¹⁰⁹ Thus, the Maryland *Act* was pre-empted in accordance with the "long established Supreme Court law that state laws which impose employee health or welfare mandates on employers are invalid under *ERISA*."¹¹⁰ Judge Motz held that the Maryland law was equivalent to a benefit-mandating law, because under the *Fair Share Act*, no rational employer would choose to pay the state rather than provide insurance.¹¹¹ Therefore, the effect of the law was to force Wal-Mart, a private employer, to provide a minimum level of health insurance benefits under an *ERISA* plan through a Hobson's choice, which was equivalent to imposing a substantive mandate.¹¹²

In a two-to-one decision, the Fourth Circuit Court of Appeals affirmed the lower court decision.¹¹³ Judge Niemeyer, for the majority, agreed with Judge Motz's reasoning that the *Act* effectively required employers to restructure employee benefit plans, conflicting with *ERISA*'s goal of permitting uniform nationwide administration of these plans.¹¹⁴ He concluded by noting that *ERISA* applied despite the "noble purpose" of Maryland's legislation because courts are

¹⁰² Monahan, *supra* note 90 at 1211. See *Fielder*, *supra* note 87.

¹⁰³ *Fielder*, Federal District Court, *supra* note 87 at 493 note 12.

¹⁰⁴ *Ibid.* at 494.

¹⁰⁵ *Ibid.*

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

¹⁰⁸ *Ibid.* at 495.

¹⁰⁹ *Standard Oil Co. v. Agsalud*, 633 F.2d 760 (9th Cir. 1980).

¹¹⁰ *Fielder*, Federal District Court, *supra* note 87 at 494.

¹¹¹ *Ibid.* at 497.

¹¹² *Ibid.*, quoting from *Travelers*, *supra* note 97.

¹¹³ *Fielder*, Fourth Circuit Court of Appeals, *supra* note 87.

¹¹⁴ *Ibid.* at 190.

not to “change the fundamental policy of *ERISA*” which they are “bound to enforce ... as the supreme law of the land.”¹¹⁵

C. Applying *ERISA* and *RILA v. Fielder* to the Massachusetts Legislation

The Massachusetts fair share contribution does raise issues concerning the nationally uniform administration of employee benefit plans, because employers have to meet the coverage or contribution requirements imposed by the Division of Health Care Finance and Policy.¹¹⁶ That is, employers must either cover 25 percent of full-time workers and contribute towards coverage or offer to pay one-third of the cost of coverage under the employer plan. For a national employer to be exempt from paying the assessment, it would potentially have to alter its benefit administration in Massachusetts, which would seem to contravene the Fourth Circuit’s holding in *RILA v. Fielder*. Indeed, several commentators, including Professor Zelinsky, argue that just as Maryland’s Wal-Mart *Act* is *ERISA* pre-empted, the Massachusetts fair share contribution is also pre-empted as “forbidden regulation of employer-provided health care.”¹¹⁷

Professor Zelinsky argues that, like the Wal-Mart *Act*, the fair share contribution is *ERISA* pre-empted under *Travelers* and its narrow interpretation of the “relate to” standard.¹¹⁸ Under *Travelers*, state laws which “mandate ... employee benefit structures or their administration” relate to *ERISA*-regulated benefit plans and are pre-empted.¹¹⁹ This, according to Professor Zelinsky, is precisely what the Massachusetts fair share contribution does: it mandates benefit levels by explicitly and directly requiring employers with eleven or more full-time employees to “offer” group health plans to which such employers must make “fair and reasonable premium contributions.”¹²⁰

Professor Zelinsky cites *Egelhoff v. Egelhoff*¹²¹ to further demonstrate his point. In *Egelhoff*, a Washington state statute provided that divorce revokes all beneficiary designations of a former spouse on a life insurance policy and pension plan provided by an employer. The United States Supreme Court held that this statute was *ERISA* pre-empted because it “instructs *ERISA*-regulated fringe benefit plans to disregard a pre-divorce beneficiary designation of a

¹¹⁵ *Ibid.* at 197. The Federal District Court for the Eastern District of New York found that a similar Suffolk County law was pre-empted in *Retail Industry Leaders’ Association v. Suffolk County*, *supra* note 90. There, the law would have required large retail stores with more than a certain amount of grocery revenues, or floor area devoted to selling groceries, to make health care expenditures at a rate that approximated the cost to the county’s public health system of uninsured workers, or to pay the difference to the city. The Court held that while the objective of the law—protecting smaller retailers that offer health benefits from unfair competition from large retailers with no or limited employee health coverage—was appropriate, the law was “strikingly similar” to the Maryland law and was pre-empted by *ERISA*. See State Coverage Initiatives, “Update on *ERISA* Court Decisions,” Academy Health/Robert Wood Johnson Foundation (March 2008), online: State Coverage Initiatives <<http://www.statecoverage.net/SCI-Erisa-Update-0308.pdf>>.

¹¹⁶ See Monahan, *supra* note 90 at 1215.

¹¹⁷ Zelinsky, *supra* note 6 at 231. Some commentators, like Schiffbauer, argue that *ERISA* further pre-emptes the section 125 “cafeteria” plans mandated by the Massachusetts *Act*. However, most commentators agree that *ERISA* “does not pre-empt the [Massachusetts] law’s requirement that employers maintain cafeteria plans qualifying under ... section 125” because the Department of Labor has held that such cafeteria plans are not considered “*ERISA*-regulated welfare plans.” See Zelinsky, *supra* note 6 at 265.

¹¹⁸ Professor Zelinsky argues that §514(a) of *ERISA* pre-emptes the employer contribution mandate of the new Massachusetts health law as “unacceptably ‘relat[ing] to’ employers’ medical plans for their employees.” See Zelinsky, *supra* note 6 at 260. He argues that the minimum creditable coverage standard would also be *ERISA* pre-empted insofar as having a mandatory minimum level of health benefits that must be provided is prohibited regulation of an *ERISA* plan. *Ibid.* at 232.

¹¹⁹ *Travelers*, *supra* note 97 at 668. Note that such laws need not mandate employee benefit structures explicitly. A state law is pre-empted if it “produce(s) such acute, albeit indirect, economic effects [as to] force an *ERISA* plan to adopt a certain scheme of substantive coverage.” *Ibid.* at 668. See also Zelinsky, *supra* note 6 at 252.

¹²⁰ Zelinsky, *supra* note 6 at 259.

¹²¹ 532 U.S. 141 (2001).

now former spouse.”¹²² The Court held that the Washington law “governs” the administration of the plan by negating existing beneficiary designations on file with the *ERISA*-regulated plan.¹²³ Professor Zelinsky argues that the Massachusetts fair share contribution similarly governs *ERISA*-regulated health plans by requiring employers to sponsor health plans and make fair and reasonable contributions to them.¹²⁴ He concludes that in both factual situations (in *Egelhoff* and the Massachusetts fair share contribution), state law would “mandate ... employee benefit structures or their administration” in violation of the interpretation in *Travelers* of § 514(a) of *ERISA* and the standard for pre-emption.¹²⁵

Despite Professor Zelinsky’s arguments, however, there are two major differences between Massachusetts’ play or pay provision and the one struck down in Maryland. These two differences should enable the Massachusetts law to avoid pre-emption. First, Massachusetts’ legislation is part of a wider package of comprehensive legislation aimed at regulating various aspects of health insurance provision. Maryland’s statute consisted only of a play or pay provision designed to affect Wal-Mart. In a suggestive footnote, Judge Motz, while striking down the Maryland legislation, stated:

I am expressing no opinion on whether legislative approaches taken by other States to the problems of health care delivery and its attendant costs would be pre-empted by *ERISA*. For example, the Commonwealth of Massachusetts has recently enacted legislation that addresses health care issues comprehensively and in a manner that arguably has only incidental effects on *ERISA* plans. In light of what is generally perceived as a national health care crisis, it would seem that to the extent *ERISA* allows, it is strongly in the public interest to permit states to perform their traditional role of serving as laboratories for experiment in controlling the costs and increasing the quality of health care for all citizens.¹²⁶

It is unclear whether this is a “personal plea”¹²⁷ or an *obiter dictum* on the state of the law, but since the judge performed no reasoned analysis of the Massachusetts legislation, it is unlikely that this footnote has any legal value as a precedent. Butler, however, argues that the footnote’s suggestion that a comprehensive program with minimal impacts on *ERISA* plans could survive a pre-emption challenge would be helpful if Massachusetts ever has to defend the law in court.¹²⁸

The second major difference is that the “pay” penalty is relatively weak in Massachusetts, compared to the one in Maryland. Some analysts like William Schiffbauer, a legal consultant to health insurers, argue that even a weak “pay” option sets a minimum contribution level of benefits for otherwise “voluntary” employer-sponsored health benefits and should still be pre-empted by *ERISA*.¹²⁹ The argument is that the Massachusetts law mandates that employers provide a benefit plan that includes health benefits, contrary to *ERISA*, because the employer assessment is earmarked into the Commonwealth Care Trust Fund, which is used to subsidize health insurance for Massachusetts residents. Employers are mandated to provide health insurance either directly or by supporting a publicly subsidized plan; there is no “none at all” choice.¹³⁰ Therefore, Schiffbauer argues, regardless of how low the employer assessment is,

¹²² See Zelinsky, *supra* note 6 at 259.

¹²³ *Egelhoff*, *supra* note 121 at 148.

¹²⁴ Zelinsky, *supra* note 6 at 259.

¹²⁵ *Ibid.* It should be noted, however, that while Professor Zelinsky thinks that key parts of the Massachusetts health care reform are *ERISA* pre-empted (by the statute and case law), at 231 he nonetheless finds this result “regrettable since health care is an area in which states should be permitted, indeed encouraged, to explore novel approaches”. His paper calls for Congress to repeal §514 of *ERISA* and abolish the jurisprudence of *ERISA* pre-emption, in order to allow Massachusetts, and other states, to fulfil its potential as a laboratory of experiment in the health care arena.

¹²⁶ *Fielder*, Federal District Court, *supra* note 87 at 496 note 15.

¹²⁷ See Schiffbauer, *supra* note 90.

¹²⁸ Butler, *supra* note 90 at 9.

¹²⁹ Schiffbauer, *supra* note 90 at 2.

¹³⁰ *Ibid.* at 2.

having any assessment interferes with national benefit administration. Employers would have to provide different levels of health benefits to employees in Massachusetts compared to employees in other states. Professor Zelinsky agrees, arguing that play or pay provisions “directly intrude ... on *ERISA* plans by mandating the *minimum* level of coverage provided by their employers.¹³¹ This is arguably the case in Massachusetts, where large employers must provide *at least* \$295 per full-time employee per year towards health insurance benefits.

To demonstrate this point Professor Zelinsky again cites *Egelhoff*, in which the Washington state law at issue allowed employers to elect out of the statute’s coverage, nullifying the retroactive effect of the participants’ divorce.¹³² However, this ability to “opt out” did not save the Washington statute from *ERISA* pre-emption. The Supreme Court held that “the statute is not any less of a regulation of the terms of *ERISA* plans simply because there are two ways of complying with it.”¹³³

By contrast, both Monahan and Butler argue that because the “pay” penalty is relatively insubstantial compared to the cost of providing insurance, the Massachusetts play or pay provision would likely survive an *ERISA* pre-emption challenge on the basis that it is a mere indirect economic incentive for a plan administrator to make certain choices with respect to its health care plan.¹³⁴ The argument is that this penalty is “so insubstantial” that it is not a *de facto* coverage mandate and therefore does not impact on the structure or benefits of the *ERISA* plans.¹³⁵

Instead of forcing an employer to provide particular health insurance benefits to its employees, Monahan argues that the assessment penalty simply “provides a small financial incentive for employers to comply with the [fair and reasonable] standards.”¹³⁶ What contrasts this law from the Maryland law is that the Massachusetts plan makes it rational for an employer to choose the “pay” option, which should be considered as a tax to the state, rather than the provision of health insurance. Therefore, it is argued that the law does not require an employer to either adopt or amend an *ERISA* plan, as the Maryland law does, because employers could rationally choose to pay the \$295 assessment, which is not connected with an *ERISA* plan.¹³⁷

The result, according to both Monahan and Butler, is that Massachusetts’ fair share contribution is more like an “indirect economic incentive” to create an *ERISA* plan (which was upheld in the *Travelers* decision) rather than a Hobson’s choice, requiring the employer to provide particular mandated benefits (which was struck down in *RILA*). Monahan argues that it is clear that “if Massachusetts required all employers to either cover 25 percent of their full-time employees or pay 33 percent of all employee health insurance premiums, such a law would be pre-empted.”¹³⁸ However, Massachusetts’ law does not require employers to cover their employees; it is simply a relatively modest financial disincentive associated with foregoing the provision of health insurance.¹³⁹

This argument would be strengthened if the assessment were paid into Massachusetts’ “general revenue” fund, rather than earmarked for the Commonwealth Care Trust Fund. (Maryland’s assessment was also earmarked for the state Medicaid fund.) That way, employers

¹³¹ See Contreras & Lobel, *supra* note 90 at 129, quoting Professor Zelinsky [emphasis added].

¹³² See Zelinsky, *supra* note 6 at 261.

¹³³ *Egelhoff*, *supra* note 121 at 150. The two ways of complying with it included (1) treating divorce as revoking prior benefits or (2) giving notice that the employer had elected against the statutory rule.

¹³⁴ Monahan, *supra* note 90 at 1214. Butler, *supra* note 90 at 8.

¹³⁵ Butler, *ibid.* at 9.

¹³⁶ Monahan, *supra* note 90 at 1215.

¹³⁷ *Ibid.* at 1216.

¹³⁸ *Ibid.*

¹³⁹ *Ibid.*

would have a true choice between providing health insurance benefits and paying an assessment that could not be perceived as a mandate to provide any type of health insurance and would have no connection at all with an *ERISA* plan.¹⁴⁰ Since up to twenty other states have enacted or are considering play or pay provisions, they may want to consider a relatively low pay assessment (providing employers a true choice as to whether to “play” or “pay”), as well as putting the assessment money into general revenues, not an earmarked fund for health care provision. That way, these states will be sure to steer clear of *ERISA* pre-emption.

An emergency order issued by the Court of Appeals for the Ninth Circuit further indicates that providing employers with a legitimate choice between two acceptable alternatives (providing health care or paying money into a fund for health care) avoids *ERISA* pre-emption. The City of San Francisco passed an ordinance, designed to take effect January 1, 2008, that requires employers with twenty to ninety-nine employees (and non-profit employers with fifty or more employees) to spend \$1.17 per hour per employee on health coverage for any employee who has been employed for more than ninety days; for-profit companies with one hundred or more employees must spend \$1.76 per hour per worker on health coverage.¹⁴¹ The ordinance also sets out several non-exhaustive qualifying health care expenditures which include contributions to Health Savings Accounts (HSAs), re-imbusement to employees for health care expenses, and direct costs incurred in the delivery of health care.¹⁴² Businesses that do not meet the per hour health care spending requirements must pay the equivalent amount to a universal access fund for a primary and preventive care program called the Health Access Program. This program is available to uninsured San Francisco residents regardless of their employment status and delivers care to participants from a network of San Francisco General Hospital, Department of Health clinics, and participating non-profit and public providers.¹⁴³

In late 2007, the Federal District Court for the Northern District of California, relying on the fourth circuit’s holding in *RILA v. Fielder*, held that *ERISA* pre-empts San Francisco’s ordinance because it is “connected with” and “refers to” *ERISA* plans.¹⁴⁴ However, in January 2008, the Court of Appeals for the Ninth Circuit granted a stay of the lower court’s order and an emergency order allowing the city’s ordinance to go ahead as planned. The court held that, as a preliminary matter, the city has a “strong likelihood of success” in its argument that the ordinance is *not* pre-empted by *ERISA*.¹⁴⁵

The Ninth Circuit held that the ordinance requires that covered employers make certain levels of health care *payments* to an *ERISA* plan or some other entity, including the city; it does not require that employers provide certain health care *benefits* to its employees, through an *ERISA* plan or otherwise.¹⁴⁶ As a result, the ordinance does not mandate employee benefit structures or administration. In fact, the ordinance “does not force employers to provide any benefits or plans, to alter their existing plans, or to even provide *ERISA* plans or employee benefits at all,” and therefore it cannot be “connected with” an *ERISA* plan.¹⁴⁷ As in

¹⁴⁰ In striking down a local San Francisco “play or pay” ordinance designed to require San Francisco employers to provide health insurance to its employees or pay a rate per hour worked into a health access program, the Federal District Court for the Northern District of California suggested that future local and state government that want to implement “play or pay” provisions should craft assessments as general revenue measures and then give a tax credit to companies for health care spending, in order to avoid *ERISA* pre-emption. See *Golden Gate Restaurant Association v. City and County of San Francisco*, 535 F. Supp 2d 968 (N.D. Cal. 2007) at 980.

¹⁴¹ *Ibid.* at 970.

¹⁴² *Ibid.*

¹⁴³ *Ibid.* at 971.

¹⁴⁴ *Ibid.* at 979.

¹⁴⁵ *Golden Gate Restaurant Association*, Ninth Circuit Court of Appeals, *supra* note 35 at 1119. Full oral arguments were heard on April 17, 2008 and the final ruling is expected in the summer of 2008. A decision in favour of upholding the ordinance could send the issue to the United States Supreme Court.

¹⁴⁶ *Ibid.* at 1119.

¹⁴⁷ *Ibid.* at 1122.

Massachusetts, a San Francisco employer may be influenced by the ordinance to choose to adopt (or alter) an *ERISA* plan to comply with the ordinance, in lieu of paying the city. However, according to *Travelers*, “such influence is entirely permissible.”¹⁴⁸ As a result, the ordinance went into effect in mid-January 2008 and is operational, pending the decision on the appeal of the merits.

Finally, from a practical perspective, the Massachusetts legislation was supported by much of the mainstream business community (likely because it was able to bargain for such a modest “pay” assessment), so it is unclear why any employer would now challenge it. It has been reported, however, that a number of “ideological” law firms from outside Massachusetts are looking for plaintiffs and preparing a lawsuit challenging the play or pay provision.¹⁴⁹ Even if the employer mandate were struck down (it had to be enacted overriding Governor Romney’s veto), it only represents a minor part of the legislation financially, and Massachusetts’ other health care reforms would continue to produce tangible benefits for Massachusetts residents.

IV

POLICY IMPLICATIONS FOR OTHER STATES

Several other states, notably California and Maine, have already tried to emulate some or all of the Massachusetts health care reform. In California, Republican Governor Schwarzenegger introduced the *Health Care Security and Cost Reduction Act*,¹⁵⁰ which was similar to the Massachusetts reform. The proposed California plan contained a “play or pay” provision for employers with more than ten employees which included a “pay” sanction (for employers not providing adequate health insurance) of 4 percent of the total employer payroll.¹⁵¹ The plan also included an individual mandate—as in Massachusetts, Californians would be required to purchase insurance through their employer, individually or through the newly created “connector-type risk pooling mechanism.”¹⁵² It would have also required health

¹⁴⁸ In addition, the Court held that the ordinance does not have a “reference to” an *ERISA* plan because it does not “act immediately and exclusively upon *ERISA* plans” and the existence of *ERISA* plans is not essential to the law’s operation: *ibid*.

¹⁴⁹ Celia Wcislo, Malini Cadambi & Yvonne Liu, *Lessons Learned to Date from the Massachusetts Health Care Reform* (August 2007) at 14, online: 1199 SEIU United Health Care Workers East <<http://www.newamerica.net/files/MA%20HC%20Reform%20Lessons%20Learned%20to%20Date%20Aug%2007%20FINAL1.pdf>>.

¹⁵⁰ U.S., A.B. 1, *An act to amend Section 2069 of, to add Sections 4040.1, 4071.2, 4071.3, and 4071.4 to, and to add and repeal Section 2838 of, the Business and Professions Code, to add Section 49452.9 to the Education Code, to add Sections 12803.2, 12803.25, 22830.5, and 22830.6 to, and to add Chapter 15 (commencing with Section 8899.50) to Division 1 of Title 2 of, the Government Code, to amend Sections 1357.54, 1365, 124900, 124905, 124910, 124920, 128745, and 128748 of, to amend, repeal, and add Section 1399.56 of, to add Sections 1262.9, 1342.9, 1347, 1356.2, 1367.16, 1367.205, 1367.38, 1368.025, 1378.1, 1395.2, 1399.58, 104376, 124905.1, 124946, and 130545 to, to add Chapter 1.6 (commencing with Section 155) to Part 1 of Division 1 of, to add Article 11.6 (commencing with Section 1399.820) to Chapter 2.2 of Division 2 of, to add Article 1 (commencing with Section 104250) to Chapter 4 of Part 1 of Division 103 of, to add Article 3 (commencing with Section 104705) to Chapter 2 of Part 3 of Division 103 of, and to add Chapter 4 (commencing with Section 128850) to Part 5 of Division 107 of, the Health and Safety Code, to amend Sections 12693.43, 12693.70, 12693.73, and 12693.76 of, to amend, repeal, and add Section 796.02 of, to add Sections 796.05, 10113.10, 10113.11, 10123.56, 10176.15, 10273.6, 12693.56, 12693.57, 12693.58, 12693.59, 12693.766, 12886, and 12887 to, to add Chapter 9.6 (commencing with Section 10919) to Part 2 of Division 2 of, and to add Part 6.45 (commencing with Section 12699.201) and Part 6.7 (commencing with Section 12739.50) to Division 2 of, the Insurance Code, to add Section 96.8 to the Labor Code, to amend Sections 19167 and 19611 of, to add Sections 17052.31, 17052.32, 19528.5, and 19553.5 to, and to add and repeal Section 17052.30 of, the Revenue and Taxation Code, to add Sections 301.1 and 1120 to, and to add Division 1.2 (commencing with Section 4800) to, the Unemployment Insurance Code, and to amend Sections 12306.1, 14005.30, and 14011.16 of, to add Sections 14005.301, 14005.305, 14005.306, 14005.310, 14005.311, 14005.331, 14005.333, 14011.16.1, 14074.5, 14081.6, 14092.5, 14132.105, and 14137.10 to, and to add Article 5.215 (commencing with Section 14167.22) to, and to add and repeal Article 5.21 (commencing with Section 14167.1) of, Chapter 7 of Part 3 of Division 9 of, the Welfare and Institutions Code, relating to health care coverage, 2007-2008, 1st Extra Sess., Cal., 2008.*

¹⁵¹ See Weeks, *supra* note 7 at 1299.

¹⁵² *Ibid*.

care providers to pay a tax of 2 percent of revenues for physicians and 4 percent for hospitals.¹⁵³ Similarly, Massachusetts already enacts a surcharge on providers and insurers to fund the UCP.

Ultimately, however, Governor Schwarzenegger's proposal failed to receive enough votes to pass out of the Senate Health Committee; it was voted down ten to one in January 2008. At present, although Governor Schwarzenegger and State Assembly Speaker Fabian Nunez have vowed to continue their fight for a comprehensive health care plan, future reform seems to be in jeopardy in that state.

As the failure to achieve comprehensive health care reform in California has shown, other states must be careful before attempting health care reforms similar to Massachusetts', because they may not be able to achieve similar results. Indeed, the Massachusetts health insurance market has several key features that enabled Governor Romney to propose, achieve, and implement meaningful health care reform. First, Massachusetts has a lower uninsurance rate than other states. Only about 11 percent of Massachusetts residents were uninsured in 2006, compared to about 16 percent nationally.¹⁵⁴ California, for example, has more uninsured residents than Massachusetts has people.

Second, Massachusetts has a history and tradition of regulating the health insurance market, including medical underwriting, guaranteed issue, and experience-rating provisions. Policy analysts argue that a viable individual mandate is much more feasible in a state with heavily regulated insurance markets.¹⁵⁵ Third, Massachusetts already had a large federal subsidy (a \$385 million Medicaid waiver) and a substantial taxpayer-funded UCP (which totaled about \$1 billion) to fund the start up costs of such a comprehensive program. It has been argued that "an equivalent harmonic convergence of [these] factors remains far less likely in other states considering similar coverage expansion initiatives."¹⁵⁶ Indeed, these features make the Massachusetts situation unique, and the costs and outcomes from a similar health care reform in another state, or federally, would likely be different.¹⁵⁷

At the same time, key features of the Massachusetts plan should serve as examples for other states. First, it is important to note that bi-partisan collaboration is possible in order to achieve meaningful health reform. Indeed, the Massachusetts plan was a unique merger of the political right and left, Republicans and Democrats, conservative and progressive approaches to comprehensive reform.¹⁵⁸ It demonstrated the willingness of leaders from across the political spectrum to agree on a common goal (moving towards universal health insurance coverage) and to compromise in order to achieve that goal. Second, incremental reform will not produce substantial results. Any state initiative that seeks to implement meaningful reform will have to apply multiple policy mechanisms in order to achieve significant policy progress.¹⁵⁹ Finally, any state that proposes health care reform will likely attempt to reform or expand employer-sponsored insurance, which is currently the mechanism through which most Americans get their health insurance. However, any state considering reforms to employer-sponsored coverage will have to be aware of the *ERISA* pre-emption implications of any employer-related health care initiatives. Unfortunately, the *ERISA* pre-emption greatly inhibits states from

¹⁵³ *Ibid.* at 1300. There were also some key differences in Governor Schwarzenegger's proposal. The plan would have required insurers to spend at least 85 percent of premiums on patient care, limited insurance company spending on administrative overhead, and would have capped profits. There were also no caps on premiums or mandatory coverage provisions. Despite these restrictions, however, insurers generally approved of the plan, which is expected to generate four to five million new customers.

¹⁵⁴ Elizabeth A. McGlynn & Jeffrey Wasserman, "Massachusetts Health Reform: Beauty is in the Eye of the Beholder" (2006) 25 Health Affairs w447.

¹⁵⁵ See McDonough *et al.*, *supra* note 13.

¹⁵⁶ Tom Miller, "Massachusetts: More Mirage than Miracle" (2006) 25 Health Affairs w450 at 450.

¹⁵⁷ McGlynn & Wasserman, *supra* note 154 at w448.

¹⁵⁸ McDonough *et al.*, *supra* note 13 at w431.

¹⁵⁹ McGlynn & Wasserman, *supra* note 154 at w448.

experimenting with meaningful health care reforms, but until it is amended, states must draft and implement their reforms in accordance with the pre-emption.

V

FEDERAL POLICY IMPLICATIONS

The failure of California, a politically significant and trend-setting state, to achieve comprehensive health care reform means that advocates of overhauling the health care system have turned their focus back to Washington and the federal government.¹⁶⁰ Comprehensive reform has been a major national policy issue, particularly for the Democrats. Senator Barack Obama has advocated comprehensive reforms that, like Senator Hillary Clinton's proposals, have incorporated several aspects from the Massachusetts reform.¹⁶¹ However, it is crucial that any federal health care initiative takes into account the successes and avoids the pitfalls of the Massachusetts reforms.¹⁶²

Both Senator Obama's and Senator Clinton's proposed health care plans include significant play or pay employer mandates. Senator Clinton's "American Health Choices Plan" contains an employer play or pay mandate whereby large employers "will be expected to provide health insurance or contribute to the cost of coverage" and "small businesses will receive a tax credit to continue or begin to offer health insurance."¹⁶³ Similarly, Senator Obama's "Plan for a Healthy America" provides that employers who do not offer meaningful coverage or make a meaningful contribution to the cost of their employees' health insurance will be required to pay a percentage of payroll towards a national health care plan.¹⁶⁴ Of course, federal health care initiatives can implement an employer play or pay mandate without conflicting with *ERISA*, and they cannot be pre-empted. This point is crucial because federal play or pay provisions are legal, and the "pay" penalty can be set at a higher level than in Massachusetts without the risk of an employer bringing an *ERISA* lawsuit. Federal play or pay employer mandates may be an effective way to increase health coverage and fund significant health care reforms without the risk of pre-emption.¹⁶⁵

Another similarity between the Democrats' plans is that they both propose an insurance exchange and pooling mechanism to help make insurance more affordable. Senator Obama's plan refers to it as a "National Health Insurance Exchange," which will contain income-based sliding-scale subsidies, like the Connector. It is interesting that both candidates have strongly advocated a Connector-type exchange, given that, as Professor Zelinsky argues, it is simply too soon to tell "if [the Connector] has in practice achieved its proponents' goals of a large scale health insurance marketplace which reduces health insurance premiums and increases the availability of health insurance coverage by pooling eligible individuals and employers while insurers compete for their business."¹⁶⁶ While in theory the Connector can potentially improve

¹⁶⁰ Christopher Lee, "Health-Care Reform to Shift Focus" *The Washington Post* (31 January 2008) A2.

¹⁶¹ Although Senator Clinton has conceded the Democratic presidential nomination to Senator Obama, as an influential member of the United States Senate and the Democratic Party she still wields considerable power in federal politics and will still likely advocate her national health care proposals.

¹⁶² On the other side of the political aisle, Republican presidential nominee John McCain has only advocated piecemeal health care reforms, including a direct refundable tax credit of \$2,500 for individuals or \$5,000 for families to offset the cost of insurance, and encouraging and expanding the benefits of Health Savings Accounts. See <www.johnmccain.com/Informing/Issues/19ba2f1c_c03f_4ac2-8cd5-5cf2edb527cf.htm> for a discussion of his health care policies.

¹⁶³ Hillary for President, Press Release, HCPO725 "The American Health Choices Plan: Insuring Quality, Affordable Health Care for All Americans" at 2, online: Hilary Clinton for President <www.hillaryclinton.com/feature/healthcareplan/americanhealthchoicesplan.pdf> [Hillary for President].

¹⁶⁴ Obama '08, "Plan for a Healthy America" at 4-5, online: Obama '08 <<http://www.barackobama.com/issues/pdf/HealthCareFullPlan.pdf>> [Obama '08].

¹⁶⁵ Of course any significant "pay" option will likely face significant backlash from the business community.

¹⁶⁶ Zelinsky, *supra* note 6 at 239; for a discussion of the potential problems with the Connector, see Weeks, *supra*

competition, increase access to health care, and lower costs, it is still a relatively unproven commodity in practice. It should, however, definitely improve the portability of health insurance.

The key differences between Senator Clinton's and Senator Obama's plans involve the individual mandate and cost containment mechanisms. Senator Clinton's proposal contains a nationwide individual mandate in which all Americans "will be responsible for getting and keeping insurance in a system where insurance is affordable and accessible."¹⁶⁷ The plan will ensure affordability by limiting premium payments to a percentage of family income (to be determined by Congress and indexed over time) and by providing subsidies to lower income individuals. In short, according to MIT Economist Jonathan Gruber, who analyzed the budget implications of the Massachusetts reforms, Senator Clinton's proposal is "very, very similar" to the plan that Governor Mitt Romney proposed and negotiated through the Massachusetts legislature.¹⁶⁸ Indeed, she claims, much like Romney did in Massachusetts, that savings would come from modernization and reform, including the reduced need for uncompensated care payments.¹⁶⁹ Clinton's plan focuses primarily on access without adequately addressing cost containment issues. The lesson learned from Massachusetts, however, is that increasing access to coverage without adequately controlling skyrocketing health care costs is not a sustainable model, either in Massachusetts or federally. Any federal mandate must address cost containment issues in a direct and significant way, or it must include the potential for a substantial tax increase to keep the mandate affordable.

By contrast, Senator Obama's plan and campaign rhetoric have focused primarily on cost containment mechanisms, but his plan does not contain an individual mandate.¹⁷⁰ He has argued that Americans do not have health insurance because they cannot afford it, not because they do not want it or are not forced to purchase it.¹⁷¹ His cost containment proposals include lowering costs through investment in electronic health information technology systems, and by increasing competition in the insurance and drug markets. In addition, a substantial section of his plan is devoted to promoting prevention and strengthening public health, which are also designed to contain costs in the long run.¹⁷² While recognizing the vital importance of cost containment, it is unclear how successful his plan will be at signing up uninsured (particularly young and healthy) people for insurance without an individual mandate.

Health care reform in Massachusetts has two main implications for federal policy initiatives. First, if a federal politician wants to expand access to health care, the success of the Massachusetts model seems to indicate that an individual mandate is necessary to significantly increase the number and percentage of uninsured individuals who sign up for health insurance. Any proposal designed to achieve universal or near-universal coverage likely requires some type of individual mandate in order to increase the number of healthy individuals who enter into and stabilize risk pools, and bring down the average costs to the insurance companies. If young and healthy (and generally poorer) individuals are not mandated to purchase health

note 7.

¹⁶⁷ Hillary for President, *supra* note 163 at 2.

¹⁶⁸ Dan Balz, "Romney's Rush to Critique Clinton Missing the Facts" *The Washington Post* (18 September 2007), online: The Washington Post Online <http://blog.washingtonpost.com/the-trail/2007/09/18/post_78.html>. Interestingly, despite the overwhelming similarities between his reforms in Massachusetts and Senator Clinton's national health care proposal, during his brief presidential run, Governor Romney criticized Senator Clinton's plan as a "European-style socialized medicine plan" and "HillaryCare 2.0," evoking images from the Clintons' failed attempt at health care reform during President Clinton's first term in office.

¹⁶⁹ Hillary for President, *supra* note 163 at 7. She also advocates reversing President Bush's tax cuts in order to raise additional revenues for her health care plan.

¹⁷⁰ His plan contains mandatory coverage for children under the age of eighteen, but no individual mandate for adults. See Obama '08, *supra* note 164 at 5.

¹⁷¹ See 2008 Democratic Debate at University of Texas in Austin: On Health Care <www.ontheissues.org/>.

¹⁷² Obama '08, *supra* note 164 at 11-13.

insurance, a substantial percentage of them are not likely to pay for it, even if costs are contained. This will lead to adverse selection in the risk pools as older and less healthy people are the only ones who purchase insurance (for example, in an insurance exchange like the Connector). This leads to higher average prices, in turn causing more individuals to forego insurance. In short, it seems as though the phenomenon that health economists refer to as the “adverse selection death spiral” will continue to exist in the absence of an individual mandate.¹⁷³

Second, expanding access and broadening coverage without controlling costs is unsustainable. A federal initiative with a subsidized individual mandate will likely require significant cost containment mechanisms and/or a federal tax increase in order to remain economically viable over the long term. Of course, as Massachusetts has demonstrated, “expanding coverage is easy compared to controlling costs.”¹⁷⁴

Any meaningful, comprehensive reform designed to ensure access to health care for a majority of the United States’ forty-seven million uninsured citizens will require both an individual mandate (or some mechanism for forcing everyone—including the healthy—into the appropriate risk pools) as well as significant, substantial, and long-term cost containment mechanisms. Massachusetts has gone part of the way; it is up to motivated and creative federal and state officials to develop health care strategies that build on Massachusetts’ successes in order to improve health care access while at the same time controlling costs.

CONCLUSION

This paper has examined both the policy and legal aspects of Massachusetts’ recently enacted health care policy reform. While the law is not perfect, it goes a long way towards ensuring that most Massachusetts residents have quality, portable health insurance and improved health outcomes. That said, the law has some areas for improvement, notably an appropriate definition of “affordability” and the pressing need for some cost-containment mechanisms.

Legally, the employer mandate (a largely symbolic but important part of the legislation) may violate federal law. While the legislation and jurisprudence is unclear regarding the *ERISA* pre-emption of “play or pay” statutes, it is argued that the Massachusetts legislation would likely be upheld and not pre-empted by *ERISA*. Nevertheless, other states considering reform must be aware of the *ERISA* pre-emption issue and its implications.

Finally, the passage of the legislation creates policy implications for other states and federal officials considering reform. While not all of the aspects of the Massachusetts plan will necessarily translate to other jurisdictions, it seems clear that political compromise from across the political spectrum, and comprehensive, rather than piecemeal, reform is necessary to achieve meaningful reductions in the number of uninsured Americans. Furthermore, in order to achieve a significant and substantial increase in access to health insurance (and therefore access to appropriate and efficient health care), a subsidized individual mandate is probably necessary. However, any such mandate *must* be accompanied with significant cost containment mechanisms if it is to remain viable and sustainable over the long term. It will be interesting to watch the implementation of the various parts of the Massachusetts legislation as parts of the *Act* come into effect over the next year, and to see whether the state is able to reign in costs effectively, or if they continue to relentlessly increase. Massachusetts’ success or failure could have a significant impact on the future of health care reform across the United States.

¹⁷³ Jonathan Cohn, “Mandate Overboard” *The New Republic* (7 December 2007), online: The New Republic Online <<http://tnr.com/politics/story.html?id=b5be7883-461b-453b-99b5-d1df748d242d>>. Cohn argues that Senator Obama’s lack of an individual mandate will lead to higher costs through the adverse selection death spiral.

¹⁷⁴ See Dembner, “Healthcare Cost Increases Dominate”, *supra* note 28, quoting Nancy Turnbull.

APPENDIX A: 2008 AFFORDABILITY SCHEDULE FOR INDIVIDUAL MANDATE
From the Commonwealth Health Insurance Connector
 (<http://www.mahealthconnector.org/>)

INDIVIDUALS

Annual Adjusted Gross Income Range		Monthly Premium	Percentage of Income		
Starting Point	End Point		Middle	Bottom	Top
\$0	\$15,315 (150% FPL)	\$0			
\$15,316	\$20,420 (200% FPL)	\$35	2.4%	2.7%	2.1%
\$20,421	\$25,525 (250% FPL)	\$70	3.7%	4.1%	3.3%
\$25,526	\$30,630 (300% FPL)	\$105	4.5%	4.9%	4.1%
\$30,631	\$35,000 (341% FPL)	\$150	5.5%	5.9%	5.1%
\$35,001	\$40,000 (391% FPL)	\$200	6.4%	6.9%	6.0%
\$40,001	\$50,000 (489% FPL)	\$300	8.0%	9.0%	7.2%
\$50,001					

MARRIED COUPLES WITHOUT DEPENDENTS

Annual Adjusted Gross Income Range		Monthly Premium	Percentage of Income		
Starting Point	End Point		Middle	Bottom	Top
\$0	\$20,535 (150% FPL)	\$0			
\$20,536	\$27,380 (200% FPL)	\$70	3.5%	4.1%	3.1%
\$27,381	\$34,225 (250% FPL)	\$140	5.5%	6.1%	4.9%
\$34,226	\$41,070 (300% FPL)	\$210	6.7%	7.4%	6.1%
\$41,071	\$50,000 (365% FPL)	\$270	7.1%	7.9%	6.5%
\$50,001	\$60,000 (438% FPL)	\$360	7.9%	8.6%	7.2%
\$60,001	\$80,000 (584% FPL)	\$500	8.6%	10.0%	7.5%
\$80,001					

FAMILIES

Annual Adjusted Gross Income Range		Monthly Premium	Percentage of Income		
Starting Point	End Point		Middle	Bottom	Top
\$0	\$25,755 (150% FPL)	\$0			
\$25,756	\$34,340 (200% FPL)	\$70	2.8%	3.3%	2.4%
\$34,341	\$42,925 (250% FPL)	\$140	4.3%	4.9%	3.9%
\$42,926	\$51,510 (300% FPL)	\$210	5.3%	5.9%	4.9%
\$51,511	\$70,000 (407% FPL)	\$320	6.3%	7.5%	5.5%
\$70,001	\$90,000 (524% FPL)	\$500	7.5%	8.6%	6.7%
\$90,001	\$110,000 (640% FPL)	\$720	8.6%	9.6%	7.9%
\$110,001					

PRESERVING SOCIAL CITIZENSHIP IN HEALTH CARE MARKETS: THERE MAY BE TROUBLE AHEAD

*Christopher Newdick**

What is social citizenship? How is it relevant to the provision of health care? Discussion of rights tends to focus on individuals, but we need greater emphasis on the position of individuals within a community. This is especially important in connection with access to care in publicly funded health care systems.

T.H. Marshall provides a model within which claims may be weighed and assessed without losing sight of their effect on other people. Thus, civil citizenship generates rights that may be more readily enforced as absolutes. By contrast, social citizenship fosters community and equality between people; the rights it creates cannot be considered without regard to their impact on others.

Social citizenship deserves to be identified more carefully, particularly in respect of health care. Social citizenship is crucial to our conception of fairness and is central to the aims of public health care systems. Unless we do so, individualistic conceptions of rights may assist the strong and articulate at the expense of those less able to look after themselves.

However, three recent decisions of the European Court of Justice, the Supreme Court of Canada, and the House of Lords in England may undermine this objective. I recommend that social citizenship should be given more attention so that rights can be assessed within a community perspective.

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INTRODUCTION

In a short but “magisterial” book,¹ which, it is said, cannot be praised too often or too highly,² T.H. Marshall describes a conception of the evolution of “citizenship.”³ Marshall traces the process over three phases. During the eighteenth century, citizenship developed to protect *civil* rights (for example, rights to freedom of speech, religion, and association—the “negative” freedoms) from unwarranted interference by the state. In the nineteenth, it generated *political* rights to vote and to participate in the process of government. Finally, in the twentieth century, it gave rise to *social* rights to minimum levels of subsistence, health, social welfare, and pensions (that is, the “positive” rights of access to the largesse of the state and the redistributive policies that this entails).⁴ As Marshall said, social citizenship creates a sense of solidarity and mutual dependency in society and

a general enrichment of the concrete substance of civilised life, a general reduction of risk and insecurity, an equalisation between the more and less fortunate at all levels—between the healthy and the sick, the employed and the unemployed, the old and the active, the bachelor and the father of a large family. Equalisation is not so much between classes as between individuals within a population which is now treated for this purpose as though it were one class.⁵

Isaiah Berlin echoes these sentiments when he compares the potential for conflict between liberty and equality. As he puts it, the Western conscience is troubled if the freedom of a majority can be acquired by the exploitation of the minority. “To avoid glaring inequality or widespread misery I am ready to sacrifice some or all of my freedom ... it is a freedom that I am giving up for the sake of justice or equality or the love of my fellow men.”⁶ Perhaps these views inspired the “communitarian” ethic that balances claims to individual rights with the interconnectedness of people and a concern for the principles of altruism and reciprocity.⁷

At one level these are uplifting and energizing sentiments that many share. At another they present a practical challenge that Marshall largely avoided. Exactly how, and how much, should social citizens be expected to invest in the welfare of others? What is social citizenship and what *duties* does it impose? These are not merely abstract questions amenable to no firm response. They go to the root of social welfare policy-making. The following assesses their impact on the way we regulate access to health care. Clearly a “communitarian” conception of rights presupposes a large measure of central supervision in pursuit of public interests. Yet modern health care policy often places confidence in market forces to drive efficiency and value for money, in which individual rights are given special emphasis.⁸ How should this “New Governance” approach to social welfare be influenced by the more traditional, public-centered view of rights?⁹ The following considers this question in the context of health care rights. I examine the nature of social citizenship and the positive rights to which it gives rise. I also

¹ Amanda Root, *Market Citizenship: Experiments in Democracy and Globalization* (London: Sage, 2007) at 23.

² See the comment by Ralf Dahrendorf, *Law and Order* (London: Stevens, 1985) at 85, cited in K.D. Ewing, “Social Rights in Constitutional Law” [1999] P.L. 104 at 113.

³ T.H. Marshall & Tom Bottomore, *Citizenship and Social Class* (London: Pluto Classic, 1992) at 33. Marshall’s work was first published in 1950.

⁴ See Charles Reich, “The New Property” (1964) 73 Yale L.J. 733; Andre Van der Walt, “Protecting Social Participation Rights within the Property Paradigm” in Elizabeth Cooke, ed., *Modern Studies in Property Law*, vol. 2 (Oxford: Hart, 2003) 27.

⁵ Marshall & Bottomore, *supra* note 3 at 33.

⁶ Isaiah Berlin, *Four Essays on Liberty* (London: Oxford University Press, 1975) at 125.

⁷ See e.g. Michael J. Sandel, *Liberalism and the Limits of Justice* (Cambridge, U.K.: Cambridge University Press, 1998).

⁸ See generally Daniel Callahan & Angela Wasunna, *Medicine and the Market: Equity v. Choice* (Baltimore: Johns Hopkins University Press, 2006).

⁹ “New Governance” describes a policy in which government relaxes its centralizing control over public policy, and encourages consumer-led, market forces to influence decision-making at local level: see text accompanying notes 34-36 below.

consider whether, in the twenty-first century, market-based approaches to public welfare management will destabilize our commitment to social citizenship by their emphasis on individualism and economic forces. The discussion will tend to focus on the National Health Service (NHS), but I hope it will also be relevant elsewhere. I consider: (I) what social rights are; (II) how to enforce social rights; (III) “New Governance” and health care “commodification” in the NHS; and (IV) health care rights and the “market citizen.”

I

WHAT ARE SOCIAL RIGHTS?

Western liberal political thought emphasizes the civil and political rights of individualism and a zone of personal autonomy upon which not even the best interests of others may intrude. “If someone has a right to something, then it is wrong for the government to deny it to him even though it would be in the general interest to do so.... [This is] the distinctive concept of an individual right against the State which is the heart ... of constitutional theory in the United States.”¹⁰ This quotation emphasizes the freedom from interference inherent in Marshall’s concept of *civil* citizenship, but to what extent should the relationships between individuals also involve elements of reciprocity, interdependence, and social solidarity? Especially with respect to health care resource allocation, how does it help us understand how priorities should be set between competing demands for finite resources? Put another way, how should individualistic, *negative*, civil rights to liberty co-exist with *positive*, social rights that emphasize equality between citizens? Constitutional theory offers no immediate answer to this question. Indeed, one side of the rights equation, it seems, has matured and developed without proper attention being given to the other. As Frank Michelman has said, commenting on Rawls’ *A Theory of Justice*,

the mainstream of our legal tradition has largely bypassed the outcome-appraising sort of distributional concern. Lawyers and jurists, like economists and political scientists, seem to have instinctively placed distributive-share questions beyond the province of their specialized analysis.... They work under the paradigm of legal order which is noticeably lacking in norms, principles and categories of analysis directly applicable to the evaluation of outcomes.¹¹

To some extent, this lacuna was addressed by the “communitarians” in the 1980s who observed that “[t]he classical vision of the self-regulating market as a universe of self-sufficient monads was a formalist fantasy divorced from social reality as most people experienced it. For those who lacked wealth and power, the private rights regime implements a frightening dependence on the arbitrary wills of those who had them.”¹² As Sir John Laws (a member of the English Court of Appeal) has said, to define autonomy in terms of rights alone is a serious mistake. Such a definition denies to society its shared morality:

If it becomes the systematic feature of a prevailing social philosophy, it would tend to give rise to a community of selfish individuals, and therefore to no community. A society whose values are defined by

¹⁰ Ronald Dworkin, *Taking Rights Seriously* (London: Duckworth, 1977) at 269.

¹¹ “In Pursuit of Constitutional Welfare Rights: One View of Rawls’ Theory of Justice” (1973) 121 U. Pa. L. Rev. 962 at 963.

¹² William H. Simons, “Rights and Redistribution in the Welfare System” (1986) 38 Stan. L. Rev. 1433 at 1435. See also the “consumer-welfare” approach to contract law in the 1970s:

[A] system in which everybody is invited to do his own thing, at whatever cost to his neighbour, must work ultimately to the benefit of the rich and powerful.... As we look back on the nineteenth century theories, we are struck most of all, I think, by the narrow scope of the social duty which they implicitly assumed. No man is his brother’s keeper; the race is to the swift; let the devil take the hindmost. For good or ill, we have changed all that.... [This reflects] the transition from nineteenth century individualism to the welfare state and beyond (Grant Gilmore, *The Death of Contract* (Columbus: Ohio University Press, 1974) at 95-96).

reference to individual rights is by that very fact already impoverished. Its culture says nothing of individual duty ... and therefore nothing of community.¹³

A wholly “rights-based” approach makes it difficult to visualize a sense of community or collective commitment to health care. We should recognize then that while civil and political rights emphasize rights against others, they do not explain why or how we may also be dependent on others, or that our rights may sometimes be subordinate to theirs. Our sense of identity with others may arise from a common culture, religion, language, history, war, patriotism, education, and so on, all of which can exercise a cohesive influence in ways that generate a social dimension to our lives. Whatever its origin, to emphasize autonomy without also considering the reciprocity created by social rights misses a crucial part of our existence.

In his influential study, Gøsta Esping-Andersen describes the logic of social rights by arguing that wage earners are “commodified” in competitive markets by being valued largely by reference to their economic contribution to a market, compelled to compete against one another, and prey to decisions and forces beyond their control.¹⁴ By contrast, “[i]f social rights are given the legal and practical status of property rights, if they are inviolable, and if they are granted on the basis of citizenship rather than performance, they will entail a de-commodification of the status of individuals *vis-à-vis* the market.”¹⁵ This is the purpose of social welfare: to insulate citizens from the adversities of the market.¹⁶ Of course, the nature and extent of national commitment to such an enterprise varies according to political and social preference. Unlike the position with respect to *civil* rights, which Western democracies broadly agree extend “negative” freedoms against the state, the nature of positive *social* rights is inherently political and cultural. Significant differences exist within Europe, and between Europe and North America, as to the nature and extent of their recognition of social rights. Esping-Andersen uses a “de-commodification” scale to distinguish three broad categories of systems: (a) Australia, Canada, the U.S., and the U.K.; (b) France, Germany, and Switzerland; and (c) Austria, Denmark, Holland, Norway, and Sweden. The more limited welfare coverage in Australia, North America, and the U.K. promises modest assistance as a back-stop against destitution. At the other end of the scale, Austria, Denmark, Holland, and the Nordic countries seek to equalize the market forces that expose individuals to insecurity with social rights that guarantee equal levels of welfare.¹⁷ The point is that, unlike arguments about freedom of speech and democracy, which may be described as fundamental freedoms, responses to access to positive rights of social welfare vary because they are inherently national, cultural, and historical.¹⁸

Conceding, therefore, that the debate about *social* rights is necessarily more complicated than that concerning civil rights, but assuming that we agree in principle that some such rights should exist, our purpose here is better served by considering how law should recognize and

¹³ Sir John Laws, “The Constitution: Morals and Rights” [1996] P.L. 622 at 624.

¹⁴ *The Three Worlds of Welfare Capitalism* (Cambridge, U.K.: Polity Press, 1990). For the logical end-point of acquisitive individualism, see Thomas Hobbes, *Leviathan* (Harmondsworth: Penguin Books, 1974), including C.B. MacPherson’s introduction in which he says that Hobbes “built his whole system of deductions from a model of man and a model of society which were ... models of bourgeois man and capitalist society” (at 52).

¹⁵ Esping-Andersen, *ibid.* at 21.

¹⁶ As Marshall explains,

civil rights were indispensable to a competitive market economy. They ... made it possible to deny [the citizen] social protection on the ground that he was equipped with the means to protect himself.... But, if you use these arguments to explain to a pauper that his property rights are the same as those of a millionaire, he will probably accuse you of quibbling.... But these blatant inequalities are not due to defects in civil rights, but to lack of social rights (Marshall & Bottomore, *supra* note 3 at 20-21).

¹⁷ See Esping-Andersen, *supra* note 14 at 52.

¹⁸ See generally Steinar Stjerno, *Solidarity in Europe: The History of an Idea* (New York: Cambridge University Press, 2004); Callahan & Wasunna, *supra* note 8. See also Alexander Somek, “Solidarity Decomposed: Being and Time in European Citizenship” [2007] Eur. L. Rev. 787.

respond to “de-commodification” rights, rather than describing in detail what they should contain. The example of health care provides a useful vehicle in which to explore the interconnected and reciprocal nature of social rights.

II ENFORCING SOCIAL RIGHTS

Although, as Marshall observes, social citizenship constitutes the core idea of the welfare state, the concept needs to be expanded and explained. For example, he states that citizenship carries with it “corresponding duties,” but as to specifics, only that “[t]hese do not require a man to sacrifice his individual liberty or to submit without question to every demand made by government. But they do require that his acts should be inspired by a lively sense of responsibility towards the welfare of the community.”¹⁹ What does this proposition entail? To make sense of the social citizenship that contributes to a sense of community and mutuality, rights theory has to distinguish between the different ways in which social rights may be created and enforced.

We should start by differentiating a number of dimensions of rights, in particular the distinction between public or private, and positive or negative rights. First, the “public-private” dimension identifies the source of the right. *Private* rights, for example in the law of contract and tort, arise between individuals and are generally enforceable between the parties themselves. By contrast, *public* rights are created within a legislative framework and are enforceable against public authorities. Within Esping-Andersen’s model, the nature and extent of public rights created by social welfare policies varies with the will of the legislature. Unlike private bodies, the freedom of welfare agencies to modify the quality of service, or benefit, they provide, or the price at which it is made available, is restricted by statute. This is what is meant by “public” rights: rights and duties conferred on a public authority and enforceable by judicial review within a framework constrained by the legislature.²⁰

Second, the “positive/negative” dimension of rights refers to the purpose of the right conferred. Marshall’s *civil* rights may be characterized as *negative* rights that intend to insulate individuals from unwarranted state interference. Thus, the *European Convention on Human Rights*²¹ and the *Canadian Charter of Rights and Freedoms*²² are largely (but not exclusively) concerned with restricting the state’s authority to limit the negative rights of autonomy and freedoms of speech, religion, and assembly. To this extent, they give rise to “*negative/public*” rights (including the need for proper investment in the apparatus of the state, for example an impartial legislature, judiciary, and police force). By contrast, to the extent that social rights are created by the state, the entitlements to which they give rise should be considered as “*positive/public*” rights that imply the existence of state largesse and a system of rules for its distribution to those who qualify for support.²³ These distinctions are imprecise and disputed,²⁴ but they are crucial if we are to understand the nature of social citizenship.

We require a further “substantive-procedural” dimension. Civil rights may be enforced *substantively* by the courts. Courts are competent to enforce these negative/public rights

¹⁹ Marshall & Bottomore, *supra* note 3 at 41.

²⁰ Of course, public authorities can also enter *private* agreements, for example when they enter contracts of employment or contracts for the sale of goods.

²¹ *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.

²² Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [*Canadian Charter*].

²³ Private contracts routinely contain private/positive rights to damages in case of non-performance of the contractual terms. Our concern with social welfare emphasises the *public* side of positive rights.

²⁴ See *e.g.* Berlin, *supra* note 6; Raymond Plant, *Modern Political Thought*, (Oxford: Basil Blackwells, 1991) c. 7.

because they represent fundamental values that liberal societies endorse. Of course, these rights may also give rise to very difficult issues for the courts, concerning, for example, the individual's right to determine the time and manner of his or her death, abortion and the rights of unborn children, and the reproductive rights of handicapped people. Importantly, however, the substantive enforcement of these rights does not usually involve awkward questions of resource allocation, because they are not dependent on equal uptake throughout the community.²⁵ They protect equality of *access*,²⁶ but not necessarily equality of outcome. For example, it is perfectly plausible for the right to freedom of association to enable successful entrepreneurs to generate more wealth for themselves than poorer members of the community, and for the press to make greater use of the right to freedom of speech than the man on the Clapham omnibus. By contrast, *procedural* rights do not guarantee access to the benefit claimed. Instead, they offer the right to a procedural framework within which the decision to grant or to restrict it may be scrutinized and reviewed. Claims to positive/public rights are often amenable to a procedural response,²⁷ because the nature of the protection they offer is more heavily dependent on the principle of equality of *outcome* (that is, like cases should receive like benefit). Courts are not well equipped to develop consistent responses across the spectrum of applicants for social welfare. Litigation, after all, is often *ad hoc* and subject to the accident of personal and financial circumstance, and may not represent public interests. Specialist agencies, appointed by virtue of their expertise, are better placed to weigh and balance the sometimes competing demands that may arise. To this extent, therefore, the right should be procedural, because the court may be inclined to defer to the judgment of the expert body appointed to the task.

This is the *procedural* framework in which positive/public health care rights have been enforced in the U.K. The position is illuminated by *R. v. North West Lancashire Health Authority ex parte A., D., and G.*,²⁸ in which applicants for sex reassignment surgery had their request for treatment refused by their health authority without the merits of their application being properly considered. Their application for judicial review succeeded, and the Court of Appeal remitted the case back to the Health Authority for reconsideration. As the Court of Appeal said, health authorities are required to make difficult decisions about NHS resource allocation. Some treatments, such as life-saving treatment for cancer or for kidney failure, may command a higher priority than sex reassignment surgery. However, although the Health Authority was not duty-bound to provide the surgery, it was obliged to have a fair and consistent system for considering applications of this nature and for considering whether they demonstrated exceptional individual need. The Health Authority had failed to respond to these cases within such a framework and was required to reconsider them in the light of this guidance (after which, as often occurs, the Health Authority resolved not to resist the case further and provided the necessary funding).

Of course, the intensity of this procedural review is crucial. Too little scrutiny and the process becomes a sham with the result that *individual* interests are given insufficient recognition. For example, in *R. v. Central Birmingham Health Authority ex parte Collier* (decided in 1988), a health authority was unable to provide life-saving treatment for a young

²⁵ Although exceptionally they may do so if negative rights impose positive duties on others. For example, in *Winnipeg Child and Family Services (Northwest Area) v. G. (D.F.)*, 1997 SCC 193, [1997] 3 S.C.R. 925, 152 D.L.R. (4th) 193, a majority of the Court refused to order the detention of a pregnant woman who was addicted to glue-sniffing in order to protect her unborn child, notwithstanding that two of her previous children had suffered permanent brain-damage as a result and were in the care of public authorities. English law takes a similar view that unborn children have no rights against the mother: see *Re MB* (1997), 38 B.M.L.R. 175 (C.A.).

²⁶ *Eldridge v. British Columbia (A.G.)*, [1997] 3 S.C.R. 624, 151 D.L.R. (4th) 577 considers the equal *access* to hospital care of those needing sign language services; this, too, has resource implications.

²⁷ Although *substantive* public rights also may be created by Parliament (for example, to a pension or an unemployment benefit), access to health care can seldom be quantified in such an exact form.

²⁸ (2000), 1 W.L.R. 977 (C.A.).

boy with a hole in the heart. It explained that the failure to treat was due to a shortage of pediatric nurses and beds. The court refused the application for judicial review on the ground that there was no evidence of irrationality and that it was in no position to organize hospital waiting lists.²⁹ Given the gravity of the case, this excess of judicial deference is unsatisfactory. The court did not ask why the boy had not been transferred to an alternative hospital and, in the absence of an explanation, offered inadequate reassurance that the merits of the case were properly weighed and balanced against the needs of others.

On the other hand, too much intensity and public authorities may be so intimidated by judicial review that they concede every challenge and, therefore, tend to overlook *community* interests. In *Otley v. Barking and Dagenham Primary Care Trust*, an applicant with terminal cancer was refused access to a drug for which evidence of general efficacy was equivocal and the cost of the treatment would have been very expensive. Granting judicial review, the court said that closer attention should have been given to the possibility that the applicant had “exceptional” clinical merits, which might have led to an exceptionally positive response to the treatment.³⁰ Clearly, if this decision suggests a trend toward over-intensive judicial review, it could put a premium on litigation and prejudice those whose interests are not brought to the court’s attention.

Bear in mind that the procedural response is not a search for the “right” answer.³¹ Rather, it is to confirm that the public authority has considered a sensible range of factors and given the various components of the decision proper consideration. It may do so, for example, by considering the effectiveness of the proposed treatment (separately and by comparison to others), its absolute cost (and its cost relative to other effective treatments), whether the treatment has priority in the health community as a whole, and whether the patient has exceptional individual need for the treatment.³² In this way, the process should balance the needs of the individual with those of the community. These distinctions are important as a way of both explaining what positive/social/procedural rights are and illuminating the differences between negative/civil/substantive rights about which understanding is so much more developed.³³

III

“NEW GOVERNANCE” AND HEALTH CARE “COMMODIFICATION” IN THE NHS

Both Marshall and Esping-Andersen wrote at a time when, at least in the U.K., public authorities were largely responsible for the provision of NHS (and other public) services. The social consensus that grew from the experience of the Second World War dramatically influenced social policy. The U.K. committed itself to combating the “five giants on the road to

²⁹ (C.A. (Civ. Div.)) (Lexis), discussed in Christopher Newdick, *Who Should We Treat?: Rights, Rationing and Resources*, 2d ed. (Oxford: Oxford University Press, 2005) at 97-100 [Newdick, *Who Should We Treat?*].

³⁰ [2007] EWHC Admin 1927, L.S. Law Med. 593.

³¹ Note, however, that interest is being expressed in enforcing *substantive*/social rights. See Geraldine Van Bueren, “Including the Excluded: The Case for an Economic, Social and Cultural Human Rights Act” [2002] P.L. 456; Navish Jheelan, “The Enforceability of Socio-Economic Rights” [2007] Eur. H.R.L. Rev. 146; L. Forman, “Justice and Justiciability: Advancing Solidarity and Justice through South Africans’ Right to Health Jurisprudence” J. Med. & L. [forthcoming in 2008]. The danger, however, is that the opportunity cost to those not before the courts may be overlooked.

³² For the evolution of law in the U.K. in this area, see Newdick, *Who Should We Treat?*, *supra* note 29 c. 5. For current practice, see Christopher Newdick, “Accountability for Rationing: Theory into Practice” (2005) 33 J. L. Med. & Ethics 660.

³³ For more on these distinctions, see Christopher Newdick, “The Positive Side of Health Care Rights” in Sheila A.M. McLean, ed., *First Do No Harm: Law, Ethics and Healthcare* (Aldershot: Ashgate, 2006) at 573; and C. Newdick, “Solidarity, Rights and Social Welfare in the NHS: Resisting the Tide of Bioethics?” J. Med. & L. [forthcoming in 2008].

reconstruction” of want, ignorance, disease, squalor, and idleness,³⁴ with the state driving the process. Within this top-down model, the state was dominant in setting policy and, through its own domestic taxation policy, provided social welfare at its own discretion. In addition, until the end of the 1970s, state-funded support was also made available to failing industries, at least partly to maintain workers in full employment. This too may be understood as indirect, state-supported, social welfare. Thus, directly or otherwise, the state was central to maintaining levels of employment, education, and standards of health and housing. Both in politics and law, this centrality encouraged collective solutions to social policy, which could be developed and controlled by national governments within their own political and economic priorities.

Today, however, the position is different. Global pressures have forced national governments to reappraise their capacity to control their economies. Now these governments compete for inward investment from international investors who favour regimes with low levels of taxation. As a result, domestic trade barriers have been dismantled and local industries exposed to free international competition.³⁵ Consequently, despite the misgivings of national authorities, domestic control over social welfare has diminished:

national governments have lost most of their former capacity to influence growth and employment in their economies—most, that is, except for the supply-side options of further deregulation, privatization, and tax cuts, which are perfectly compatible with EU law.... [This is] in conflict with the political aspirations and commitments of countries which, in the post-war decades, had adopted a wide-range of market-correcting and redistributive policies, creating “social market economies” in which the effects of the capitalist mode of production were moderated...³⁶

Within this New Governance, trans-national, commercial forces have wrested power from nation states. Now, instead of control exercised by single public authorities subject to judicial review, diffuse, experimental, and largely pragmatic influences have been introduced by government with the intention of reducing public expenditure and enhancing efficiency. Dominant amongst them is the use of the pressures of the market-place as a lever to encourage less complacent, more active competition between service providers.³⁷ Clearly, in moral and political terms, the impact of these New Governance forces is not neutral.³⁸ How have they affected Marshall’s notion of social citizenship?

In the NHS in particular, market competition has been introduced to force quality up and to put downward pressure on prices.³⁹ Private providers now compete with public authorities to provide public services. For example, independent sector treatment centres have been introduced to the NHS in direct competition with NHS hospitals. At present, their work is largely in respect of acute, out-patient care such as the removal of cataracts, but over time they may be expected to offer a full-range of hospital services. Also, “foundation hospitals” have been established out of ordinary NHS hospitals to inject a greater sense of competition in

³⁴ Sir William Beveridge, *Social Insurance and Allied Services* (New York: Macmillan, 1942) at 6.

³⁵ See generally OECD, *Governance in Transition: Public Management Reforms in OECD Countries* (Paris: OECD, 1995); David M. Andrews, “Capital Mobility and State Autonomy” (1994) 38 *Int’l Stud. Q.* 193.

³⁶ Fritz W. Scharpf, “Legitimate Diversity: The New Challenge of European Integration” in Tanja Börzel & Rachel A. Cichowski, eds., *The State of the European Union*, vol. 6 (Oxford: Oxford University Press, 2003) at 92.

³⁷ Politicians refer to the process as “modernization.” See generally Gráinne de Búrca & Joanna Scott, eds., *Law and New Governance in the EU and US* (Oxford: Hart Publishing, 2006); Neil Walker & Gráinne de Búrca, “Reconceiving Law & New Governance” (2007) 13 *Colum. J. Eur. L.* 519. See also Charles F. Sabel & William H. Simon, “Destabilization Rights: How Public Law Litigation Succeeds” (2004) 117 *Harv. L. Rev.* 1016 (contending that these forces intend to increase uncertainty and enhance opportunities for parties at local level to agree on solutions to problems).

³⁸ See E. van Leeuwen, “Changing Moral Experiences in European Healthcare” *J. Med. & L.* [forthcoming in 2008].

³⁹ For an argument, however, that health care markets drive health care costs up, see Steffie Woolhandler & David U. Himmelstein, “Competition in a Publicly Funded Healthcare System” (2007) 335 *B.M.J.* 1126. See also Nigel Edwards, “Using Markets to Reform Health Care” (2005) 331 *B.M.J.* 1464; and, more cautiously, Nicholas Timmins, “Backpedalling from Blair’s Privatisation Agenda” (2007) 335 *B.M.J.* 794.

secondary care. On the basis of their previous good performance, foundation hospitals are awarded greater independence (including the right to borrow money) and may compete (for example, by expanding or absorbing other hospitals) more aggressively than other hospitals for patient throughput.⁴⁰

These market-based changes are not limited to hospital “providers.” Under the “Choice Agenda,” patients are encouraged to regard themselves as “consumers” of health care services. Patients should be offered at least four providers (including a private hospital) in which to receive treatment.⁴¹ Hospital managers will be concerned about the way in which their hospitals present themselves to the public. The advantage is that competition will encourage hospitals to aspire, for example, to better clinical outcomes, standards of cleanliness, shorter waiting times, more attractive facilities, and car-parking. On the other hand, there is a risk that hospitals that wish to foster the *appearance* of having the most modern facilities may be encouraged to purchase equipment as a shop window rather than out of necessity. The point has been made by a U.S. commentator who said that “because we have too many mammography machines, each is underutilized. This doubles the cost of each test. As a result, many women cannot afford screening. Thus, because we have too many mammography machines, we have too little breast cancer screening.”⁴² The consequences of this pressure to appeal to consumer preferences may lead to a distortion of public health priorities. As has been said in the U.S., the risk is that we will find hospitals “doing more and more for fewer and fewer people, at higher and higher cost, for less and less benefit.”⁴³ We should be aware of similar competitive pressures arising in the NHS. These pressures argue for a more unified system of responding to health needs in the community, rather than the diversification that competition brings.⁴⁴

Whatever the balance of the argument, government in the U.K. is committed to the market as a principal mechanism for improving NHS care. Yet social citizenship presupposes a significant public commitment to social welfare and a public consciousness of the need to unite to reduce the risks of individual adversity. Will the New Governance undermine that sense of community and the concept of public rights? Concern is expressed at the commodification of health care in which commitments to human values will be diluted by the market in which every transaction, and every patient, has a cost. Will social citizenship survive the health care market? Or will it create a “market citizen” more interested in individual, rather than community, interests? And will it also reduce the range of cases amenable to judicial review and thereby undermine the role of the courts in bringing a public perspective to dispute resolution? Whereas public rights ought to foster notions of equality and trust in public institutions, the process of commodification tends to enhance the rights of the individual *against* public institutions. The emphasis is toward liberty rather than equality, and toward substantive rather than procedural rights. The point is made by Pellegrino:

⁴⁰ See generally Newdick, *Who Should We Treat?*, *supra* note 29 at 81-86.

⁴¹ See Julian Le Grand, *The Other Invisible Hand: Delivering Public Services Through Choice and Competition* (Princeton: Princeton University Press, 2007). However, choice often offers little variety and may confuse consumers: see Barry Schwartz, *The Paradox of Choice: Why More is Less* (New York: Harper Perennial, 2004). Our concern is health care, but the tension between consumer and “solidarity”-based approaches is likely to be the same whenever market forces are used in welfare services, for example in education.

⁴² Gordon D. Schiff *et al.*, “A Better Quality Alternative: Single-Payer National Health System Reform” (1994) 27 J.A.M.A. 803 at 806.

⁴³ G.J. Annas *et al.*, eds., *American Health Law* (Boston: Little Brown, 1990) at 293.

⁴⁴ See Christopher Ham, “Clinically Integrated Systems: The Next Step in English Health Reform?” (Nuffield Trust Briefing Paper, 2007), online: The Nuffield Trust <http://www.nuffieldtrust.org.uk/members/download.asp?f=/ecomm/files/Clinically_Integrated_Systems.pdf&a=skip>. The English NHS has recently introduced a system of fixed payments for hospital procedures based on *Health Related Groups* (comparable to Diagnostic Related Groups) that may deal with this risk, although the new system may also encourage hospitals to generate income from treatments that could otherwise have been dealt with less expensively in the community.

[T]he commodification of health and medical care means that the transaction between physicians and patients has become a commercial relationship. That relationship, therefore, will be primarily or solely regulated by the rules of commerce and the laws of torts and contracts rather than the precepts of professional ethics. Profit-making and pursuit of self-interest will be legitimated. Inequalities in distribution of services and treatments are not the concerns of free markets.⁴⁵

“Commodification” emphasizes the negative rights of freedom from coercion, but it says nothing about communitarian ethics and the common good.⁴⁶ It is not just that professional ethics are diminished in importance. Notions of trust and the public interest are also likely to suffer, together with our sense of unity against adversity. Clearly, any such trend is largely alien to the notion of social citizenship discussed by Marshall.

IV

HEALTH CARE RIGHTS AND THE MARKET CITIZEN

Can the model of the *social* citizen withstand the prominence given to individualism, especially within the New Governance framework of public sector management? Or is it more accurate to regard the model as a temporary and insubstantial creature, likely to become extinct outside the favourable, post-war habitat of its own time? The social welfare system envisaged by Marshall imposes implicit duties on citizens to contribute to a pool of welfare “insurance.” If we assume, consistent with experience in the NHS, that demand for welfare is likely to exceed the supply of resources available to fund it, sensitive and controversial choices will be required as to priorities. This is why judicial review has developed a system which recognizes public/positive/procedural rights within which claims for priority may be assessed against a range of other factors.

But the concept of the *market* citizen is impatient with such an approach, which seems to distance consumers from a more active role in their own care.⁴⁷ Instead, this concept encourages patients to assert themselves against the NHS by means of “choice” and the bodies within the NHS itself to compete with each other to promote their own interests. Economic theory suggests that such market-based relationships will tend to improve quality and reduce cost. But will they also dilute the sense of *duty* to others, which is implicit in social citizenship, by emphasizing the rights of the *individual*? This tendency away from community interests and toward the sanctity of market transactions is illuminated in a series of cases from the European Court Justice (ECJ), the Supreme Court of Canada (SCC), and the U.K. House of Lords, which illustrates the tensions involved between pursuing “public” and “private” objectives in health care policy. Let us consider each in turn.

We commence with the case of *R. (Watts) v. Bedfordshire Primary Care Trust and Secretary of State*,⁴⁸ in which a patient aged seventy-two required bilateral hip replacements. Consistent with contemporary NHS policy on maximum waiting times, her Primary Care Trust (PCT) reassured her that her operation would be performed within twelve months.⁴⁹ Mrs.

⁴⁵ Edmund D. Pellegrino, “The Commodification of Medical and Health Care: The Moral Consequences of a Paradigm Shift from a Professional to a Market Ethic” (1999) 24 J. Med. & Phil. 243 at 252.

⁴⁶ See *ibid.* at 258.

⁴⁷ In the E.U., until the late 1990s, the concept of the “market citizen” referred more formally to those whose *economic* contribution to a “host” Member State entitled them to receive social welfare there. Since *Martinez Sala v. Freistaat Bayern*, C-85/96, [1998] E.C.R. I-2691 and *Grzelczyk v. Centre public d’aide sociale d’Ottignies-Louvain-la-Neuve*, C-184/99, [2001] E.C.R. I-6193, however, these restrictions have been relaxed so that some non-economically active citizens may also obtain social welfare in host Member States: see generally Catherine Barnard, *The Substantive Law of the EU: The Four Freedoms* (Oxford: Oxford University Press, 2004) at 405-20. The following discussion, therefore, takes a broader, less legalistic, view of the concept.

⁴⁸ C-372/04, [2006] E.C.R. I-4325, 3 W.L.R. 213 [*Watts*].

⁴⁹ The waiting time target is now eighteen weeks. Primary Care Trusts (PCTs) are statutory NHS bodies responsible for purchasing primary and secondary care for the benefit of the population they serve: see the *National Health Service Act 2006* (U.K.), 2006, c. 41 [*NHS Act*]. Their statutory duties include the duty not to exceed their

Watts declined to wait for such a period and arranged to have treatment in France. Shortly before leaving, she was offered treatment at home within four months. She declined the offer, had her hip replacements in France, returned to the U.K., and presented the PCT with a bill for £4,700. The PCT declined to pay, and the case was referred to the ECJ by the English Court of Appeal. The arguments in the case turned on one of the fundamental principles of E.U. law, namely that of freedom of movement of services (that is, that the market for services should be freely available without trade restrictions throughout the Member States).⁵⁰

The U.K. and Bedfordshire PCT argued that this principle should not apply in the case of publicly funded health care. Legal authority for the argument was based on European case law establishing that the right of free movement of services applied to *private enterprises* that wished to obtain access to markets elsewhere in the E.U. Thus, accountants, banks, and insurance companies are entitled to promote themselves throughout the E.U. on the same basis as domestic companies. *Public* services, on the other hand, were said to be different. For example, the ECJ had previously said cross-border education is not available because it is not a “service,” since no commercial remuneration is provided; instead, it promotes activities in the social and cultural field.⁵¹ This argument had also been approved by Advocate-General Ruiz-Jarabo Colomer in *Geraets-Smits v. Stichting Ziekenfonds Vgz, Peerbooms v. Stichting Cz Groep Zorgverzekeringen*, who advised that national health insurance systems should be regarded in the same way, because “sickness funds must be able to expect that, barring rare exceptions subject to their consent, any health care which insured persons require will actually be provided by the practitioners and institutions contracted.” Otherwise, it would be difficult to manage the flows of patients in and out of local health authorities (especially those close to national borders).⁵² If the activity anticipated by a public provider was upset by unpredictable patient flows, so that some hospitals had unexpected waiting lists, and others had empty beds and closed wards, the optimum efficiency of the service would be undermined to the detriment of the public generally.

Similar concerns were expressed by the English Court of Appeal when it referred the case to the ECJ for resolution. Given that demand for health care exceeds supply, a reasonable process of priority setting is required that seeks to respond to patient need in a fair and logical manner. This objective aims to promote a sense of equality between community interests. The Court asked the ECJ to consider whether, particularly in the state-funded NHS, the principle of freedom of movement in the E.U. should in any way be tempered by the fact that it “would permit patients with less urgent medical needs to gain priority over patients with more urgent medical needs.”⁵³ The ECJ ruled in Mrs. Watts’ favour.⁵⁴ The response of Advocate-General Geelhoed to the question put by the Court of Appeal precisely summarizes the individualist, “market citizenship” view of patients’ rights in the ECJ. He said simply that

[w]here conditions granting authorisation to receive hospital care in another member state are designed to guarantee the financial stability of the national health system, considerations of a purely budgetary or economic character cannot justify a refusal to grant such authorisation.⁵⁵

income (s. 229). When treatment is delayed or denied, action in judicial review is normally taken against the responsible PCT. See generally Newdick, *Who Should We Treat?*, *supra* note 29 c. 4.

⁵⁰ EC, *Treaty Establishing the European Community*, [2002] O.J. C 325/33, art. 49.

⁵¹ *Belgium v. Humbel and Edel*, C-263/86, [1988] E.C.R. 5365.

⁵² C-157/99, [2001] E.C.R. I-5473 at para. 72 [*Geraets-Smits/Peerbooms*]. This argument was rejected, however, by the ECJ: see note 55 below.

⁵³ *Watts*, *supra* note 48 at para. 42, Judgment.

⁵⁴ Following earlier cases on public health insurance systems in which the ECJ had approved cross-border access to health care. See *Decker v. Caisse de Maladie des Employés Privés*, C-120/95, [1998] E.C.R. I-1831; *Kohll v. Union des Caisses de Maladie*, C-158/96 [1998] E.C.R. I-1931 [*Kohll*]. See also Vassilis G. Hatzopoulos, “Killing National Health Insurance Systems but Healing Patients?: The European Market for Health Care Services after the Judgments in the ECJ in *Vanbraekel* and *Peerbooms*” (2002) 39 C.M.L. Rev. 683.

⁵⁵ *Watts*, *supra* note 48 at para. 92, Geelhoed Adv. G., Opinion.

The public interest in social cohesion, institutional stability and procedural fairness could not obstruct the private, economic right to obtain health care in another Member State. The ECJ endorsed this view and held that if “normal” treatment cannot be obtained within the “home” state without “undue delay,” as assessed according to the patient’s *individual* need, the patient is entitled under E.U. law to secure the treatment elsewhere. As a result, those who require “normal” treatment, but who do not command priority at home, may oblige the local purchaser to pay for their care on their return and, for accounting purposes, become its *priority*. Fair and reasonable *procedures* to promote equality of community interests are unlikely to withstand the substantive, *individual*, market right of access to goods and services in the E.U.⁵⁶ This right puts health authorities in an invidious position. They are duty-bound to promote a “comprehensive” health service in the interest of the community as a whole⁵⁷ and, within finite budgets, may have to prioritize some treatments over others. On the other hand, the ECJ in *Watts* tends to encourage patients who have not been given priority to seek treatment elsewhere in the E.U. This result has an inescapable logic. The system will continue to work within the constraints of finite resources. Neither the E.U. nor the ECJ carries a budget to support cross-border treatment. But, if Peter secures access to resources otherwise intended for Paula, then Paula’s treatment may have to be cancelled, delayed, or diluted as a result. What is striking, especially in the debate about access to health care, is for private, economic solutions to be implemented to the *exclusion* of considerations based on a commitment to social welfare. Despite its rhetoric of protecting public health care systems,⁵⁸ the ECJ refused to discuss the implications for others of introducing market-based rights to health care. Such is the strength of “market citizenship” in the E.U.

The SCC considered an analogous tension in *Chaoulli v. Quebec (A.G.)*.⁵⁹ The case concerned the balance of private and public interests in the availability of private health insurance. The province of Quebec, concerned to promote the equal access of its citizens to health care, made private health insurance unlawful. The broad policy for the restriction was that:

The time a doctor spends working in the private sector is time that cannot be spent in the public system. In the absence of a significant increase in the number of medical professionals in Canada (which would require significant investment of public spending) or a significant increase in the overall hours worked, the emergence of a flourishing duplicate or parallel private tier must mean less time overall will be spent by medical professionals in the public system treating public patients.⁶⁰

Assuming public health care providers were working at capacity, private health insurance would divert clinicians from their public obligations and encourage two-tier access to health care to the detriment of those without private insurance. Accordingly, the province legislated for a single tier of health care provision throughout Quebec with the intention of promoting equality of access.⁶¹ The applicant argued that fundamental rights were infringed by obliging patients to join long waiting lists, increasing health risks which, with private health insurance, many could choose to avoid.

⁵⁶ See Christopher Newdick, “Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity” (2006) 43 C.M.L. Rev. 1645.

⁵⁷ See *NHS Act*, *supra* note 49, s. 1.

⁵⁸ See *e.g. Watts*, *supra* note 48 at paras. 103-06, Judgment; *Garaets-Smits/Peerbooms*, *supra* note 52 at para. 53; *Kohill*, *supra* note 54 at para. 41.

⁵⁹ 2005 SCC 35, [2005] 1 S.C.R. 791, 254 D.L.R. (4th) 577 [*Chaoulli*]. See the excellent consideration of the implications of the case in Colleen M. Flood, Kent Roach & Lorne Sossin, eds., *Access to Care, Access to Justice: The Legal Debate Over Private Health Insurance in Canada* (Toronto: University of Toronto Press, 2005).

⁶⁰ C. Flood & S. Zavier, “Health Care Rights in Canada: The *Chaoulli* Legacy” J. Med. & L. [forthcoming in 2008].

⁶¹ Precisely this question troubled the U.K.’s Department of Health during the 1970s, but never resulted in litigation. See Michael Ryan, “Hospital Pay Beds: A Study in Ideology and Constraint” (1975) 9 Soc. Pol’y & Admin. 164. See generally Charles Webster, *The National Health Service: A Political History*, 2d ed. (Oxford: Oxford University Press, 2002). The matter has recently been tackled in the NHS by requiring hospital doctors to fulfil their NHS duties before accepting additional private work.

Reversing the decisions of the trial judge and appeal court, the SCC held by a majority that the restriction infringed the right to life, and to personal security, inviolability, and freedom under Quebec's *Charter of Human Rights and Freedoms*,⁶² and was not justified by reasons of social policy. The policy was held to be a disproportionate infringement of the rights of the individual. No clear evidence was available to demonstrate the justification for an outright ban; other provinces of the country had less draconian responses to private insurance and prohibition was not thought necessary elsewhere amongst O.E.C.D. nations. In the absence of persuasive evidence of the need to protect the public interest in this way, individual choice and market forces should not be restricted, even if the consequence tends to increase inequality between those who can afford private insurance and those who cannot.

The opposite perspective was expressed by the minority, who understood the case to raise issues concerning social values, rather than constitutional rights.⁶³ For them, the matter remained within the reasonable discretion of the legislature, which was entitled to believe that the major beneficiaries of a relaxation of the policy would be restricted to a segment of the community with access to private insurance. The rights in contention were better viewed as social and economic rights within the legitimate jurisdiction of the legislature. In the absence of evidence that existing waiting time limits were unacceptable (given that they could never be eliminated completely), the minority considered that the restriction was neither arbitrary nor disproportionate, and cautioned that the "*Charter* should not become an instrument to be used by the wealthy to 'roll back' the benefits of a legislative scheme that helps poorer members of society."⁶⁴ Here too, therefore, despite the paucity of hard evidence to support the conclusion, or substantive comparative data from health care systems elsewhere, individual economic interests were given precedence over the more recondite demands of social solidarity.⁶⁵

Before considering the third case, let us pause to consider an argument that may be implicit both in the ECJ in *Watts* and in the majority of the SCC in *Chaouli*, namely that citizens should be free to "exit" from a failing system, both as an expression of their own right and as a lever to encourage improved performance. In truth, however, although this may be persuasive in respect of private providers of goods and services, the dynamics of "exit" from public providers may be very different. As Albert O. Hirschman says, we cannot exit from *public* services in the same way.⁶⁶ First, exit tends to diminish the pool of welfare resources available for the remainder, to impoverish the system and, as the process accelerates, increasingly to encourage those with sufficient means to abandon the system, thereby eroding the interests of those that remain. Exit, in the sense of absolving some from the duty to contribute to social welfare, could undermine support for the redistributive ethic on which social rights are dependent. Second, to the extent that we all have an interest in and a right to benefit from public welfare, exit from the system is neither wished for nor possible. Although exit may appear popular when we are young, strong, healthy, and fit (with only short-term, acute illness), our need for public assistance may be very different when we are old, frail, poorly, and disabled—especially if the possibility of "exit" is effectively foreclosed because private health insurance is unavailable to cover long-term, chronic illness. From both a personal and societal point of view, therefore, we should understand the context in which discussion of exit takes place.

⁶² R.S.Q. c. C-12, s. 1 [*Quebec Charter*]. A majority (of 4-3) found a breach of the *Quebec Charter*. However, there was an equal division of opinion (of 3-3) as to the position under the *Canadian Charter*, *supra* note 22, because Deschamps J. expressed no view on this question.

⁶³ *Chaouli*, *supra* note 59 at paras. 166, 276, *per* Binnie and LeBel JJ.

⁶⁴ *Ibid.* at para. 274. Though the minority was speaking here of the *Canadian Charter*, its reasoning applies to the *Quebec Charter* as well.

⁶⁵ For criticism of the case, see Flood & Zavier, *supra* note 60.

⁶⁶ See *Exit, Voice and Loyalty: Responses to Decline in Firms, Organizations, and States* (Cambridge, MA: Harvard University Press, 1970) at 98-105 (distinguishing between "exit" from organizations supplying "private" and "public" goods).

Our third case was decided in the U.K. House of Lords. It was not concerned with access to care. Instead, it considered the policy implications of New Governance for the remedies available to individuals under the *Human Rights Act 1998*.⁶⁷ Whereas, in the past, judicial review was the appropriate mechanism for testing whether public authorities had fulfilled their statutory obligations to the community, the issue is blurred when *private* bodies are engaged to do so on their behalf. This question is pressing in respect of health and social care in the U.K. How should the law respond as private bodies and charities become enmeshed in the structure of *public* service provision? Should service users (that is, patients and residents) have the same rights of redress as would otherwise be available against those providing public services? Or should private providers be entitled to insist that they are immune from public law review on the ground that they are commercial bodies and should be governed by private law and market forces? To what extent should a public policy to de-regulate service provision also hollow out the legal remedies available to patients and residents of nursing homes? This was the issue in *YL v. Birmingham City Council*.⁶⁸

The applicant was eighty-four years old and suffered from Alzheimer's disease. She was resident in a care home run by Southern Cross Healthcare Ltd. The company had a contract with Birmingham City Council, a public authority, to provide accommodation for residents placed with them by the Council. About 80 percent of the company's business was with public authorities. Dispute arose between the care home and the applicant's relatives, and culminated with the home terminating the applicant's contractual right to remain a resident in the home (within the terms of a contract between the Southern Cross and the Council). The question arose whether the decision of the private nursing home to terminate her right to remain fell within the *Human Rights Act*. The *Act* applies only to a "public authority", which is loosely defined as "any person certain of whose functions are functions of a public nature."⁶⁹ However, the *Act* continues that "[i]n relation to a particular act, a person is not a public authority by virtue only of subsection (3)(b) if the nature of the act is private."⁷⁰

A majority of their Lordships found that these facts provoked no *Human Rights Act* issue against the nursing home. Adopting a commercial analysis of the case, they said that Southern Cross was a private business providing services to a public authority purchaser at commercial rates. It received no public funding, was not a charity, had no special powers, and was free to accept or reject residents in its own lawful discretion. It had to compete in a commercial market with others. Although it was performing a function equally undertaken by public bodies, it was necessary to look at the reason why the body was doing so. Southern Cross was doing so for profit. This was fundamentally different from a public authority fulfilling statutory duties. From a *corporate* perspective, the majority speak with an inevitable logic.

By contrast, the minority sought to balance against the corporate, market-based concerns the broader public interests at work. They said that a number of factors should be weighed to determine whether the private body was subject to public law supervision within the *Human Rights Act*, for example whether the state has undertaken a statutory responsibility for seeing that a service is provided, the public interest in having that task undertaken at public expense, whether funding for the service is provided by public sources, and whether the authority

⁶⁷ *Human Rights Act 1998* (U.K.), 1998, c. 42 [*Human Rights Act*].

⁶⁸ (2007), 96 B.M.L.R. 1 [*YL*].

⁶⁹ *Supra* note 67, s. 6(3)(b).

⁷⁰ *Ibid.*, s. 6(5). As Lord Neuberger said in *YL*, *supra* note 68 at para. 130,

[s]ection 6 is, at least in some respects, not conspicuous for the clarity of its drafting [especially as to the] distinction between 'acts' and 'functions' in the section. In my view, both as a matter of ordinary language and on a fair reading of the section, there is a difference between 'functions', the word used in section 6(3)(b), and 'act[s]'.... The former has a more conceptual, and perhaps less specific, meaning than the latter.

includes coercive powers of restraint. Thus, in *YL*, Baroness Hale, dissenting, said: “This was a function performed for the appellant pursuant to statutory arrangements, at public expense and in the public interest. I have no doubt that Parliament intended that it be covered by s 6(3)(b)... The company is potentially liable to the appellant ... for any breaches of her convention rights.”⁷¹

I do not suggest that if the *Human Rights Act* had applied to *YL*, the applicant should have been entitled to remain in the nursing home. After all, the *Act* consistently requires the courts to have regard to the interests of others;⁷² there may be circumstances in which the removal of an individual or the closure of an entire home can be justified in the interests of (respectively) the other residents of the home or the viability of other nursing homes operated by the owner. The point is that the *Human Rights Act* requires the court to address the public dimension of the dispute by balancing the interests of others, rather than responding as if it were a matter arising only between private parties to a commercial contract.

What trends do these authoritative cases suggest for rights claims within the New Governance of public services located in market-based systems of reward and incentives? Arguably, they demonstrate that the new framework of rights has become less cohesive and more individualistic, less public and more economic. We have noted the post-War concern with personal insecurity and the need for collective insurance to protect against it. For the theorists of the public domain, such as William Henry Beveridge, John Maynard Keynes, and Richard Titmuss, social needs “take precedence over market wants; the long-term health of the social organism is to be prioritized over the satisfaction of short-term wants through the market mechanism.”⁷³ Yet this post-War commitment may be undermined by arguments for individualism and freedom from interference. In the U.S., for example, where a culture of individual responsibility for personal welfare is more entrenched, it has been said that

[i]t is as though, by some unspoken consensus, constitutional lawyers, unlike political and moral liberal theorists, have tacitly agreed that American constitutionalism somewhere along the line simply turned its back on the bedrock tenet of both classical and modern liberal theory.... That we should take individual rights seriously, in other words, does not imply that we should not take legislative duties seriously as well.⁷⁴

Should these concerns now trouble the New Governance environment developing elsewhere (especially within the E.U.)? If we continue to value Marshall’s post-War idea of social citizenship, we may need a clearer commitment to preserve it which recognizes the role of public/positive/procedural rights.

CONCLUSION

In the E.U., the contradiction between the *political* aspiration to preserve social welfare and the *economic*, market-oriented, fundamental freedoms has been described as a “constitutional asymmetry.”⁷⁵ We are all concerned with concepts of social solidarity and the

⁷¹ *YL*, *ibid.* at para. 73. See also Leslie Turano, “Charitable Trusts and the Public Service: The Public Accountability of Private Care Providers” (2007) 18 *King’s Law Journal* 427.

⁷² For example, the right to “family and private life” exists “except such as is in accordance with the law and is necessary in a democratic society in the interests of ... the protection of the rights and freedoms of others” (*Human Rights Act*, *supra* note 67, s. 8(2)).

⁷³ David Marquand, *Decline of the Public: The Hollowing Out of Citizenship* (Cambridge, U.K.: Polity Press, 2004) at 60.

⁷⁴ Robin West, “Unenumerated Duties” (2006) 9 *U. Pa. J. Const. L.* 221 at 223, 240. She continues, this Dworkinian drenching of law ... with moralism can likewise limit our moral sense, obfuscate our moral intuition, and dangerously dull our capacity for moral criticism.... And surely, a part of what the Constitution might be faulted for is its understatement with respect to the affirmative moral duties of legislatures (*ibid.* at 253-54).

⁷⁵ Fritz W. Scharpf, “The European Social Model: Coping with the Challenges of Diversity” (Max Plank Working

need to protect weaker members of society. Yet economic rights have advanced in ways that favour the (articulate) consumer and those who compete most effectively for market share. Markets react quickly and efficiently to the pressures of supply and demand, but they respond less well to recondite concepts of public interests and the general good. They take a disengaged view of the normative aspirations of equality and solidarity by respecting rights negotiated in a free market. This concept of “market citizenship,” it is said, is “embedded within an ideological paradigm which undertheorizes collective agency and debate and overemphasizes individual choice and models of economic determinism.”⁷⁶

The danger of these approaches is that they undermine a sense of solidarity and social cohesion. In the E.U. context, for example, market citizenship may have developed to engage individuals with the personal benefits of free-market values. But a policy of promoting citizen self-interest will not necessarily generate a sense of allegiance.⁷⁷ At the national level, too, if consumerism comes to dominate the concept of social welfare rights, it would not be surprising if patients felt diluted concern for the institutions that provided their care, or for the welfare of their fellow citizens. Perhaps unwittingly, the New Governance ideology undermines traditional concepts of social welfare. Its “consumer orientation directs attention away from the political context. The bright light that is made to shine upon the consumer [casts] a gloomy shadow upon the citizen and the broader consequences of personal choice remain undisclosed in those very same shadows.... This attitude and solidarity do not go well together.”⁷⁸ If this view is correct, Marshall’s analysis of the evolutionary forces within the concept of citizenship requires re-evaluation to accommodate a less cohesive, more individualistic notion of the market, or consumer citizen.

Some may say these concerns are overstated; solidarity, after all, is so emotive and intangible and, in any case, people should recognize the limitations of the modern welfare state and become more self-sufficient and independent. Indeed, compared to the allure of individualism, “solidarity begins to appear both ugly and unkind.”⁷⁹ But a competitive market implies the existence of winners and losers, and the sections of the population most at risk of a dilution of “community” tend to be the latter. They are likely to be the least articulate, least “popular” groups of patients with limited pressure group support. Elderly, infirm, and disabled (especially mentally disabled)⁸⁰ patients are most likely to be left behind. For example, a recent report of the House of Lords on the human rights of older people found “historic and embedded ageism” within the NHS and demanded “an entire culture change in the way that healthcare services for older people are run.”⁸¹ This goes to the root of the modern challenge to social welfare: to reconcile the tendency of market-based incentives to focus on the individual with the culture of social citizenship in order to foster solidarity and social cohesion. Unless we can develop a system of rights capable of recognizing both, the benefit of encouraging “equalization between the more and less fortunate” that Marshall valued so highly is unlikely to thrive as a political value.

Paper 02/08, Max Planck Institute for the Study of Societies, July 2002).

⁷⁶ Root, *supra* note 1 at 152.

⁷⁷ “Being instrumentalized, the market citizen had no choice but to become instrumentalist ... Europe ... has given rise only to a self-interested ‘citizen’ whose allegiance to Europe may not simply be taken for granted” (M. Everson, “The Legacy of the Market Citizen” in Jo Shaw & Gillian More, eds., *New Legal Dynamics of the European Union* (New York: Clarendon Press, 1995) at 88).

⁷⁸ Stjerno, *supra* note 18 at 338.

⁷⁹ Somek, *supra* note 18 at 816.

⁸⁰ See U.K., Healthcare Commission, *A Life Like No Other: Specialist Healthcare Services for People with Learning Difficulties in England* (London: U.K. Commission for Healthcare Audit and Inspection, 2007), online: British Institute of Learning Disabilities <http://www.bild.org.uk/hcc/LD_audit_report1.pdf>.

⁸¹ U.K., H.L., “Human Rights of Older People in Healthcare”, 156-1 in *Sessional Papers*, vol. 18 (2006-07) at para. 59. See also U.K., Healthcare Commission, *Caring for Dignity: A National Report on Dignity in Care for Older People in Hospital* (London: U.K. Commission for Healthcare Audit and Inspection, 2007), online: Healthcare Commission <http://www.healthcarecommission.org.uk/_db/_documents/Caring_for_dignity.pdf>; David Oliver, “What’s Wrong with the NHS?: Well, If You Are Old or Frail...” (2007) 335 B.M.J. 1059.



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