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EDITOR'S NOTE

*Virginie Marier**

The MJLH continues to grow by leaps and bounds. After graduating from experimental Publication to full-fledged Journal last summer, we issued a first and, as the articles in this issue demonstrate, highly successful open call for submissions. Fortuitously complementary pieces resulted in this three-themed volume.

Drugs top the list. At the input level, Ron Bouchard and Monika Sawicka's dual contribution explains Canada's drug licensing regime from scientific and legal perspectives. At the output level, Amir Attaran decries procedural lacunae in patient access to these drugs.

Viennent ensuite les accommodements raisonnables en milieu de travail. Judith Mosoff nous offre notre premier commentaire d'arrêt, dans lequel elle explore quelques développements récents dans la jurisprudence canadienne. Pour leur part, Anne-Marie Laflamme and Sophie Fantoni-Quinton apportent une critique comparative des systèmes français et canadien afin de déterminer l'approche légale la plus susceptible d'avantager les travailleurs.

Finally, Denise Avard, Bartha Knoppers, and Gillian Nycum present a comprehensive, international look at potential sources of legal obligations to communicate genetic risk within families. In this, we welcome and celebrate the fruitful contribution of an MJLH founder to the academic health law community beyond the walls of the Faculty.

* * *

The MJLH family is expanding. Enthusiastic, enterprising medical students joined our ranks last fall and were instrumental in turning the idea of a Student Colloquium on Law and Health into a successful reality. Five distinguished members of the McGill extended community also accepted an invitation to join our advisory board: the Honourable Senator David W. Angus, Professor emeritus Paul-André Crépeau, Maître Amélie Dionne-Charest, the Honourable Justice Allan Hilton, and Professor Robert Kouri. Welcome!

For five years, McGill students have invested their time and devoted their energies to the MJLH as a work of love. This fall, thanks to the ardent support of Associate Dean David Lametti and to the collaborative efforts of the editors-in-chief of the McGill Law Journal and the McGill International Journal of Sustainable Development Law and Policy, the MJLH becomes a fully accredited endeavour.

I would like to thank our departing Dean Nicholas Kasirer, whose belief in the nobility of volunteer work and trust in the greatness of the Faculty inspired us, and whose unbending support bolstered and concretized not only this Journal but also McGill's blossoming health law specialty.

En terminant, je remercie notre conseillère aguerrie, Mme Angela Campbell, ainsi que mon équipe de rédacteurs qui a su bien choisir et corriger les articles que vous lirez dans ce volume. Plus particulièrement, j'exprime ma gratitude envers l'extraordinaire Dorian Needham, le minutieux Narimane Nabahi, et le dévoué Mike Huynh, qui ont formé un cercle exécutif imbattable pendant l'année. I am proud to pass the mantle on to Mike, who shouldered more than his fair share of work in getting Volume III to press and whose innovative touch will no doubt lead the way to a remarkable fourth Volume in 2010.

À votre santé!

* Editor-in-Chief, *McGill Journal of Law and Health*, Vol. 3.

TAKE YOUR MEDICINE?: THE RISK OF PATIENT-LED LITIGATION IN CANADA’S MEDICINE ACCESS SYSTEM

*Amir Attaran**

The system for public financing and access to medicines in Canada lags global standards and is frequently inconsistent, non-transparent, and arbitrary—which makes it extremely vulnerable to patient-led lawsuits. Medicines that the federal government deems safe, effective, and fairly priced are often publicly financed in one province but not in another. The criteria that provinces apply when selecting medicines for public financing are not generally made public, nor are the committees in which the selection takes place generally open to public participation. Legislatures have enacted statutes singling out “lucky” patients with certain diseases for public financing of medicines, while “unlucky” patients arbitrarily are denied financing, with no clinical or cost-effectiveness evidence explaining the differential treatment. To the extent that the federal government has jurisdiction under the Canada Health Act to defend Canadians’ access to medicines, it has never exercised it, and some provinces openly flout their non-compliance. The political result is that the standard of care in some provinces is arbitrarily higher or lower than in others.

In this article, the author discusses the serious litigation risk facing health systems in Canada due to patient-led lawsuits for access to medicines. Internationally, the World Health Organization reports that there is an increasing trend in successful patient-led lawsuits for access to medicines. It is argued that this trend will eventually reach Canada, as it has reached other common law jurisdictions (including England, for example). Current experience indicates a potentially negative impact on health care budgets and a potentially positive impact on the standard of clinical care. This article draws attention to some potential litigation vulnerabilities of health systems so that health system planners may proactively mitigate the budgetary damage and accelerate the clinical benefits.

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INTRODUCTION

The Canadian health care system is undergoing an episode of uncertain public confidence. A recent public survey by the Canadian Medical Association shows that the number of Canadians who think services are excellent continues to fall: “from 33% in 2003 to 26% in 2005”.¹ Much of the public’s anxiety over health care focuses on access to medicines, as a sampling of headlines shows:

- “Bankrupted by Drugs” (16 August 2005);
- “The Staggering Price of Survival” (15 August 2005);
- “Our Cancer System Needs a Cure for Drug-Care Inconsistency” (10 August 2005);
- “Why Medicare has to Offer Herceptin” (2 August 2005);
- “Paying the Price for Treatment” (1 August 2005);
- “At War with their Illness and their Government” (26 July, 2005);
- “The Real Monster in the Health-Care Closet” (26 July 2005);
- “Ontario Myeloma Patients Want their Life-Saving Drug” (23 July 2005);
- “Three More Provinces Approve Herceptin” (July 22 2005);
- “Drug Costs Count: Sometimes We Have to Tell the Dying ‘No’” (21 July 2005); and
- “Ontario Wrestles with Responsible Drug Spending” (16 July 2005).

One does not have to look hard for such headlines: this sample is from only one newspaper, the *Globe and Mail*, in midsummer 2005. The rhetoric is heated and worrisome: “Bankrupted” patients are “at war” with their government, which is insensitive to the “staggering price of survival”. Clearly, access to medicines is upsetting Canadians to a remarkable extent.

This article concerns an emergent social phenomenon: aggrieved patients, upset that the health system denies them access to medicines in seemingly unfair ways, are increasingly restive and are poised to begin suing government. Although access to medicines litigation has been very rare in Canada, it is a more common occurrence in other countries, which is perhaps a harbinger of things to come. If Canadian patients do reach for the courts, it is entirely possible they will win a substantial number of cases. In the most complete study done to date, the World Health Organization’s (WHO) essential medicines unit surveyed drug access litigation around the world. The WHO’s results show that when patients in foreign countries sued governments for access, they won an astonishing 83% of the time.²

One would have to be naïve to imagine that Canada is immune to what those researchers called an “increasing trend towards successful litigation”. At over \$18 billion annually, the cost of prescription medicines in Canada already exceeds payments for all services provided by physicians, and it is rapidly rising.³ It would take only a small miscalculation on the part of health system planners to underestimate litigation risk, followed by a successful patient-led lawsuit that enlarged government’s financial obligations, for the medicines budget to explode beyond even current projections. Litigation risk, it stands to reason, surely has to be better understood and reckoned with by health system planners.

¹ Canadian Medical Association & Ipsos Reid, 2005 National Report Card: General Population, (15 August 2005), online: <http://www.cma.ca/multimedia/CMA/Content/Images/Inside_cma/Media_Release/pdf/2005/Report-Card-Embargoed-E.pdf>.

² Hans V. Hogerzeil *et al.*, “Is Access to Essential Medicines as part of the Fulfilment of the Right to Health Enforceable through the Courts?” (2006) 368 *The Lancet* 305.

³ Steve G. Morgan, “Canadian Prescription Drug Costs Surpass \$18 Billion” (2005) 172 *Canadian Medical Association Journal* 1323.

The purpose of this paper is to describe Canada's current practices and laws that control access to new and innovative medicines, and in the course of that exposition, to explain didactically some of the health system's vulnerabilities to patient-led litigation (and specifically, vulnerabilities to judicial review on administrative law grounds, since this is the commonest method of challenging government decisions). The exercise is meant to be thought-provoking: not in the sense of fanning grievances so that patients telephone their lawyers en masse, but in the sense of causing health system planners to look with fresh eyes at whether they could improve drug evaluation and selection systems to better minimize litigation risk and to improve patient satisfaction at the same time.

This paper is divided into two parts and a conclusion. Part One is a brief explanation of the administrative, legal, and pharmacoeconomic framework by which medicines are evaluated, chosen, and funded at the federal and provincial levels. Part Two recounts a recent case of patient-led litigation in the Court of Appeal of England as an example of the sort of litigation that will in due course probably be seen in Canada (notably because England and Canada have similar health and legal systems, and developments in one frequently are copied in the other). The Conclusion briefly synthesizes the two Parts and, it is hoped, persuades the reader that the risk of patient-led litigation is real but in large part avoidable if authorities make wise public policy decisions.

I

ACCESS TO MEDICINES IN THE PROVINCES AND FEDERALLY

There are no easy answers when it comes to access to medicines in Canada. The system by which a medicine is or is not paid, in a given province and for a given patient, can be Byzantine, with overlapping jurisdictions and rules or processes that sometimes seem contradictory. Unlike in most other countries where a national scheme for medicines exists—the United Kingdom and Australia are two examples from the common law world—in Canada, the process by which a medicine comes to be publicly insured involves intersecting federal and provincial jurisdictions and the administrative agencies of each.⁴ In short, the Canadian system is more complex. Before getting into those complexities, however, it is first helpful to review how new, innovative medicines come to be approved in Canada.

The process begins at the federal level, when a pharmaceutical manufacturer applies to Health Canada to issue a “notice of compliance” for a medicine that the manufacturer has previously shown in clinical trials meets the required standards for efficacy and safety.⁵ Next, the pharmaceutical manufacturer applies to another federal agency, the Patented Medicine Price Review Board, which regulates both the launch price of a new medicine and price adjustments that may occur from time to time, having regard to the price of the medicine in other countries.⁶ In short, Health Canada and the Patented Medicine Price Review Board—federal agencies both—regulate the process up to the stage of marketing approval.

Only after the federal government has done its work does the burden shift in any practical way to the provincial governments, each of whom is confronted with this question: Is the new medicine good value and worth paying for in the provincial care system? And on this question, the provinces often express differences of opinion, which are not always appreciated.

Professor Aslam Anis writes that a great deal of avoidable “discord” arises from splitting drug regulatory decisions (federal) from drug payment decisions (provincial).⁷ The constitution probably does not oblige so deep a split, but it is a reality nonetheless.⁸ Professor Anis explains:

⁴ Steve G. Morgan *et al.*, “Centralized Drug Review Processes in Australia, Canada, New Zealand, and the United Kingdom” (2006) 25 *Health Affairs* 337.

⁵ *Food and Drug Regulations*, C.R.C. c. 870, s. C.08.004.

⁶ *Patented Medicines Regulations*, S.O.R./94-688; *Patent Act*, R.S.C. 1985, c. P-4, ss. 79-103.

⁷ Aslam H. Anis, “Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord” (2000) 162 *Canadian Medical Association Journal* 523.

⁸ As written elsewhere, the federal government actually has a large, unutilized residue of constitutional jurisdiction in the health sector that it chooses not to exercise. See Martha Jackman, “Constitutional Jurisdiction over Health in Canada” (2000) 8 *Health L. J.* 95; Amir Attaran and Kumanan Wilson, “A Legal and Epidemiological Justification for Federal Au-

One key failing in the system is that the federal government is almost completely insulated from feeling the impact of its policies because, although it regulates drug prices, it does not buy any drugs. Conversely, provincial governments have no jurisdiction over market competitiveness or pricing, yet they end up paying for most of the drug expenditures incurred. The various regulations at each level of government that affect the pharmaceutical marketplace have both intended and unintended impacts.⁹

The curious way in which federal and provincial regulation fail to interface is often the root of the injustice that Canadian patients feel over access to medicines. Once the federal government has deemed that a new and innovative medicine is safe, effective, and correctly priced, how likely is it that a patient will simply accept his or her provincial government's refusal to pay for it? Worse, how likely is it that a patient will accept the province's refusal if all around him or her, patients in other provinces are getting the very medicine that he or she is denied?

As formulas for grievance go, these are very potent ones. When patients receive mixed signals from different levels of government or feel disadvantaged by a "postcode lottery" that determines one's ability to receive medically needed treatment, it should not be surprising if litigious sentiments are forged, and those may be directed at either level of government. It also stands to reason that the roles and legal responsibilities of each level of government could give rise to patient-driven litigation. The first subsection below discusses the federal mandate, followed by a longer subsection that explores the more extensive provincial mandates.

A. The Federal Mandate

Generally speaking, the federal government is not a direct provider of drug benefits to Canadians.¹⁰ Rather, Parliament has set out various statutory mandates, which the provinces are legally obligated to fulfil. Section 2 of the *Canada Health Act (CHA)* defines "insured health services", which are the services that provinces must provide at public expense.¹¹ The *CHA* then stipulates that insured health services include "hospital services", which in turn include medically necessary "drugs, biologicals and related preparations when administered in the hospital" to either an inpatient or outpatient.¹² Note the careful wording of the latter mandate: unexpectedly it is the *location* where the medicine is administered (in hospital), combined with the medical necessity of the medicine, which determines whether a province must as a matter of federal law supply the medicine as an insured health service.

Hand in glove, the provinces' own legislation tends to parallel the federal mandate's wording, though not always perfectly, and with some uncertainty where there is residual scope for interpretation.¹³ For instance, the *CHA* omits to define what kind of facility counts as being "in the hospital", presumably leaving it up to the courts to interpret those words in litigation.¹⁴ (A commonsensical interpretation: if a medicine is administered to outpatients in a clinic on designated hospital grounds, or received by patients admitted on a hospital ward, it is "in the hospital" for the *CHA*'s purposes.)

Yet even in the clearest of cases, the *CHA*'s federal mandate for provision of medicines is openly flouted. In the most recent (2006–2007) federal report on the *CHA*, British Columbia bluntly states that "certain hospital drugs are not insured".¹⁵ Ontario just as forthrightly concedes that "out-patient

thority in Public Health Emergencies" (2007) 52 McGill L.J. 381.

⁹ Anis, *supra* note 7 at 524. Note that Anis should have mentioned that the federal government buys some drugs, such as those for aboriginal people on reserve. Nonetheless his basic point remains valid.

¹⁰ It should be noted that there also exist a few special federal and territorial pharmaceutical schemes, as for First Nations, the armed forces, Convention refugees, or prisoners of federal institutions. The provinces also have special schemes, such as those for workers' compensation. For simplicity's sake, I do not focus on these special schemes, and it is only the mainstream entitlements of the federal and provincial governments that are discussed in this paper.

¹¹ *Canada Health Act*, R.S.C. 1985, c. C-6, as amended [*CHA*].

¹² See subsection (d) of the definition of "hospital services" in s. 2 of the *CHA*, *ibid*.

¹³ See e.g. ss. 1(h)(iv) and 1(j)(viii)(D) of the *Hospital Insurance Regulations*, N.S. Reg. 11/58, or para. 4 of Schedule A of the *Hospital Services Insurance and Administration Regulation*, Man. Reg. 48/93. See also Ontario's regulations, *infra* note 17.

¹⁴ Most provinces have a *Hospitals Act* or some equivalent thereof whose definitions could aid in this interpretation.

¹⁵ Minister of Health, *Canada Health Act Annual Report 2006-2007*, (Ottawa: Health Canada, 2007) at 167, online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/chaar-ralcs-0607/chaar-ralcs-0607-eng.pdf> [*Annual Report 2006-2007*].

hospital visits solely for administering drugs, subject to certain exceptions,” are not insured.¹⁶ The latter province has even gone so far as to legislate a loophole for itself, which exempts payment for such medicines *even if they are medically necessary*.¹⁷

Plainly, this kind of derogation is not likely to be legal. From the provincial perspective, the downside to breaking the law is minor, because Health Canada's enforcement of the *CHA* is so consistently jejune. The Auditor General of Canada delicately calls Health Canada's enforcement efforts “non-intrusive”, and points to instances of non-compliance that “remained unresolved for five years or longer”.¹⁸ Although Ottawa is obliged by law (*i.e.* there is no discretion) to withhold transfer payments when a province levies user charges on patients for *CHA*-mandated insured health services, it almost never does so. In over two decades of enforcement, under \$10 million has been clawed back in this way—an insignificant amount, and none of it apparently for breaching the federal mandate for in-hospital medicines.¹⁹ Succinctly put, it appears that no province has ever been penalized a dollar for shortchanging its people of medically necessary medicines administered in hospital, as is patients' legal entitlement under the *CHA*.

Professor Sujit Choudhry has written that, absent meaningful federal enforcement, “it may be left to individuals, acting as ‘private attorneys-general’, to enforce the terms of the *CHA* through the courts.”²⁰ Perhaps so. The Federal Court was not receptive to this approach when labour unions brought a far-reaching suit on the non-enforcement of the *CHA* in all its aspects, calling compliance monitoring a discretionary political matter that is “not ... justiciable”.²¹ But there is arguably no discretionary political matter where the legal challenge under the *CHA* is narrowly confined and is brought by a directly-affected patient seeking just the particular medically necessary, in-hospital medicines that he or she requires. In this case there is absolutely no doubt that the *CHA* imposes a legal duty on the province to pay, as the *CHA* frames that duty in mandatory language.²² The Federal Court acknowledged such a distinction, and it is hard to imagine it being disregarded in future cases, particularly if the facts establish that the patient needs treatment and cannot afford it otherwise—and even more so if the patient's life would even depend on it.²³

Regrettably, the scenarios where directly-affected patients are in just this kind of peril are all too common. Cancer patients, who are numerous, furnish a leading example. Many chemotherapeutic medicines cannot be taken orally, but need to be infused intravenously or parenterally (*i.e.* by needle). Infusions tend to be administered in hospital wards, or in outpatient oncology clinics attached to hospitals, both because that is where the cancer specialists are, and because patients can suffer adverse drug reactions, such as anaphylaxis, stroke, or cardiac arrest, for which a hospital's backup can be life-saving.²⁴ One would therefore predict that the infusible chemotherapeutics would be paid for by the provinces fairly uniformly across Canada, if the *CHA*'s federal mandate were regularly followed.

¹⁶ *Ibid.* at 88.

¹⁷ See R.R.O. 1990, Reg. 552, *General*, promulgated under the *Health Insurance Act*, R.S.O. 1990, c. H.6 [*Ontario Regulation 552*]. In particular, see s. 8(1)(5)(iv), which makes it clear that out-patient hospital visits to receive medicines are exempt from insurance, without distinction as to whether they are medically necessary. Ontario's approach, which is inconsistent with the *CHA* and therefore unlawful, is nicely contrasted against Alberta's, where any medicine that is medically necessary and administered in hospital certainly will be paid for; see *Hospitalization Benefits Regulation*, Alta. Reg. 244/1990, and particularly the benefit in s. 4(1)(a)(iii) as qualified by s. 5.2(3) and ss. 4(2)(f) and 4(2)(g).

¹⁸ Auditor General of Canada, “Chapter 3: Health Canada—Federal Support for Health Care Delivery” in *2002 September Status Report of the Auditor General of Canada* at 19, online: <<http://www.oag-bvg.gc.ca/internet/docs/20020903ce.pdf>>.

¹⁹ *Annual Report 2006–2007*, *supra* note 15 at 11–13. See also *CHA*, *supra* note 11, ss. 19–20.

²⁰ On the historically poor enforcement of the *Canada Health Act*, see Sujit Choudhry, “The Enforcement of the Canada Health Act” (1996) 41 McGill L.J. 461.

²¹ *Canadian Union of Public Employees v. Canada (Minister of Health)* (2004), 244 D.L.R. (4th) 175 at para. 44 [*CUPE v. Canada*]. See also *Cameron v. Nova Scotia (A.G.)*, (1999), 177 D.L.R. (4th) 611, 1999 CanLII 7243 at paras. 96–97 (N.S. C.A.).

²² Another obvious difference is that the directly-affected patient has *locus standi*, which the union would not. This was decided in *British Columbia Nurses' Union v. British Columbia (A.G.)*, 2008 BCSC 321 at paras. 44–45.

²³ *CUPE v. Canada*, *supra* note 21 at para. 47, citing for the distinction *Finlay v. Canada (Minister of Finance)*, [1986] 2 S.C.R. 607.

²⁴ Carl Shanholtz, “Acute Life-threatening Toxicity of Cancer Treatment” (2001) 17 Critical Care Clinic 483.

But according to research by the Cancer Advocacy Coalition of Canada (CACC), there is actually tremendous variation between provinces regarding the chemotherapeutics each pays for. For instance, patients in British Columbia have about triple the number of chemotherapeutics unconditionally paid for, as do patients in Ontario (see Figure 1).²⁵ Among the omissions are several chemotherapeutics that Ontario recommends but does not fund, which is in effect a concession that the medicines are actually medically necessary.²⁶ Also among the omissions are some infusible chemotherapeutics that normally would be administered in hospitals.²⁷ These and other specific instances are better described in the data tables of the CACC's report. It is not uncommon for these omitted treatments to cost tens of thousands of dollars, which is the likely reason that Ontario declines to pay for them, even as British Columbia does.²⁸

While it is not the only factor, it also is not coincidental that in Atlantic Canada, where access to paid cancer medicines is markedly poorer (see Figure 1), the epidemiological odds of surviving cancer are also significantly lower.²⁹ Faced with that grim evidence, it should not be too surprising if someday a patient, fearful of losing in this postcode lottery, resolves instead to sue for an infusion medicine that is due him or her under the *CHA*'s federal mandate.

Of course, whether it is *desirable* for the public purse to pay for expensive medicines is a meaningful policy question, which is examined closely in the next section. But at the close of this section, it must be emphasized that the federal mandate transcends any consideration at all of desirability: all it says is that if a drug, biological, or related preparation is medically necessary and administered in the hospital, it *must*, as a matter of law, be an insured health service for which the province, and not patient, will pay. It is alarming that this legal mandate is not consistently honoured, for therein lies a significant litigation risk and all indications are that if a patient sued to receive a medicine that he or she is entitled to under the *CHA*, that patient would (and should) win.

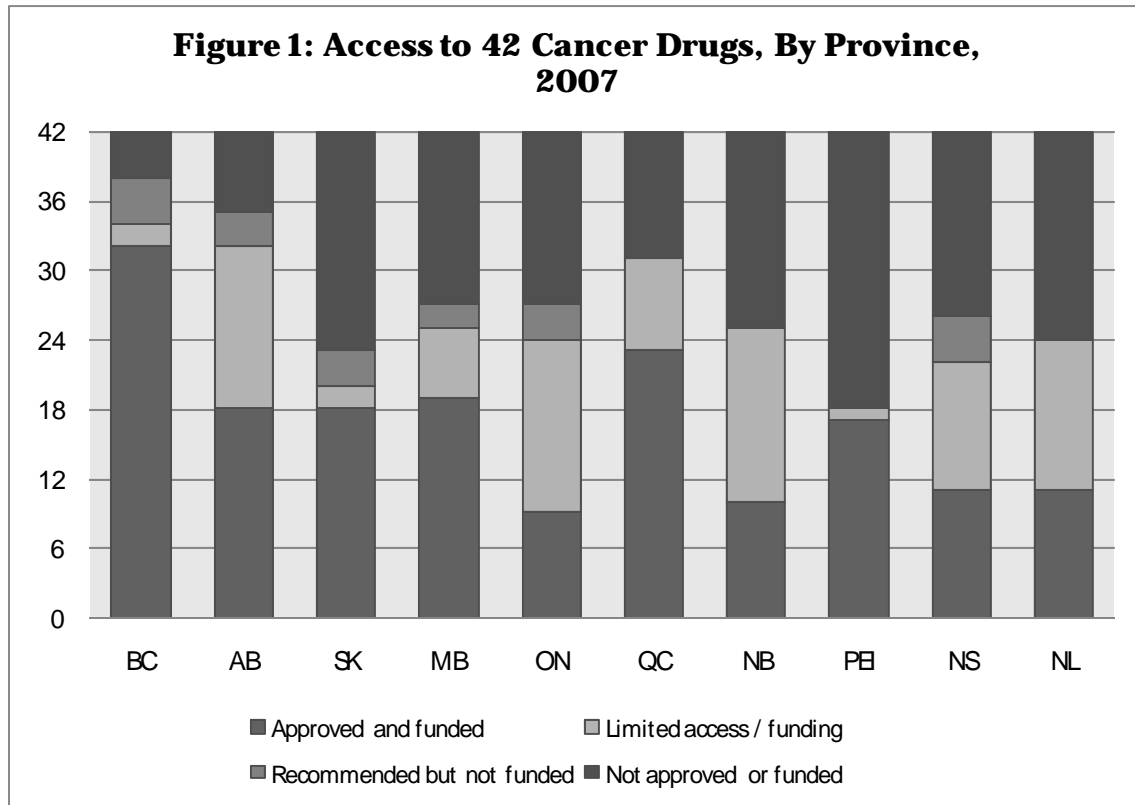
²⁵ Cancer Advocacy Coalition of Canada, *Report Card on Cancer in Canada 2007* at 46, online: <<http://www.canceradvocacy.ca/reportcard/2007/Report%20Card%20on%20Cancer%20in%20Canada,%202007.pdf>> [*Report Card*].

²⁶ The situation of medicines which are recommended but not funded in Ontario is distinguishable from medicines for which no such recommendation exists and which are not funded. Here I am concerned only with the situation of the former medicines. As Professor Colleen Flood correctly observes, the latter medicines could be termed by the province as not medically necessary and outside the scope of the federal mandate; see Colleen M. Flood & Lorian Hardcastle, "The Private Sale of Cancer Drugs in Ontario's Public Hospitals: Tough Issues at the Public/Private Interface in Health Care" (2007) 1 *McGill J.L. & Health* 5 [Flood, "Private Sale"].

²⁷ Examples of chemotherapeutics that must always be infused include any of the monoclonal antibodies, customarily denoted by a name ending in the suffix "mab". See *Report Card*, *supra* note 25 at 41–44.

²⁸ *Ibid.* at 41.

²⁹ A.-M. Ugnat *et al.*, "Survival Patterns for the Top Four Cancers in Canada: The Effects of Age, Region and Period" (2005) 14 *European Journal of Cancer Prevention* 91.



Source: Cancer Advocacy Coalition of Canada, *Report Card on Cancer in Canada 2007*

B. The Provincial Mandates

The ten provinces control the bulk of Canada's drug access system. More people are affected by the provinces' decisions, because it is the provinces that have jurisdiction over medicines that are administered out of the hospital.

And the provinces do not have a simple job. Fundamentally, each province grapples with this exceedingly tough policy problem: how to evaluate, select, and optimize the medicines the provincial insurance scheme will pay for, having regard to the medical and financial resources at hand. Because there are as many answers to this riddle as there are provinces, summarizing the administrative and legislative frameworks at play necessarily calls for imperfect generalizations, and there will always be a few provinces that do things differently. Accordingly I set out three generalizations in this section, but with said caveat to the reader.³⁰

First, each province sets eligibility criteria for persons seeking drug benefit. To be clear, whether one is eligible for drug benefit is not the same thing as how much value one gets from the drug benefit, although the two often interdigitate in practice. Eligibility *stricto sensu* often depends on membership in a specific demographic group, but within that group, some may benefit more than others; for example, all provinces deem that seniors and those on social assistance are eligible for drug benefit, but the threshold of eligibility, or the quantum of benefit, often varies with age, means-testing, possession of private insurance, and other factors.³¹ Some, but not all, provinces provide benefits to

³⁰ Readers seeking more detail are referred to the cited studies and to this superb 2006 report by the OECD on drug benefit coverage in Canada: OECD, V. Paris & E. Docteur, *OECD Health Working Papers No. 24: Pharmaceutical Pricing and Reimbursement Policies in Canada* (Paris: OECD Publishing, 2006).

³¹ Vishnu Kapur & Kisalaya Basu, "Drug Coverage in Canada: Who is at Risk?" (2005) 71 *Health Policy* 181. See particularly Table 2 in that paper.

widows or children.³² The four western provinces and Ontario open eligibility more widely and allow any resident to enrol in their drug insurance plans, although many residents choose not to enrol or prefer to obtain coverage from private insurers because of the deductibles that are charged.³³ Overall, about 25% of Canadians receive drug benefit coverage in some guise through their province.³⁴

Second, and in flagrant disregard of the usual practice of health technology assessment (described later in this paper), provinces single out a few diseases, the medicines for which are covered for all patients, *including* those who are otherwise normally ineligible for drug benefit.³⁵ In New Brunswick, for example, the Lieutenant-Governor in Council enacted regulations singling out patients having cystic fibrosis, multiple sclerosis, and HIV/AIDS, by adding them to the statutory definition of a “beneficiary”.³⁶ Similarly, in Ontario, the Lieutenant-Governor in Council singled out particular medicines (rather than diseases), such as clozapine for schizophrenia, cyclosporine for organ transplantation, or antiretroviral medicines for HIV/AIDS.³⁷ How these chosen diseases or medicines come to be singled out is often a triumph of politics over reason. Advocates for particular diseases lobby for “their” treatment, but when the government capitulates, it often creates serious, perhaps justiciable, inequities in the legal framework.

A decade ago, Ontario came under what has been called “a widely publicized attack led by the National Gaucher Foundation of Canada” to pay for the treatment of patients with Gaucher’s disease, which is a rare genetic disorder.³⁸ In response, Ontario amended its laws to single out and pay for alglucerase enzyme replacement therapy—but without making the amendment broad enough to accommodate other persons suffering from rare genetic disorders. The net effect is that persons who are “lucky” enough to have Gaucher’s disease in Ontario receive alglucerase costing up to US\$550,000 annually, while persons affected by other rare genetic disorders—say, Pompe’s disease, or Hunter’s syndrome—get no equivalent financial help for their similarly costly enzymes.³⁹ Clinical experts in the treatment of genetic conditions correctly ask if such an *ad hoc*, arbitrary approach is not tantamount to condemning these neglected patients to death.⁴⁰

If Ontario’s singling-out law were ever challenged as a violation of equality rights under s. 15(1) of the *Canadian Charter of Rights and Freedoms*⁴¹ because it gives a benefit of treatment to persons who have the Gaucher’s genetic disability, but not persons who have other treatable genetic disabilities, one would have to assess that lawsuit as having extremely high odds of success based on current jurisprudence.⁴² Enzyme replacement therapy functions, at a biomolecular level, like a “crutch” to compensate

³² See Kapur & Basu, *ibid.* See also Wendy J. Ungar & Maciej Witkos, “Public Drug Plan Coverage for Children Across Canada: A Portrait of Too Many Colours” (2005) 1 *Healthcare Policy / Politiques de Santé* 100 at 106.

³³ OECD, *supra* note 30 at para. 47. Ontario is not mentioned in the OECD report, but its Trillium Drug Program is open to all who apply. Online: Ontario Drug Benefit Program <http://www.health.gov.on.ca/english/public/program/drugs/funded_drug/fund_trillium.html>.

³⁴ Kapur & Basu, *supra* note 31.

³⁵ OECD, *supra* note 30 at para. 46.

³⁶ *Prescription Drug Regulation - Prescription Drug Payment Act*, N.B. Reg. 84-170, s. 2.1.

³⁷ See *Ontario Regulation 552*, *supra* note 17. See particularly the Table appearing under s. 8(2) of *Ontario Regulation 552*.

³⁸ Joe T.R. Clarke, Dominick Amato & Raisa B. Deber, “Managing Public Payment for High-Cost, High-Benefit Treatment: Enzyme Replacement Therapy for Gaucher’s Disease in Ontario” (2001) 165 *Canadian Medical Association Journal* 595 at 595.

³⁹ *Ibid.*

⁴⁰ Joe T.R. Clarke, “Is the Current Approach to Reviewing New Drugs Condemning the Victims of Rare Diseases to Death? A Call for a National Orphan Drug Review Policy” (2006) 174 *Canadian Medical Association Journal* 189.

⁴¹ *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.

⁴² See *Nova Scotia (Workers’ Compensation Board) v. Martin and Laseur*, 2003 SCC 54, [2003] 2 S.C.R. 504. The Court considered the constitutionality of a Nova Scotia law which provided certain workers’ compensation benefits for those affected by employment-related injuries, but not if those injuries were classed as “chronic pain”. As to whether this differential treatment breached s. 15(1), Justice Gonthier wrote for the unanimous Court (at para. 76) that “differential treatment can occur on the basis of an enumerated ground despite the fact that not all persons belonging to the relevant group are equally mistreated.” In the result, the Court found the scheme discriminatory and unconstitutional, because as Justice Gonthier wrote (at para. 104) “[I]njured workers suffering from chronic pain are ... denied an opportunity to access the compensation scheme available to other injured workers in the province, on the basis of the nature of their disability. They are also de-

for a broken metabolic gene. Ontario's discriminatory solution to the Gaucher's disease problem is akin to deciding that persons with a right broken leg can have a free crutch at public expense, but those with a left broken leg must pay for their own crutch.⁴³ Other provinces single out medicines or diseases for special dispensation too, with similarly arbitrary distinctions.

Last, and most importantly, each province is constantly reviewing and updating its drug benefit "formulary". A formulary, in the jargon, is a list of the drugs and their corresponding clinical uses that the province is willing to pay for. Here is a definition of formularies and their *raison d'être* from the medical literature:

A drug formulary is a list of drugs that a private or public insurance scheme will pay for. Drugs not on the formulary are generally not reimbursed, although some plans do reimburse drugs not on their formulary for specific patients. Formularies are used by payers because they do not wish to pay for drugs that are more expensive but of similar effectiveness as other drugs or because they are concerned that some drugs will be used for indications [jargon for "medical conditions"] for which they have not been demonstrated to be effective. Also, they are attempting to ensure that drugs used in clinical practice are cost effective.⁴⁴

Medicines that make it on to the formulary may be paid for in general use, or paid for only if a patient meets specific clinical criteria, or paid for only upon special application by the patient's prescribing physician.⁴⁵ Whether a medicine succeeds in getting onto the formulary, and on which terms, is decided by processes known collectively as health technology assessment.

Succinctly put, the purpose of health technology assessment is to gauge a new medicine's effectiveness, safety, and cost-effectiveness, as compared to existing therapies.⁴⁶ The process is initiated by the pharmaceutical manufacturer after Health Canada has approved a new medicine, or a new use for an old medicine. The manufacturer can apply to each province's formulary committee individually, but increasingly applications are directed to a joint federal-provincial committee process called the Common Drug Review (CDR), whose Canadian Expert Drug Advisory Committee (CEDAC) evaluates and makes recommendations to the participating provinces (all but Quebec).⁴⁷ The manufacturer will buttress its application with pharmacoeconomic data on the treatment's costs and benefits, which may be actual data from clinical experience or, if the medicine is so new and innovative that clinical experience is scarce, it may be guesstimated data from statistical models. Pharmacoeconomic merit can be reckoned in many ways, but probably the commonest statistical method is to report how many dollars of treatment are needed to gain a "quality adjusted life-year" for the patient (\$/QALY).⁴⁸ If the new medicine's safety and efficacy compare favourably to existing treatments—remember that health technology

prived of ameliorative benefits...." Exactly the same can be said of persons with genetic disease, but not Gaucher's disease, in Ontario. See also *Auton (Guardian ad litem of) v. British Columbia (Attorney General)*, 2004 SCC 78, [2004] 3 S.C.R. 657.

⁴³ The analogy would break down if other enzyme replacement therapies were inferior in treatment benefits to alglucerase replacement therapy, but the state of the science cannot support such a conclusion. A perpetual difficulty with rare genetic diseases is that, being rare, often it is impossible (literally) to perform the clinical trials to answer the scientific questions one wants. The science of epidemiology as applied to drug efficacy clinical trials depends on statistical methods which require experimenters to enroll a certain number of consenting patients in the trial, and if the minimum number cannot be found because the disease is too rare, then the clinical trial is futile and the scientific question is unanswerable. How the legal standard of proof for plaintiffs with rare diseases ought to be relaxed is a fascinating question which I do not propose to answer here, but it is indisputable that for genuine reasons of scientific epistemology, relaxing the standard is just in such cases—or else one is asking plaintiffs to prove that which is impossible to prove using the standard epidemiological methods.

⁴⁴ Wendy Levinson & Andreas Laupacis, "A Call for Fairness in Formulary Decisions" (2006) 166 *Archives of Internal Medicine* 16 at 16 [footnote omitted].

⁴⁵ Andreas Laupacis, "Inclusion of Drugs in Provincial Drug Benefit Programs: Who is Making These Decisions, and Are They the Right Ones?" (2002) 166 *Canadian Medical Association Journal* 44.

⁴⁶ M. Tierney M & B. Manns, "Optimizing the Use of Prescription Drugs in Canada through the Common Drug Review" (2008) 178 *Canadian Medical Association Journal* 432 at 432.

⁴⁷ Andreas Laupacis, "Economic Evaluations in the Canadian Common Drug Review" (2006) 24 *Pharmacoeconomics* 1157 [Laupacis, "Economic Evaluations"]; Meghan McMahon, Steve G. Morgan & Craig Mitton, "The Common Drug Review: A NICE Start for Canada?" (2006) 77 *Health Policy* 339.

⁴⁸ It would be incorrect to describe pharmacoeconomics as a hard science; it is more like applied economics. Especially in the instances where real cost-effectiveness data are lacking and modeled data have to be used, decisions about whether a treatment is worthwhile turn on maxims or rules of thumb, such as this: "For medical therapies, it is not uncommon to spend \$50,000 to \$100,000 to achieve a one-year gain in life expectancy": A. S. Detsky & D. A. Redelmeier, "Measuring Health Outcomes: Putting Gains Into Perspective" (1998) 339 *New Eng. J. Med.* 402 at 404. See also B. George, H. Harris & A. Mitchell, "Cost-effectiveness Analysis and the Consistency of Decision Making" (2001) 19 *Pharmacoeconomics* 1103.

assessment is concerned with *relative*, and not just absolute, merit, as between many medicines competing for limited funds—then CEDAC will recommend it for listing, unless its expected benefits are too limited to justify the cost.⁴⁹

This sort of health technology assessment is very popular. Although the provinces retain the statutory and *de jure* authority to set formularies as they like, as a *de facto* reality, the provinces often follow suit with CDR's recommendation of whether or not to list a medicine.⁵⁰ It is not clear whether the provinces are carrying out their own evaluations and agreeing with CDR or are just mimicking CDR; those who have studied it think the reality lies in the middle.⁵¹

But health technology assessment is controversial too.⁵² As a method of building a formulary, health technology assessment is an attractive way of achieving a *substantive* balance of competing interests—and that is fortunate, since courts are not well equipped to choose which medicines are good or bad value in so technical a subject matter.⁵³ But it definitely does not follow that the *procedural* aspects of health technology assessment are sound or outside the ability of courts to scrutinize—and here, there are worrying vulnerabilities with respect to basic rules of administrative law.

In a striking article, the former Chairman of CDR and Ontario's formulary committee, Professor Andreas Laupacis, and the Chair of the Department of Medicine at the University of Toronto, Professor Wendy Levinson, have warned that “many formularies are falling short” on fairness.⁵⁴ Certainly they support health technology assessment in principle, but they also worry that in practice, the public is excluded from participation, which threatens to undermine perceptions of legitimacy. Professors Laupacis and Levinson therefore urge greater “accountability for reasonableness” in formulary processes, by respecting these four procedural hallmarks:

- (1) the rationales for priority setting must rest on principles that fair-minded people can agree are relevant in the context,
- (2) the rationales and decisions must be publicly available,
- (3) there must be a mechanism to challenge the decisions, and
- (4) there must be regulation of the process to ensure that the first three conditions are met.⁵⁵

Coming from two physicians, naturally these indicia of fairness were not meant as a legal critique. But they bear an uncanny resemblance to the common law requirements of procedural fairness in administrative action. Succinctly: item (1) echoes the rule against arbitrariness; item (2) parallels the right to know the case to be answered and the right to reasons; item (3) is the right to judi-

⁴⁹ A major failing of the CDR process is that it was never given the mandate to negotiate for lower prices. Accordingly, as Laupacis writes, CEDAC “is often in the position of recommending against reimbursing a drug, when it would likely have recommended reimbursement if the cost of the drug was lower.” Laupacis, “Economic Evaluations”, *supra* note 47 at 1159.

⁵⁰ One source cites a 90% rate of acquiescence: Mike Tierney & Braden Manns, “Optimizing the Use of Prescription Drugs in Canada through the Common Drug Review” (2008) 178 *Canadian Medical Association Journal* 432 at 433. The author's own empirical research suggests the actual rate may be somewhat lower.

⁵¹ As McMahon *et al.* write: “it appears as though provincial drug plans are following CDR recommendations regarding ‘what’ to list, and are tasking themselves with the job of deciding ‘how’ to list these drugs”, *supra* note 47 at 343. The authors conclude however, that since CDR has existed only since 2003, it is too soon to tell.

⁵² It is outside the scope of this paper to review the controversies about health technology assessment, but suffice it to say there are dissenters, and some of their critiques are legitimate. Many academics believe that pharmacoeconomic assessments are “gamed” by pharmaceutical companies to win approval for medicines, and that the field lacks scholarly rigor: see Drummond Rennie & Harold Luft, “Pharmacoeconomic Analyses: Making Them Transparent, Making Them Credible” (2000) 283 *Journal of the American Medical Association* 2158. Professor Bob Evans, a noted health services expert at the University of British Columbia, goes so far as to voice the scathing indictment that pharmacoeconomics is a “pseudo-discipline ... conjured into existence by the magic of money, with its own practitioners, conferences, and journals. There are a lot of drugs, and there is a lot of money, so the ‘field’ is booming.” See Robert Evans, “Manufacturing Consensus, Marketing Truth: Guidelines for Economic Evaluation” (1995) 123 *Annals of Internal Medicine* 55.

⁵³ See the discussion of deference to polycentric decision-making in *Pushpanathan v. Canada (Minister of Citizenship and Immigration)*, [1998] 1 S.C.R. 982. See also Christopher P. Manfredi, “Déjà Vu All Over Again: *Chaoulli* and the Limits of Judicial Policymaking” 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) 139.

⁵⁴ Levinson & Laupacis, *supra* note 44 at 16.

⁵⁵ *Ibid.* at 16.

cial or other review and the rule of *audi alteram partem*; and item (4) is a plea for normativity in all the above. Not only is there much legal authority for these propositions, but there is an entire branch of legal jurisprudence and scholarship—administrative law—that is built around them. It would be passing strange if the standards of procedural fairness expressed in leading Supreme Court of Canada cases such as *Cardinal, Knight*, and *Baker* somehow evaporated and had no application to government decisions about drug benefit.⁵⁶

On the contrary, one of the most basic maxims of administrative law argues that procedural fairness should apply *a fortiori* in the drug benefit context. Procedural fairness, as every law student learns, exists on a sliding scale: the more important the interest affected by a government decision is to a person, the more extensive the content of procedural fairness that the government shows before depriving that person of the interest must be.⁵⁷ Surely, the interest a patient has in receiving medically necessary treatment—perhaps even lifesaving treatment—is at the high end of importance, which in turn obliges governments to show a high degree of procedural fairness.

That said, it is not possible to carry out a major disquisition on the procedural unfairness of provincial formulary processes here—recall the caveat that generalizations are at best imperfect when talking of ten provinces. The better approach is to show that the CDR process, which is the closest thing to an “all provinces” process, is failing to meet the applicable legal standards of procedural fairness, and that consequently provinces which *de facto* adopt CDR decisions with little or no supplementary public process of their own to ensure procedural fairness are vulnerable to legal challenge.

Anyone knowledgeable in administrative law who reads CDR's current procedures would be shocked.⁵⁸ Currently, CDR decisions are reached *in camera* by an expert advisory committee (CEDAC), at which the only observers are an advisory committee of government officials (called ACP)—there is absolutely no participation by patients or the public. External expert reviewers, the provinces, and the pharmaceutical manufacturer have several opportunities in the process to make submissions to CEDAC—but again, neither patients nor the public do. In fact, there is absolutely *no occasion* in the entire CDR process for patients or the public to attend in the decision-making forum, to make submissions, to challenge evidence submitted by others, or to seek an appeal or reconsideration, as the flowchart on the following page shows.⁵⁹

When finally a recommendation is reached and released to patients and the public on the CDR website, it is as if God has spoken: CDR's recommendations run a terse one or two pages, give few explanatory reasons, and cite zero references to public scientific or economic evidence—not even a footnote.⁶⁰ Of course, CDR possesses more fulsome reasons for its decisions, but those are very closely guarded and are not for patients' or the public's eyes. Remarkably, all these deficiencies remain in place, even *after* CDR underwent a makeover and a new “transparency” initiative in 2007.⁶¹ (And it should be noted that the provinces' own processes may be just as deficient.)⁶²

So is it necessary for Canada's CDR process to be both so exclusive and untransparent? Certainly not. In the United Kingdom, a health technology assessment process operated by the National Institute for Health and Clinical Excellence (feliculously known as “NICE”) also makes formulary recommenda-

⁵⁶ *Cardinal v. Director of Kent Institution*, [1985] 2 S.C.R. 643; *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817 [*Baker*]; *Knight v. Indian Head School Division No. 19*, [1990] 1 S.C.R. 653.

⁵⁷ See *Baker*, *ibid.* at para. 25 (“The more important the decision is to the lives of those affected and the greater its impact on that person or those persons, the more stringent the procedural protections that will be mandated.”)

⁵⁸ Canadian Agency for Drugs and Technologies in Health, *Procedure for Common Drug Review* (April 2008), online: <http://cadth.ca/media/cdr/process/CDR_Procedure_April%202008.pdf>.

⁵⁹ *Ibid.* at 3.

⁶⁰ This is readily apparent by downloading any of the “completed” drug reviews at CDR's webpage, online: <http://cadth-acmts.ca/index.php/en/cdr/search?&status=complete&order_field=drug_name>.

⁶¹ Canadian Agency for Drugs and Technologies in Health, *CDR Update—Issue 39*, (10 September 2007), online: <<http://www.cadth.ca/index.php/en/cdr/cdr-update/cdr-update-39>>.

⁶² For example, the four provinces of Atlantic Canada have the Atlantic Common Drug Review, which takes up CDR's recommendations, and again there is no role for patients or the public. See especially the flowchart of the ACDR process and the membership of the Atlantic Expert Advisory Committee, online: <<http://www.gov.ns.ca/health/Pharmacare/committees/acdr.asp>> (accessed 10 August 2008).

tions, but with more fairness and transparency toward patients and the public. NICE's procedures allow patients and the public the opportunities to:

- Comment on the scope of the drug appraisal;
- Submit evidence to the Appraisal Committee;
- Recommend other consultees whom they think should take part;
- Comment on the "assessment report" (a review of the evidence prepared by an independent academic centre);
- Comment on the Appraisal Committee's provisional recommendations;
- Appeal against the Appraisal Committee's final decision, which is set out in a document called the "final appraisal determination".⁶³

In contrast, patients and the public in Canada have none of these opportunities, because CDR's decision-making processes are closed to all but government officials and health system elites. In private conversation, it has been told to this author that opening CDR to the *hoi polloi* would make it unworkable, but the evidence suggests that precisely the opposite is true. Professor Laupacis cites the example of very expensive medicines for rare genetic diseases: in Britain, NICE facilitated public discussions which led to consensus on which of these medicines should be paid for. Meanwhile, in Canada, CDR's closed process has laboured in stalemate for years without reaching any satisfactory resolution.⁶⁴ Other scholars who have studied CDR also agree that Canada's formulary processes are inferior to those in other countries with regards to procedural fairness toward patients and the public.⁶⁵

For these reasons, it is highly likely that a CDR decision eventually will face a patient-led judicial review, whether in its own right or via a collateral attack on a provincial formulary decision that follows CDR guidance. One such case was filed in Alberta by a patient having a rare genetic disease, but now appears to be settled.⁶⁶ Another recent case, brought in Ontario not by a patient but by a drug company, affirmed that CDR's host institution "is subject to a duty of procedural fairness".⁶⁷ When a patient does eventually bring such a matter to the courts, there is no reason why a reviewing judge should excuse even a scintilla of procedural unfairness in formulary processes, especially if the evidence shows that similar processes in other countries (such as Britain's NICE) are fairer to patients and the public. No doubt, the Attorney General will make the forensic point that courts should show deference in the judicial review of technical, polycentric matters that lie beyond their regular expertise, but that argument is only compelling when the subject of judicial review requires a court to second-guess a substantive outcome. It has no merit at all where the subject of judicial review is procedural fairness, which courts are very well placed to evaluate.

⁶³ United Kingdom, National Health Service, *A Guide to NICE* (April 2005) at 16, online: NHS <http://www.nice.org.uk/media/EE5/AF/A_Guide_to_NICE_April2005.pdf>.

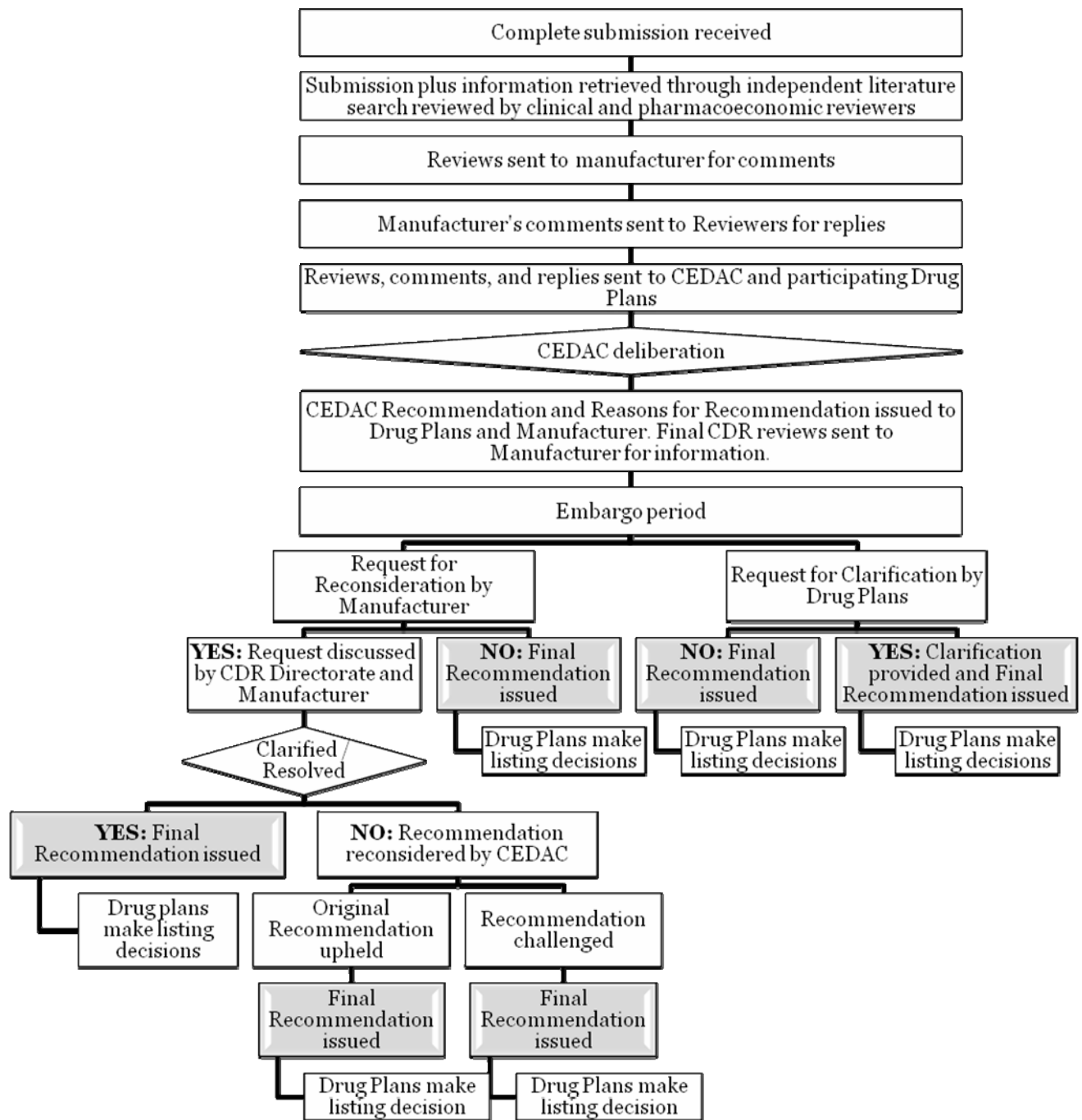
⁶⁴ Laupacis, "Economic Evaluations", *supra* note 47, at 1161.

⁶⁵ "[T]he Canadian and Australian agencies can be criticized for their lack of opportunity for patients and citizens to directly influence coverage decisions of new drugs." See Craig R. Mittona *et al.*, "Centralized Drug Review Processes: Are they Fair?" (2006) 63 *Social Science & Medicine* 200 at 208.

⁶⁶ The case involved an Aboriginal child. *Mackenzie Olsen (an infant) v. The Queen and Calgary Health Region* (28 April 2005), Action No. 0501-06380 (Alta. Q.B.).

⁶⁷ *Boehringer Ingelheim (Canada) Ltd. v. Canadian Agency for Drugs & Technologies in Health* (2008), 243 O.A.C. 200 (Ont. Sup. Ct.).

Figure 2: CDR Process



Source: Canadian Agency for Drugs and Technologies in Health, *Procedure for Common Drug Review*

Indeed, if the courts took too deferential an approach, a paradoxical and unintended result could be to perpetuate a decline in health care outcomes. In Ontario, where the formulary of paid cancer medicines is Canada's least generous, a disturbing and cautionary story is now emerging in the health sciences literature: clinical oncologists are "gaming" the system—that is, wilfully breaking the formulary's rules—to obtain appropriate medicines for patients in their care.⁶⁸ Researchers found oncologists diverting "considerable time and effort" away from their usual duties to manipulate records and to circumvent Ontario's ungenerous rules, which had "a substantial impact on their practice".⁶⁹ "You wind up lying," as one doctor in the study confided, "because you want to help your patients".⁷⁰ By deferring in such a situation, rather than intervening against it, a court would become complicit in government processes that depress the clinical standard of care.

To close this section: the foregoing assessment of formulary processes, and especially of CDR, is unquestionably harsh. However, the arguments should not be taken as condemning health technology assessment and a national formulary process for Canada, which are indispensable to a just and equitable allocation of resources. But reaching that best outcome requires one to question if the processes themselves are the best that they could be. In particular, one has to question the mediocrity and injustice of a system so bereft of procedural fairness that, currently, no patient or concerned person is given the opportunity to make submissions such as this: '*Here are reasons A through Z why the medicine to treat my disease ought to be on the paid formulary.*' Nor does the system allow for a patient or concerned person to submit this: '*Here are reasons A through Z why the submission you received from that other party is misleading and not credible.*' And certainly the system has not countenanced that it could make a mistake, to deserve this: '*Here are errors A through Z in your recent decision denying me treatment, and for which you should allow my appeal.*'

Although the patient's life may depend on it, there is no forum for these and other just challenges. Even a parking ticket attracts greater procedural fairness than that: at least there is a forum in provincial court where an aggrieved person can go to argue that his or her ticket was issued unfairly. How it has come to pass in Canada that access to one's lifesaving medicine obtains less procedural fairness than a parking ticket worth perhaps \$50 is beyond all possible rational explanation, and it surely is wrong.

II THE ROGERS CASE

Despite all the foregoing, some may still find it hard to believe that the courts would ever interfere with governments in the public provision of medicines. But that belief would be folly. Recall that the WHO study cited in introduction found an "increasing trend towards successful litigation" in drug access matters, and found that patients won such lawsuits more often than governments did.⁷¹ So far, Canadian case law shows no such trend, but that is not to say that the courts cannot take healthcare planners by surprise in the future. The famous *Chaoulli* case is one such example.⁷²

Until recently, Britain, like Canada, also had held off the global trend in drug benefit litigation. That changed in 2006, with the decision of the English Court of Appeal in *R. (on the application of Rogers) v. Swindon NHS Primary Care Trust*.⁷³ This case, which took the English government by surprise, clearly shows that drug benefit decisions are subject to judicial review just the same as other government actions.

Ann Marie Rogers was diagnosed with early stage breast cancer, of a genetic type known as HER2-positive. Her physician proposed to treat her with a new and innovative monoclonal antibody, called

⁶⁸ Scott R. Berry *et al.*, "The Effect of Priority Setting Decisions for New Cancer Drugs on Medical Oncologists' Practice in Ontario: A Qualitative Study" (2007) 7 BMC Health Services Research.

⁶⁹ *Ibid.* at 3.

⁷⁰ *Ibid.* at 4.

⁷¹ Hogerzeil *et al.*, *supra* note 2 at 11.

⁷² *Chaoulli v. Quebec (A.G.)*, 2005 SCC 35, [2005] 1 S.C.R. 791 [*Chaoulli*].

⁷³ *R. (on the application of Rogers) v. Swindon NHS Primary Care Trust*, [2006] EWCA Civ 392 [*Swindon*].

trastuzumab (also known by the brand name, Herceptin®). At the time, trastuzumab was not approved by either Britain's drug regulatory authority or by NICE for early stage cancers, but that did not preclude Ms. Rogers's physician prescribing it "off-label" as is sometimes done. She and her doctor agreed to try trastuzumab forthwith.

While it is a general policy in England (and Canada) that off-label medicines are not paid for, it sometimes happens that emerging scientific discoveries create pressure for it to be done. Soon after Ms. Rogers was diagnosed, a breakthrough clinical trial was reported at the American Society of Oncology's annual meeting and in the *New England Journal of Medicine*, which demonstrated that trastuzumab had significant benefits in some patients having early-stage disease.⁷⁴ Energized by these results, Ms. Rogers began to buy the medicine at her own expense, and her doctor waived his fees to treat her.⁷⁵ But at £26,000 (or \$46,000) for a course of trastuzumab, Ms. Rogers soon ran out of money, and she had no choice but to stop treatment.⁷⁶

The United Kingdom government was not wholly unsympathetic to women in Ms. Rogers' plight. When the clinical trial results broke, NICE began an expedited review of the new evidence, and the Secretary of State for Health decided as an interim measure that Primary Care Trusts (PCTs) in England "should not refuse to fund Herceptin solely on the grounds of its cost."⁷⁷ The latter statement would give rise to the legitimate expectation that a woman in Ms. Rogers' shoes should be given serious consideration for access to trastuzumab.

The Swindon PCT accordingly adopted a special policy for screening women to receive trastuzumab for early stage HER2-positive breast cancer. It was decided that each patient should be evaluated on a case-by-case basis, and access to trastuzumab would be granted when "extenuating circumstances surrounding [a patient's] case ... would warrant an exception."⁷⁸ The PCT made a considerable effort to implement this policy fairly, and convened three separate hearings on Ms. Rogers' case.⁷⁹

First, the PCT sought submissions from both Ms. Rogers' oncologist and general practitioner, as to whether circumstances made her an exceptional case. Personal questions were asked, such as whether Ms. Rogers was a carer for others. The physicians' submissions emphasized that Ms. Rogers had an especially poor prognosis without the trastuzumab, but apart from that, there were no other exceptional circumstances.

The PCT then convened a panel to consider the submissions. As the Secretary of State had instructed, the panel decided that cost alone should not be a consideration and that only the presence or absence of exceptional circumstances would be the grounds for decision.⁸⁰ The panel reasoned that because Ms. Rogers was comparably ill as other HER-2 positive breast cancer patients, and did not enjoy any better of a prognosis without trastuzumab. As such, Ms. Rogers' situation was not exceptional, and trastuzumab would not be furnished.

Next, the PCT offered a right of appeal, which Ms. Rogers exercised. A fresh panel reviewed the same evidence, and rather ambivalently concluded that Ms. Rogers fell into a "grey area between unexceptional and exceptional." Stymied, the appeal panel chose not to make any decision of its own, but opted instead to refer the case to the PCT's Board.

Finally, at the Board, a decision was made. The Board reasoned that while it would not consider cost, it would insist on evidence of *individual* exceptionality before agreeing to pay for trastuzumab. As there was a *group* of women who would have a poor prognosis without trastuzumab, Ms. Rogers could

⁷⁴ *Ibid.* at para. 12.

⁷⁵ *Ibid.* at para. 4.

⁷⁶ *Ibid.* at para. 5.

⁷⁷ *Ibid.* at para. 27.

⁷⁸ *Ibid.* at para. 34. It bears digressing that in Canada, this same sort of case-by-case evaluation happens in just the same circumstance, where the medicine is not on the formulary but the physician believes it has clinical use in the specific patient.

⁷⁹ *Ibid.* The details of the three steps are summarized in Part VIII of the Court of Appeal's judgment.

⁸⁰ *Ibid.* at para. 45.

not be considered individually exceptional within that group. She was accordingly denied payment for trastuzumab by the Board.

Now, before talking about the court case, it is helpful to review the steps that were taken to this point. Ms. Rogers had applied for payment for trastuzumab on three separate occasions: to the first panel, to the appeal panel, and ultimately to the PCT's Board. Prior to these decisions, she and her doctors had been invited to make submissions, which they did do. Yet those submissions had not been persuasive in the eyes of decision-makers at any of the three levels, and so Ms. Rogers was denied her trastuzumab. Still, she had been shown an impressive degree of procedural fairness along the way—a degree of fairness, recall, which does not exist in Canada.

But fair or not, Ms. Rogers was unhappy with the result, and so she turned to judicial review. She lost in the Administrative Court, but was successful in quashing the PCT's decision in the Court of Appeal. The Lord Justices of Appeal—a bench of three men, a bit ironically, assigned to a breast cancer case—based their ruling on a single proposition of administrative law: the rule against arbitrariness, which in this instance they held was violated. Thus the Justices conducted full-blown *substantive* review of PCT's treatment refusal, not just procedural fairness review. As the Justices reasoned:

The court may not interfere with the exercise of an administrative discretion on substantive grounds save where the court is satisfied that the decision is unreasonable in the sense that it is beyond the range of responses open to a reasonable decision-maker. But in judging whether the decision-maker has exceeded this margin of appreciation the human rights context is important. The more substantial is the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable in the sense outlined above.⁸¹

As Ms. Rogers's appeal was “concerned with a decision which may be a life or death decision for the appellant,” the Justices were persuaded that, “it is appropriate ... to subject the decision to refuse funding for the treatment (and thus in practice the treatment) to rigorous scrutiny.”⁸²

The Court then proceeded to consider whether the PCT's policy was unreasonable because it was arbitrary. Certainly, the PCT erred when it omitted to define with precision what it meant by “exceptional” circumstances. That is, in a group of women all having severe early stage HER2-positive breast cancer, how would the PCT distinguish any single woman's case as “exceptional” and different from the others? The Court noted that no answer to this question could be found in either the PCT's policy or the decisions it had taken about Ms. Rogers,⁸³ and in the *dénouement* of its reasons, it wrote:

The PCT has not put any clinical or medical evidence before the court to suggest any such clinical distinction could be made. In these circumstances there is no rational basis for distinguishing between patients within the eligible group on the basis of exceptional clinical circumstances any more than on the basis of personal, let alone social, circumstances. In short, we accept [the appellant's] submission that once the PCT decided (as it did) that it would fund Herceptin for some patients and that cost was irrelevant, the only reasonable approach was to focus on the patient's clinical needs and fund patients within the eligible group who were properly prescribed Herceptin by their physician. This would not open the floodgates to those suffering from breast cancer because only comparatively few satisfy the criteria so as to qualify for the eligible group.⁸⁴

Judgment was made accordingly. Rather than order treatment, the Court quashed the PCT's decision and remitted the matter back to the PCT for redetermination. Fortunately, the PCT acted with good grace, both in speedily welcoming the Court's clarification of the law, and in giving treatment not just to Ms. Rogers but also to the other women in her situation who were not directly covered by the Court's order.⁸⁵ Ms. Rogers had won a victory for more than herself.

⁸¹ *Ibid.* at para. 56, citing in turn *R. v. Ministry of Defence, Ex p. Smith*, [1996] QB 517 at 554E, (Bingham M.R.). Compare this *dictum* to virtually the same as uttered by the Supreme Court of Canada in *Baker*, *supra* note 57.

⁸² *Ibid.* at para. 56.

⁸³ *Ibid.* at paras. 62–63.

⁸⁴ *Ibid.* at para. 81.

⁸⁵ “Woman wins Herceptin treatment court appeal” *The Independent (London)*, (12 April 2006).

CONCLUSION

This paper has tried to do three things: (1) call into question certain inequities and long-established practices of Canada's drug benefit systems, which might attract patient lawsuits; (2) demonstrate some of the illegalities and hence vulnerabilities of those systems to lawsuits, particularly those brought on administrative law grounds, and; (3) dispel the notion that litigation is an abstract or theoretical concern by showing an instructive example of it in England, which is a country whose legal and health care systems are quite similar to our own.

Two points emerge, which are of great importance.

First, the *Rogers* case encouragingly shows how one patient's insistence on her legal rights was not "selfish", or "radical", but actually entirely helpful to health system planners and to other women with breast cancer. Before the Court gave guidance, even the PCT's appeal board struggled to make sense of its own policy and waffled over whether to give treatment in the "grey area between unexceptional and exceptional". The Court's judgment did away with that, and provided secure rules to follow in the months between the revolutionary clinical trials and the conclusion of careful studies by the drug regulatory authorities and NICE. When those studies were completed, the recommendation was positive: trastuzumab became Britain's standard of care for early stage, HER2-positive breast cancer despite a £100 million (\$213 million) annual cost.⁸⁶ In retrospect, Ms. Rogers's litigation did not work at cross purposes with health policy, but merely hastened the arrival of a higher standard of care that health policymakers soon adopted.

For the cynics who believe that litigation must always harm, rather than help, priority-setting in healthcare, here is a powerful repudiation of that unwarranted and prejudiced idea.

Second, the *Rogers* decision demolishes the belief that the common law courts must approach judicial review of healthcare with timid or deferential hands. In choosing to quash the PCT's decision for unreasonableness, the English Court of Appeal, it should be noted, far exceeded the audacity of anything that might soon come about in Canada. This paper's main observation regarding provincial control of access to medicine in Canada (where the provinces are gatekeepers of the care system, much as the PCTs are in England) was that *procedural* unfairness in formulary selection left vulnerabilities that could give rise to litigation. But in England, the courts have moved beyond judicial review of procedures, into the much more controversial territory of substantive review. That is, they are quashing decisions which, although reached after a fair process, are not reasonable to the Court. The bolder approach is probably explained by the fact that in England, unlike in Canada, the procedural imperatives are already well respected. For example, Ms. Rogers was shown impeccable procedural fairness by the PCT prior to taking up litigation, and as a general matter, NICE goes to lengths that CDR has not remotely approached to involve patients and the public in decision-making.

If Canada is ever to catch up with England's positive example, either our drug access system must considerably evolve, or our courts must solve the problem by becoming less deferential, as the English courts already are. The memorable *dictum* of the Supreme Court of Canada in *Chaoulli* is worth recalling in this regard:

The government had plenty of time to act. Numerous commissions have been established ... and special or independent committees have published reports Governments have promised on numerous occasions to find a solution ... [but] it seems that governments have lost sight of the urgency of taking concrete action. The courts are therefore the last line of defence for citizens.

For many years, the government has failed to act; the situation continues to deteriorate While the government has the power to decide what measures to adopt, it cannot choose to do nothing in the face of the violation of Que-

⁸⁶ U.K., H.C., *Hansard Written Answers*, col. 2018W (13 March 2006), online: United Kingdom Parliament Publications & Records <<http://www.publications.parliament.uk/pa/cm200506/cmhansrd/vo060313/text/60313w47.htm>>; U.K., H.C., *Hansard Written Answers*, col. 45WS (12 June 2006), online: U.K. Parliament Publications & Records <<http://www.publications.parliament.uk/pa/cm200506/cmhansrd/vo060612/wmstext/60612m0001.htm#060612200097>>.

beckers' right to security. The government has not given reasons for its failure to act. Inertia cannot be used as an argument to justify deference.⁸⁷

In *Chaoulli* the Court's majority expressed impatience about keeping patients on long waiting lists for surgery. But the same judgment fits equally well as a criticism of the leisurely pace at which Canadians have had relief from other fundamental healthcare failures, such as the postcode lottery of access to cancer treatment, or the discriminatory access to enzyme replacement therapy for some patients with rare genetic diseases but not others. These problems have dogged the system for at least two decades without resolution. While courts are not the best forum for solving such issues, bureaucratic inertia and the slovenly pace of policy reform have made it so that arguably the courts are now the only remaining forum. Taking *Chaoulli* at its word, then, judges should avoid being deferential and should decide where governments have failed.

It would be better if this did not happen. Judicial intervention can be largely, if not totally, forestalled by a proactive approach to litigation risk reduction. In 2002, the Romanow Commission on the Future of Health Care in Canada recommended both a National Drug Agency and national formulary to ensure consistency of access to medicines across the country.⁸⁸ Six years later, neither of those entirely praiseworthy ideas is in fruition, or even gestation. To those two priorities of the Romanow Commission, two others are worth adding: the federal government should enforce unfailingly the *Canada Health Act* mandate that provinces must pay for in-hospital medicines; and all governments should develop a bespoke policy regarding the very costly medicines for patients with rare diseases.

If these four priorities are advanced with sincere and visible urgency, then optimistically one can expect to avoid patient-led litigation in Canada. But if they are not advanced, all indications are that litigation, including possibly very costly and disruptive litigation, is a certainty. That is the fundamental choice for governments which waits to be made.

⁸⁷ *Chaoulli*, *supra* note 72 at paras. 96–97 [footnotes omitted].

⁸⁸ Commission on the Future of Health Care in Canada, *Building on Values: the Future of Health Care in Canada* (Ottawa: 2002).

INTRA-FAMILIAL OBLIGATIONS TO COMMUNICATE GENETIC RISK INFORMATION: WHAT FOUNDATIONS? WHAT FORMS?

Gillian Nycum, Bartha Maria Knoppers, & Denise Avard*

Genetic information is not only personal information, it is also familial as well as universal. Although most individuals who undergo genetic testing report feeling some obligation to communicate their results with family members, such communication is highly context specific and will be shaped by many factors, including the type of genetic condition at issue (i.e., a single-gene or multifactorial genetic condition), familial relationships, individual personalities and perceptions of what is in the family's best interest. Moreover, the foundation and forms for such an obligation are not clear. How would such an obligation be grounded? Is it a moral obligation? Is it a legal obligation?

This article explores the possible foundations and forms for an intra-familial obligation to communicate genetic information. Possible foundations could lie in approaches to defining the genetic family and genetic information, the special obligations that arise as members of families, notions of autonomy, theories of ownership and control of genetic information, the limits of health care providers' obligations, and the role of privacy within the family.

These foundations function as justifications in some of the international, regional, and national normative documents that articulate an intra-familial obligation to communicate genetic information. These articulations do not create a binding legal obligation and can therefore be said only to acknowledge a moral obligation. Such an obligation is not created in any legislative regime worldwide and, moreover, it would be difficult to make out a claim for civil liability under Canadian common law and Quebec civil law rules. It is therefore important for policy makers to address this issue and clarify whether there is or is not a legal obligation to communicate genetic information within families. Legislation that creates a legal obligation is ill-advised as it may cause difficulties for families, given the context specificity of decision-making around intra-familial communication. Rather, such a regime should acknowledge perceived obligations and provide mechanisms for individuals and families to meet these obligations in a manner and setting that is appropriate for each family context.

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INTRODUCTION

Developments in genetics have been accompanied by, or have perhaps even instigated, a shift in medical ethics. Stalwart ethical principles of the second half of the twentieth century, such as privacy, justice, equality, equity, and above all, autonomy, are still prominent today. However, the complexity of genetic factors around common, multifactorial diseases, as well as the familial and social implications of genetic information, have given rise to new trends in ethics, namely, the emergence of the principles of reciprocity, mutuality, solidarity, citizenry, and universality.¹ One mark of this shift toward more “relational” principles is found in the growing consensus that health professionals may, in certain circumstances, justify a breach of patient confidentiality in order to inform a patient’s genetic relatives of their own genetic risk. Another possible mark is emerging in the debate that is confronted in this article: whether there are intra-familial obligations to communicate genetic risk information.

Both of these “marks” of the shift in ethics around genetics highlight the philosophically divisive task of settling on the contours of duties that arise with respect to genetic information. It has been argued that defining the very nature of genetic information is less a matter of circumscribing the information itself than contemplating an embodiment of the philosophical debate between liberalism and communitarianism.² This is because genetic information is not only personal, insofar as it reveals an individual’s unique genetic code, but also familial, because it has the potential to unveil information relevant for genetic relatives, and universal, because it imparts knowledge that is relevant for all of humanity.³

While the issue may be divisive at the level of principles, matters become even more complicated in clinics and within families. Basic tasks such as defining genetic testing, genetic information, and the genetic family are challenging enough. Accounting for familial relationships and context compounds these challenges. Although most individuals who undergo genetic testing report feeling some obligation to communicate their results with family members, such communication is highly context specific and will be shaped by many factors, including the type of genetic condition at issue (*i.e.*, a single-gene or multifactorial genetic condition), familial relationships, individual personalities, and perceptions of what is in the family’s best interest.⁴ Moreover, the foundation and forms for such an obligation are not clear. How would such an obligation be grounded? Is it a moral obligation? Is it a legal obligation?

These questions are important for several reasons. An increasing prevalence of genetic testing will result in greater awareness of genetic risk information among individuals and families. It is important to consider whether such knowledge ever gives rise to obligations so that individuals and families can prepare for the implications of genetic testing. Also in need of clarification is whether and how health professionals’ obligations to disclose to patients’ at-risk relatives intersect with individual obligations, so all are better able to understand their roles with respect to genetic information. Additionally, an increasing prevalence of direct-to-consumer (DTC) genetic testing will give rise to situations where health professionals may be absent in the genetic testing process. DTC genetic testing is a separate and complex issue that is outside the scope of this paper; nonetheless, it is important to acknowledge this development in the context of intra-familial obligations.⁵ Finally, although there is a growing body of research, and perhaps an emerging consensus, on the obligations of health

¹ Bartha Maria Knoppers & Ruth Chadwick, “Human Genetic Research: Emerging Trends in Ethics” (2005) 6 *Nature Reviews Genetics* 75.

² Dean Bell & Belinda Bennett, “Genetic Secrets and the Family” (2001) 9 *Medical Law Review* 130 at 157.

³ Bartha Maria Knoppers, “Genetic Information and the Family: Are We Our Brother’s Keeper?” (2002) 20 *Trends in Biotechnology* 85.

⁴ Gillian Nycum, Bartha Maria Knoppers & Denise Avaré, “Factors Influencing Intra-Familial Communication of Hereditary Breast and Ovarian Cancer Genetic Information” (25 March 2009) *European Journal of Human Genetics* 1.

⁵ See Kathy Hudson *et al.*, “ASHG Statement on Direct-to-Consumer Genetic Testing in the United States” (2007) 110 *Obstetrics & Gynecology* 1392 for more information on direct-to-consumer testing.

professionals with respect to genetic information⁶ and with regards to research addressing intra-familial *experiences* with communication of genetic information,⁷ very little work has addressed intra-familial *obligations* in this context.⁸

This article tackles these questions in three parts. Part I is a background discussion that defines the genetic family and genetic information. Part II is a discussion of possible *foundations* for intra-familial obligations to communicate genetic risk information according to the following components: special obligations as members of families; notions of autonomy and relational autonomy; ownership and control of genetic information; the limits of health professional obligations to communicate genetic information with patients' relatives; and the role, or possible lack thereof, of individual privacy within the family sphere. Part I and II both draw on ethics literature and international, regional, and national laws and policies. Their transdisciplinary outlook seeks to open up a range of potential definitions for the genetic family and for genetic information as it explores possible foundations for intra-familial communication obligations. Part III is a discussion of the potential *form* for such obligations as either moral or legal. It draws on national and international policy that articulates an obligation to communicate genetic information within families and it assesses whether a failure to communicate genetic information to potentially at-risk genetic relatives could give rise to a claim in civil liability in Canadian common law and Quebec civil law.

While this paper references the positions developed both through laws and regulations enacted by legislative bodies, and via policy statements issued by international non-governmental and governmental organizations, the reader is reminded of the distinction between the two. Generally, adherence to laws and regulations is enforced through the judicial system, whereas policy statements do not carry the same obligatory force. Nevertheless, as policy documents often provide rich analysis and important insight, their conclusions can shape public opinion, and may carry significant weight in the political domain.

A brief word about the terminology used in this paper is in order. *Disclosure* refers to the revealing of information that is secret by one person or group to another; it is a marked and singular event characterized by the use of language in a sender-receiver model of communication.⁹ It can also be understood as a long process of linguistic and non-linguistic signs, signifiers, and silences.¹⁰ This latter understanding is closer to *communication* as used here. Within families, communication can be complex, as members are often able to read non-verbal cues and behaviours and to gather meaning from informal or unstructured interactions. In the context of genetic risk information, "clues" such as family history information may pair up with other indicators, with the result that communication about genetic risk is nuanced. *At-risk relative*, *genetic relative*, *biological relative*, or simply *relative* are the terms used here to refer to those members of a family who are biologically related and who therefore might share some of the same genes. In contrast, *family* or *family members* refers to the family as a social unit and includes non-biologically related members.

This analysis focuses on genetic information that living adults obtain in a clinical context in Canada. The analysis does not explicitly consider obligations with respect to information about deceased adults, or information generated in the context of research. The analysis also concerns only genetic information generated as health information to the exclusion of that generated for other purposes, such as paternity testing.

⁶ Béatrice Godard *et al.*, "Guidelines for Disclosing Genetic Information to Family Members: From Development to Use" (2006) 5 *Familial Cancer* 103.

⁷ Nycum, Knoppers & Avar, *supra* note 4.

⁸ But see Ellen Wright Clayton, "What Should the Law Say About Disclosure of Genetic Information to Relatives" (1998) 1 *J. Health Care L. & Pol'y* 373; Rosamond Rhodes, "Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge" (1998) 23 *Journal of Medicine and Philosophy* 10 at 11; Lori d'Agincourt-Canning, "Experiences of Genetic Risk: Disclosure and the Gendering of Responsibility" (2001) 15 *Bioethics* 231.

⁹ Brenda J. Wilson *et al.*, "Family Communication About Genetic Risk: The Little That Is Known" (2004) 7 *Community Genetics* 15 at 16.

¹⁰ *Ibid.*

I

BACKGROUND: DEFINING THE GENETIC FAMILY AND GENETIC INFORMATION

A. Who is the “Family”?

Starting by defining the “family” in the genetics context is important because it not only aids in identifying who is at genetic risk, but it also helps define the scope of individuals to whom familial obligations, if any, may be owed. The following discussion outlines approaches to defining “family” used in Canadian family law, discusses policy documents that suggest approaches to linking “family” and “genetics”, and outlines approaches to defining the “genetic family” proposed by scholars.

There are two prevailing approaches to defining “family” used in Canadian family law. One is the biological or “formal” approach, which relies on “objective criteria” for determining family status such as relation “by blood or marriage”.¹¹ The other is the social or “functional” approach whereby family membership is based on relationships and on whether a group of individuals “as a whole act” like a family and meet the “day-to-day functions” of a family.¹² For example, while parental links may be determined solely based on biological relation, such as where DNA testing is ordered to establish filiation,¹³ they may also be based solely on social relationship, such as when step-parents are found to stand in the place of biological parents.¹⁴ The biological approach is more common historically, but the functional approach has become increasingly common in Canadian law as reconstituted families have come under the legal microscope.¹⁵ In the context of genetics, a purely social or functional approach to defining family may mean that some biological relatives will fall outside familial boundaries. A purely biological approach may omit some non-biological relatives even where genetic information may have relevance for their life plans.

Given these important distinctions between the biological and sociological definitions of the family, one can ask how the “genetic family” is defined. One approach to defining the “genetic family” links “family” to those who have an interest in the information.¹⁶ One justification for this approach is that shared biological risks create special interests with respect to the information.¹⁷ This approach is the closest that normative documents come to defining the “genetic family”. The European Commission states that “genetic testing has consequences not only for the individual, but also for relatives, including offspring.”¹⁸ The French National Consultative Ethics Committee for Health and Life Sciences agrees, opining that “[t]he results of a genetic test are not the sole concern of the [individual tested]. They also affect the whole family, ascendants, descendants, collaterals, and possibly spouses.”¹⁹ More broadly, the German Society of Human Genetics declares that information that becomes available from medical genetic studies is also “relevant to the personal health, family planning and future plans of family members and relatives.”²⁰ Finally, the Australian *Genetic Privacy and Non-Discrimination Bill* leaves the door open to great flexibility, envisioning that family “means the biological and legal relatives of an individual who may have a material interest in the genetic infor-

¹¹ Roy Gilbar, *The Status of the Family in Law and Bioethics* (Hampshire: Ashgate Publishing Group, 2005) at 60–61.

¹² See e.g. *ibid.* at 61; Philippe Jestaz, “La parenté” (1996) 41 McGill L.J. 387; Benoît Moore, “Quelle famille pour le XXI^e siècle: Perspectives québécoises” (2003–2004) 20 Can. J. Fam. L. 57 at 91–93.

¹³ See e.g. art. 535.1 C.C.Q.; *Child and Adult Support Services Regulation*, Alta. Reg. 61/2004, s. 5(1)(c).

¹⁴ *Divorce Act*, R.S.C. 1985, c. 3, ss. 2, 15, 16; *Family Law Act*, R.S.O. 1990, c. F.3, s. 1 (“child”).

¹⁵ See e.g. *Chartier v. Chartier*, [1999] 1 S.C.R. 242, 168 D.L.R. (4th) 540; *V.A. v. S.F.*, [2001] R.J.Q. 36 (C.A.).

¹⁶ Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002) at 113–129.

¹⁷ Joan Stephenson, “Ethics Group Drafts Guidelines for Control of Genetic Material and Information” (1998) 279 *Journal of the American Medical Association* 184.

¹⁸ The Independent Expert Group of the European Commission, “Ethical, Legal and Social Aspects of Genetic Testing: Research, Development, and Clinical Applications” (2004), s. 7.1.1, online: <http://ec.europa.eu/research/conferences/2004/genetic/pdf/report_en.pdf>.

¹⁹ France, National Consultative Ethics Committee for Health and Life Sciences, *Opinion No. 76 Regarding the Obligation to Disclose Genetic Information of Concern to the Family in the Event of Medical Necessity* (2003) at 2 [*Opinion No. 76*]. All Opinions are available in French online: Comité Consultatif National d’Éthique <<http://www.ccne-ethique.fr/avis.php>>.

²⁰ German Society of Human Genetics, “Position Paper of the German Society of Human Genetics” (1998) at 6.

mation of the individual.”²¹ Whereas the European Commission arguably limits interest in genetic information to biologically related relatives, the French, German, and Australian documents appear to take a broader approach to linking family and interest in genetic information. The French document includes the *whole* family and possibly spouses. The German document suggests that family members and relatives are separate categories. The Australian document refers to legal as well as biological relatives. While there are differences among these groups regarding the scope of the family, there appears to be a consensus within the normative literature that accepts a broad definition of the genetic family.

Conceptions of the genetic family emanating from the academic community appear to impart a dynamic dimension to the idea. Graeme Laurie categorizes interests in genetic information as follows: personal, economic, societal, and paternalistic. However, he defines “family” as a unit of biological relatives and spouses.²² With interests defined broadly, but family conceptualized narrowly, the implication is that health and medical interests prevail over other interests. An approach that gives priority to health and medical interests will not have a static family membership; such membership will instead change depending on the nature of the information, including patterns of inheritance and disease penetrance, meaning the probability that an individual carrying a given genetic mutation will go on to develop the disease. There may be less medical interest in awareness of risk for conditions like Huntington’s Disease (HD), a serious, non-preventable disease with 100% penetrance, than there is for a condition like genetic breast cancer, which has less than 100% chance of disease onset and for which surveillance and prevention measures are available. However, non-medical interests, such as financial planning, may be associated with a serious degenerative disease such as HD. Additionally, family membership premised on medical interest may change based on the life stage of the informee. For example, if the informee is too young or too old to be considered at risk of developing the genetic condition associated with a mutation, he or she may be perceived as lacking a medical interest in the information. Finally, defining interest in a purely medical way leads to difficulties since it requires a deep understanding of the complexities of genetic information. Such an understanding typically exceeds the capabilities of the general population.

Roy Gilbar critiques Laurie’s approach and argues that defining the genetic family based on medical interest limits one’s understanding to biology or formalism.²³ Gilbar advocates in favour of a biosocial definition of the genetic family, where both biology and social relationships play a role, but argues that if there is no social relationship whatsoever, recognition of genetic family status cannot come out of biology alone.²⁴ This approach causes difficulties. For example, Gilbar flags the issues that arise in cases where a child who discovers he has a genetic mutation was raised by his mother and has no relationship with his biological father.²⁵ However, Gilbar may be too restrictive in his definition of a social relationship. If the child in his example was conceived naturally, the mother is likely to know the identity of the father. This awareness may suffice to ground a biosocial relationship and establish the father as a member of the child’s genetic family. This scenario stands in contrast to situations of artificial insemination where the sperm donor’s identity is unknown; in such cases, paternity is not recognized.²⁶

Defining the “genetic family” based on who has an interest in genetic information may represent less of a challenge for policy makers, legislators, and health care providers if *interest* is defined broadly. Loose categories for defining interest could include: reproductive risk management, personal risk management, and management of family history. Reproductive risk management would include awareness of the potential for reproductive risk and planning to manage the risk accordingly. Personal risk management is a broader interest category and can include everything from health and

²¹ *Genetic Privacy and Non-Discrimination Bill 1998* (Cth.), s. 7 [*Genetic Privacy Bill*].

²² Laurie, *supra* note 16 at 114–117.

²³ Gilbar, *supra* note 11 at 65.

²⁴ *Ibid.* at 67–68.

²⁵ *Ibid.* at 68.

²⁶ See art. 538.2 C.C.Q where it states that the contribution of genetic material to a “third party parental project” does not create a bond of filiation unless the material was provided by sexual intercourse.

lifestyle management, to financial management and life planning, to family care management. Finally, management of family history involves awareness of genetic risk in the family and ensuring that the information is managed appropriately and in accordance with the needs and values of the family as a whole as well as with those of individual members.

B. What is “Genetic Information”?

Like defining “genetic family”, characterizing “genetic information” in one way or another can form the basis of arguments for or against communication obligations. Obligations to communicate within families follow more readily from characterizations of genetic information as distinct from other kinds of personal information in that it is shared between genetic relatives and belongs to the kinship. If unique, and uniquely shared, this may justify a special legal and ethical regime for genetic information.²⁷ A contrary view characterizes genetic information as no different from other forms of medical information, and thus properly regulated using existing regimes for medical or health information.²⁸

This section begins by highlighting the difficulties in defining precisely what is included within the ambit of the term “genetic information”, including whether family history information is or should be included therein. Then, various characterizations of genetic information found in Canadian law and policy, as well as selected national, regional, and international laws and policies are discussed.

1. Defining Genetic Information

What kinds of information are included in the phrase “genetic information”? Is genetic information strictly the result of DNA or other tissue testing as implied in normative documents from UNESCO,²⁹ Australia,³⁰ Switzerland,³¹ and Israel?³² Or, might it be broader and also include any information that points to hereditary characteristics in an individual or related individuals as implied in documents from the Council of Europe,³³ the European Commission,³⁴ the United Kingdom,³⁵ the United States,³⁶ Luxembourg,³⁷ and Estonia.³⁸ Of particular concern is whether family history information falls into the category.

A step back to consider how “genetic testing” is defined may be of assistance. In a recent document, the European Commission’s Eurogentest, discussed a narrow and a broad definition of genetic testing.³⁹ The narrow definition is based on the *methods used* to obtain genetic information, for example DNA assay testing, protein analysis, or constructing a family pedigree from family history information.⁴⁰ The broad definition is based on the *information generated* by the test. If the informa-

²⁷ Loane Skene, “Patients’ Rights or Family Responsibilities? Two Approaches to Genetic Testing” (1998) 6 Med. L. Rev. 1 at 35.

²⁸ Bell & Bennett, *supra* note 2 at 158.

²⁹ UNESCO International Bioethics Committee OR, 32d Sess., 20th Plen. Mtg., UN Doc. 32 C/Res. 22 (2003) 39, art. 2(i).

³⁰ *Genetic Privacy Bill*, *supra* note 21 art. 8(1).

³¹ *Loi fédérale sur l’analyse génétique humaine*, R.S. 810.12, 8 October 2004, art. 3(l).

³² *Genetic Information Law*, 5761–2000, 13 December 2000, art. 2.

³³ Council of Europe, Committee of Ministers, *Recommendation R(97)5 on the Protection of Medical Data* (1997) 39 Inf. Bull., art. 1.

³⁴ EC, Data Protection Working Party, *Working Document on Genetic Data*, [2004] 12178/03/EN WP91, art. 2.

³⁵ U.K., Human Genetics Commission, *Balancing Interests in the Use of Personal Genetic Data* (May 2002) at 26, online: <<http://www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation.pdf>>.

³⁶ U.S., Bill H.R. 493, *Genetic Information Non-Discrimination Act of 2008*, 110th Cong., 2008, s. 101 (d)(6)(A) [*Genetic Information Act*].

³⁷ *Loi no. 91 du 2 août 2002 relative à la protection des personnes à l’égard du traitement des données à caractère personnel*, J.O., 13 August 2002, 1835, art. 2(g).

³⁸ *Human Genes Research Act 2001*, RT I, 13 December 2000, at art. 2(9).

³⁹ Jorge Sequeiros & Bárbara Guimarães, “Definitions of Genetic Testing”, 3rd draft (2007) Eurogentest, online: Eurogentest <<http://www.eurogentest.org/web/files/public/unit3/DefinitionsGeneticTesting-3rdDraf18Jan07.pdf>>.

⁴⁰ This approach was adopted by the Council of Europe in the *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Genetic Testing for Health Purposes*, Council of Europe, 27 November 2008, Eur. T.S. 164, at

tion generated reveals genetic risk, the test is properly defined as a genetic test. Using the broad definition, genetic risk revealed through the collection of family history would constitute genetic information.

Whether family history is classified as genetic information can impart significant consequences on how it is shared. Like genetic test results, family history information may reveal a previously unknown genetic risk for specific individuals in a family. This means that family history information, like genetic information, may make individuals and families vulnerable to discrimination on the basis of future health status,⁴¹ and has led to efforts in the United Kingdom to protect against insurance discrimination based on family history.⁴² Moreover, the informed consent requirements that apply to genetic testing may not apply to the collection of family history information.⁴³ For those who are unaware of the predictive implications of family history, a more stringent informed consent process for the collection of family history information may be required.⁴⁴

There are also implications inhering in the *source* and the *certainty* of the information at issue. Family history information is revealed in many ways: through day-to-day family life, through intra-familial communication of health information, and through active seeking of family history. The information obtained is often incomplete or inaccurate, as patterns of communication within families are influenced by complex factors.⁴⁵ In comparison, information that results from DNA testing has a clearer source: the individual tested. The results may be inconclusive or may reveal a multifactorial condition, which perforce entails some degree of uncertainty. This uncertainty, however, is medical; it does not stem from complex family relationships and communication. This is not to suggest that one form of uncertainty is somehow preferable to the other; but it is important to consider whether the same obligations arise with respect to these two sources of information.

The complex relationship between genetic information and family history information is a topic that requires additional consideration. For simplicity, this article will not distinguish starkly between family history information and genetic information: we will adopt the broad definition of genetic testing, which is based on the *information generated* by the test.

2. Characterizing Genetic Information

Similar difficulties arise when it comes to characterizing genetic information, as it does not fall naturally into any established legal category. Although it is *personal*, it also possesses characteristics of shared, familial, and universal information. As a result, the views of legislative and policy documents regarding the confidential nature of genetic information fall along a continuum. At one end of the spectrum, some bodies consider that genetic information is like any other type of personal information and should be treated likewise. At the other end, some groups deem genetic information to be unique, and thus recommend the reexamination of the extent of the confidential status granted to it. In between, we find bodies that hold no specific position regarding the nature of genetic information. Here we review the current Canadian federal and provincial legislated positions regarding genetic information before turning our attention to the perspectives adopted in policy documents worldwide.

Canadian provincial and national laws only rarely offer explicit characterizations of genetic information. Where they do mention it, they often lack clarity. In Alberta, the *Freedom of Information And Protection of Privacy Act (2000) (FIPPA)* defines “personal information” as “recorded information about an identifiable individual, including... the individual’s fingerprints, other biometric information, blood type, genetic information, or inheritable characteristics.”⁴⁶ This definition would seem

art. 2.

⁴¹ Dagmar Schmitz & Urban Weising, “Just a Family Medical History?” (2006) 332 *British Medical Journal* 297; Anneke Lucassen, Michael Parker & Robert Wheeler, “Implications of Data Protection Legislation for Family History” (2006) 332 *British Medical Journal* 299.

⁴² U.K., Human Genetics Commission, *supra* note 35 at 121ff.

⁴³ Schmitz & Weising, *supra* note 41 at 298.

⁴⁴ *Ibid.*

⁴⁵ Nycum, Knoppers & Avard, *supra* note 4.

⁴⁶ *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25, art. 1(n)(vi) [FIPPA].

to include both the results of DNA testing as well as family history information under the umbrella of *personal* information. Interestingly, however, the *FIPPA* includes health information in its definition of personal information, but on a separate subsection.⁴⁷ This suggests that genetic information falls into a category of personal information different from the category into which health information falls. Also in Alberta, the *Health Information Act (HIA)* defines “health information” as “diagnostic, treatment and care information,”⁴⁸ which is further defined, *inter alia*, as “any [...] information about an individual that is collected when a health service is provided to the individual.”⁴⁹ This is a very broad definition and would quite reasonably include information derived from genetic testing. Given these inconsistencies between *FIPPA* and *HIA*, the Alberta information protection regime does not provide a clear indication as to whether genetic information should be considered similar to other health information or treated as unique and thus meriting special consideration with regards to confidentiality.

Elsewhere in Canada, however, more coherent views have emerged. For example, in Manitoba the *Personal Health Information Act* and the *Freedom of Information and Protection of Privacy Act* adopt consistent positions with regards to health information where personal health information is defined as “recorded information about an identifiable individual that relates to the individual’s health, or health care history, including genetic information about the individual.”⁵⁰ Further, the federal *Assisted Human Reproduction Act* also includes genetic information in its definition of “health reporting information”,⁵¹ an approach taken up by the Council of Europe in its definition of “medical data”, and by the Australian legislature in its definition of “health information”.⁵² The implication is that genetic information is to be treated similarly to health information generally.

While they are aware of the distinction between the two, some policymaking bodies have adopted a classification for genetic information that is similar to the one they use for medical information. For example, the Manitoba position is reflected in the guidelines of the Canadian Medical Association (CMA) that state that

[h]ealth information’ means any information about a patient that is confided or collected in the therapeutic context, including information created or generated from this information and information that is not directly or indirectly linked to the provision of health care.⁵³

This broad definition of health information would seem to include genetic information as equivalent to other medical information. For the purpose of confidentiality protections, the CMA makes no exception for genetic information: “information about oneself is considered worthy of protection against use or disclosure despite its potential benefit to others for example, genetic information or HIV, Hepatitis C status.”⁵⁴ Likewise, the Canadian College of Medical Geneticists (CCMG) and the American Society of Human Genetics (ASHG) do not differentiate between medical and genetic information when it comes to confidentiality protections. The ASHG states that for the purposes of confidentiality, “genetic information should be considered as medical information.”⁵⁵ However, it goes on to recognize that genetic information is “both individual and familial in nature,”⁵⁶ thus differentiating genetic information from health information.

⁴⁷ *Ibid.*

⁴⁸ *Health Information Act*, R.S.A. 2000, c. H-5, art. (1)(k)(i) [*HIA*].

⁴⁹ *Ibid.* art. (1)(i).

⁵⁰ *Personal Health Information Act*, S.M. 1997, c. S1, C.C.S.M. c. P33.5, s.1; *Freedom of Information and Protection of Privacy Act*, S.M. 1997, c. S1, C.C.S.M. c. F175, s. 1.

⁵¹ *Assisted Human Reproduction Act*, S.C. 2004, c. 2, art. 3(a).

⁵² *Privacy Act 1988*, (Cth.), s. 6.

⁵³ Canadian Medical Association, *Health Information Privacy Code (1998)*, s. B (“health information”), online: Canadian Medical Association <http://www.cma.ca/index.cfm/ci_id/3216/la_id/1.htm>.

⁵⁴ Canadian Medical Association, “Listening to our Patient’s Concerns: Comments on Bill C-54”, Submission to the House of Commons Standing Committee on Industry (18 March 1999).

⁵⁵ American Society of Human Genetics, Social Issues Subcommittee on Familial Disclosure, “Professional Disclosure of Familial Genetic Information” (1998) 62 *American Journal of Human Genetics* 474 at 474.

⁵⁶ *Ibid.* at 476.

Other policy approaches also acknowledge that genetic information has special characteristics while endorsing strict confidentiality protections. UNESCO's International Declaration on Human Genetic Data states that genetic information has special status because of its impact on the family, offspring, and future generations,⁵⁷ yet the regime uses a standard medical confidentiality approach for genetic information.⁵⁸ Similarly, the European Commission acknowledges public perceptions that genetic information is somehow special, but also states that genetic information should have equivalent confidentiality protection as other comparably sensitive medical data.⁵⁹

By contrast, other international policy documents acknowledge that the special nature of genetic information with respect to family members requires an exceptional stance when considering the regulation of its confidentiality. The Human Genome Organisation (HUGO) maintains that "special considerations should be made for access [to genetic information] by immediate relatives"⁶⁰ and the HUGO Ethical, Legal and Social Issues (ELSI) Committee finds that although confidentiality must be protected, special considerations may be needed to protect the "actual or potential" interests of family members.⁶¹ The UK's Nuffield Council has stated that if genetic information is to be treated with special status, this should be limited to information about monogenic conditions and not extended to genetic information generally.⁶²

Finally, some documents are explicit as to the unique or shared nature of genetic information. The World Health Organization (WHO) put forth the view that genetic information gives rise to unusual situations by virtue of being "both uniquely personal and the shared property of families."⁶³ The WHO also supports the view that in some genetics cases, the "true patient" may be the family.⁶⁴ Similarly, the European Commission believes that genetic information has characteristics that make it singular, namely, its family dimension, which transforms it into a form of shared information.⁶⁵ In Australia, the National Health and Medical Research Council (NHMRC) acknowledges that genetic information is "distinguished from other medical information in that it can potentially provide information about people other than the individual concerned."⁶⁶ The 2008 U.S. *Genetic Information Non-Discrimination Act* includes genetic information about "the genetic tests of family members" in its definition of information about the individual.⁶⁷

As indicated above, while current legislative positions in Canada appear to favour the notion that genetic information is subject to the same regime of confidentiality as other types of personal health information, efforts aimed at acknowledging the limitations associated with this view are underway. Ontario's Provincial Advisory Committee on New Predictive Genetic Technologies asserts that genetic information "brings the ethical, legal and social issues involved in the use of health information to a different level." It adds that the information's familial implications complicate the rules regarding third-party notification and give rise to ethical dilemmas.⁶⁸ At the federal level, on the other

⁵⁷ UNESCO International Bioethics Committee OR, *supra* note 29, s. 4; see also *Report on Confidentiality and Genetic Data*, UNESCO OR, 2000, BIO-503/99/CIB-6/GT-2/3 at 4.

⁵⁸ UNESCO International Bioethics Committee OR, *ibid.*, s. 14.

⁵⁹ EC, *25 Recommendations on the Ethical, Legal and Social Implications of Genetic Testing* (Brussels: EC, 2004), art. 10.

⁶⁰ Human Genome Organization, "HUGO Ethics Committee Statement on DNA Sampling: Control and Access" (1998) 8 *Eubios Journal of Asian and International Bioethics* 56, online: Human Genome Organization <<http://www.eubios.info/HUGO2.htm>>.

⁶¹ Human Genome Organization, "Statement on The Principled Conduct of Genetic Research" (1996) 6 *Eubios Journal of Asian and International Bioethics* 59, online: Human Genome Organization <<http://eubios.info/HUGO.htm>>.

⁶² Nuffield Council on Bioethics, *Pharmacogenetics Ethical Issues* (London: Nuffield Council on Bioethics, 2003) at paras. 3.43, 5.34–5.35, online: Nuffield Council on Bioethics <http://www.nuffieldbioethics.org/fileLibrary/pdf/pharmacogenetics_report.pdf>.

⁶³ D.C. Wertz, J.C. Fletcher & F.K. Berg, *Review of Ethical Issues in Medical Genetics*, WHO/HGN/ETH/00.4 (2003) at 50, online: WHO <http://www.who.int/genomics/publications/en/ethical_issuesin_medgenetics%20report.pdf>.

⁶⁴ *Ibid.*

⁶⁵ EC, Data Protection Working Party, *supra* note 34 at 4.

⁶⁶ Austl., National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: An Information Paper* (Canberra: Commonwealth of Austl., 2000) at 48.

⁶⁷ *Genetic Information Act*, *supra* note 36, s. 101(d)(6)(A).

⁶⁸ Ontario Provincial Advisory Committee on New Predictive Genetic Technologies, *Genetic Services in Ontario: Map-*

hand, the Canadian Biotechnology Advisory Committee has stated that while familial issues in genetics are important, “family relevance of genetic information *per se* does not make genetic information unique.”⁶⁹

While efforts to acknowledge the unique nature of genetic information are laudable, we should understand the consequences of conceiving of genetic information as shared. There are at least two alternative implications. Either relatives of patients are themselves data *subjects* and as such have personal rights with respect to the information, or relatives have not *rights* but *interests*, which are limited to instances when the genetic information is relevant to their own health and future life.⁷⁰ The former would correspond with the view that the true patient in genetics may be the family.⁷¹ This approach subverts the individual as the *source* of the information,⁷² either by having his or her own tissue tested or by providing a family history, and arguably fails to account for the *personal* or *individual* aspect, alongside the *familial* aspect, of the information. This approach may also imply that the consent of relatives is required before generating genetic information, a requirement whose complexity threatens to bar access to genetic services in most cases.⁷³ For these reasons, the second interpretation of the “shared information” perspective, which de-emphasizes relatives’ rights and embraces their interests, may be preferable.

II

THE BASES OF INTRA-FAMILIAL OBLIGATIONS TO COMMUNICATE GENETIC INFORMATION

As noted above, who is the “genetic family” and what is “genetic information” can point to bases for intra-familial obligations to communicate genetic information. Who is considered a genetic family member will determine the range of family members to whom such an obligation is owed. Some characterizations of genetic information are more amenable to communication obligations than others. This section explores other possible bases for intra-familial communication obligations, including the following: special obligations as members of families; notions of autonomy and relational autonomy; ownership and control of genetic information; the limits of health professionals’ obligations to communicate genetic information to relatives; and the role, or possible lack thereof, of individual privacy within the family sphere.

A. Special Obligations to Communicate Genetic Information as Members of Families

Being a member of a family incurs certain rights as well as duties with respect to other members of that family.⁷⁴ Some of these rights and duties are moral, and some are legally mandated. Is there a right to be informed of familial genetic information and a corresponding duty to communicate such information to family members? What might be the justification for such an obligation and its possible contours? The following discussion takes up these questions.

Several international normative documents that address genetic information ground the moral obligation to communicate genetic information on the kinship bond and on an assumed desire to protect family members.⁷⁵ This is primarily a moral obligation between family members. As dis-

ping the Future (2001) at 27, online: Ontario Legislative Assembly <<http://www.ontla.on.ca/library/repository/mon/3000/10301455.pdf>>.

⁶⁹ Trudo Lemmens & Lisa Austin, Canadian Biotechnology Advisory Committee, *Of Volume, Depth and Speed: The Challenges of Genetic Information* (Ottawa: Industry Canada, 2001) at 23, online: Industry Canada <[http://strategis.ic.gc.ca/eic/site/cbac-cccb.nsf/vwapj/GenInfo_Challenges_Lemmens_e.pdf/\\$FILE/GenInfo_Challenges_Lemmens_e.pdf](http://strategis.ic.gc.ca/eic/site/cbac-cccb.nsf/vwapj/GenInfo_Challenges_Lemmens_e.pdf/$FILE/GenInfo_Challenges_Lemmens_e.pdf)>.

⁷⁰ EC, Data Protection Working Party, *supra* note 34.

⁷¹ Wertz, Fletcher & Berg, *supra* note 63 at 50.

⁷² Bell & Bennett, *supra* note 2 at 132.

⁷³ Michael Parker & Anneke Lucassen, “Concern for Families and Individuals in Clinical Genetics” (2003) 29 *Journal of Medical Ethics* 70 at 72.

⁷⁴ Gilbar, *supra* note 11 at 70.

⁷⁵ Laura E. Forrest *et al.*, “Communicating Genetic Information in Families—A Review of Guidelines and Position Papers” (2007) 15 *European Journal of Human Genetics* 612 at 615 [emphasis added, Laura E. Forrest *et al.*, “Communicating”].

cussed in more detail below,⁷⁶ legal obligations between parents and children, as well as spouses, and obligations to care for dependent adults are typically limited to alimentary support; however, they are sometimes broader than this and can include non-financial obligations. There is no legal grounding for obligations between other family members, although one scholar has argued that siblings owe each other respect and care that would be breached by a failure to communicate genetic information.⁷⁷

In the context of genetic information, one justification for special family obligations is that although only one family member obtains it in the course of testing or treatment, it has implications for the entire family. If genetic testing is predictive rather than diagnostic, the patient's account of her family history may have given away clues about the possibility of a genetic risk in the first place. Information about genetic relatives will typically be collected as part of a pre-test consultation,⁷⁸ and a family history may be needed to supplement test results, to make them meaningful, or to confirm a diagnosis.⁷⁹ Once a treating physician generates genetic information on behalf of an individual by any means, the new knowledge may have health implications for other genetic relatives and future generations.⁸⁰ Thus, family ramifications exist and matter both at the outset and in the aftermath of genetic testing. In this way, the familial implications of genetic information are full circle, appearing at every stage of the genetic investigation. Indeed, direct family involvement is often needed for genetic testing to be effective.⁸¹

Real life perceptions of who is "family", and the corresponding perceived obligations to share information with identified family members, are often determined by social relationship rather than by biological relationship.⁸² Moreover, lay knowledge about genetic inheritance is often inconsistent with Mendelian patterns of inheritance,⁸³ giving rise to difficulties in identifying at-risk genetic relatives. Often, but not always, there is no sense of obligation to communicate with (biological) family members with whom there is no, or a distant, relationship.⁸⁴ The lack of moral impulse in the absence of a social relationship mirrors the biosocial approach to defining the genetic family suggested by Gilbar and discussed above.⁸⁵

Rosamond Rhodes refutes the moral obligation to communicate genetic information on the basis of genetic ties, noting that although human beings are genetically similar to mice, we do not feel the same moral obligations to mice as we do to fellow human beings.⁸⁶ Rhodes argues that moral responsibility comes out of intimacy, dependency, a history of interactions, and the current context.⁸⁷ It follows from this view that distance in a relationship might weaken the moral obligations shared between the parties, even among genetic relatives. Rhodes nonetheless makes room for certain instances where obligations may be based on biology alone, such as legally enforceable support obligations. She also allows for moral obligations arising in situations where an individual with genetic information may be the sole source of an indication of genetic risk. Ultimately for Rhodes, as well as

⁷⁶ See part III, section 2, below.

⁷⁷ Charles Weijer, "Family Duty is More Important than Rights" (2000) 321 *British Medical Journal* 1466 at 1466.

⁷⁸ Skene, *supra* note 27 at 6–7.

⁷⁹ This may play out for example in the context of hereditary breast and ovarian cancer, where it may be necessary for family members to undergo genetic testing in order to verify a patient's risk or to clarify the meaning of the results. See Beth N. Peshkin *et al.*, "BRCA 1/2 Testing: Complex Themes in Result Interpretation" (2001) 19 *Journal of Clinical Oncology* 2555 at 2556.

⁸⁰ Bell & Bennett, *supra* note 2 at 156; Skene, *supra* note 27 at 40.

⁸¹ Robert J. Moss, Shelly A. Cummings & Mary B. Mahowald, "Genetic Testing as a Family Affair" in Mary B. Mahowald *et al.*, eds., *Genetics in the Clinic: Clinical, Ethical, and Social Implications for Primary Care* (St. Louis: Mosby, 2001) 189 at 192–3.

⁸² Nycum, Knoppers & Avard, *supra* note 4.

⁸³ Martin Richards, "Families, kinship and genetics" in Theresa Marteau & Martin Richards, eds., *The Troubled Helix: Social and Psychological Implications of the New Human Genetics* (Cambridge: Cambridge University Press, 1996) at 268.

⁸⁴ Nycum, Knoppers & Avard, *supra* note 4.

⁸⁵ See part I, section A, above.

⁸⁶ Rhodes, *supra* note 8 at 21.

⁸⁷ *Ibid.*

for other scholars, obligations around genetic information will depend primarily on the multiple contextual factors of any given situation.⁸⁸

Proximity, be it social or biological, might help delineate intra-familial obligations to communicate genetic information. Communication around genetic risk information is often considered a parental responsibility.⁸⁹ For example, aunts and uncles may not inform nieces and nephews of their risk directly. Rather, the communication of genetic risk will be left to their siblings—the parents.⁹⁰ This could be done out of respect for intimate family relationships and to avoid the appearance of usurping parental authority.⁹¹ This scenario offers plausible contours for intra-familial obligations to communicate genetic information: sharing information with members of one's own nuclear family could exhaust obligations by transferring them to the sphere of another nuclear family. Within these boundaries, once communication with a sibling occurs, communication within the sibling's nuclear family becomes the sibling's own responsibility. This would apply similarly in the context of disclosure to aunts and uncles by proceeding through a parent.⁹² These parameters both respect the perceived intimacy of the nuclear family and place a limit on the obligations to disclose genetic information within families. At the same time, they are problematic given that “nuclear” families are uncommon and that family constitutions extend well beyond the limits of the so-called nucleus.

Another basis for obligations to communicate genetic information within families is the notion of assumed obligations. These are the obligations that parents undertake toward their children because failure to do so might cause harm to the child. The parents' obligations are “assumed” because they flow from the fact that the parents chose to bring the child into the world.⁹³ As such, assumed obligations on this basis do not extend to other family relationships. It is worth noting, however, that, particularly in the case of minor children, the communication of genetic risk information may not lead to any immediate benefit for the child, especially where the information relates to adult-onset conditions. Moreover, such communication may cause harm to the child by leading to negative social, financial, and psychological consequences.⁹⁴

In sum, rationales to impose special obligations to communicate genetic information on family members may be based on perceptions of who has an interest in the information and is therefore owed a duty. These perceptions often stem from social rather than biological relationships. While the drawbacks of a strictly social approach to defining the genetic family are that this may leave interested biological relatives uninformed, a strictly biological approach could give rise to obligations to distant relatives with whom there is no contact or relationship whatsoever. In some cases, the nuclear family and the assumed obligations of parents toward their children may create useful contours for the intra-familial obligation to communicate genetic information. In all cases where context points to communication obligations however, the issue of the autonomy of those possessing genetic information arises.

B. Autonomy as a Ground for Communication or Non-Communication

The notions of individual autonomy that are valued within the legal and democratic societies can represent a challenge for policy makers and health care providers in the context of genetics. In Western society, autonomy has developed as an individual right and the “group” nature of claims con-

⁸⁸ *Ibid.* at 25; d'Agincourt-Canning, *supra* note 8.

⁸⁹ Karen Forrest Keenan *et al.*, “It's Their Blood not Mine': Who's Responsible for (Not) Telling Relatives About Genetic Risk?” (2005) 7 *Health, Risk & Society* 209; Karen Forrest *et al.*, “To Tell or Not to Tell: Barriers and Facilitators in Family Communication About Genetic Risk” (2003) 64 *Clinical Genetics* 317 [Karen Forrest *et al.*, “Barriers”].

⁹⁰ Keenan *et al.*, *ibid.*

⁹¹ Keenan *et al.*, *ibid.* at 216.

⁹² Josephine Green *et al.*, “Family Communication and Genetic Counseling: The Case of Hereditary Breast and Ovarian Cancer” (1997) 6 *Journal of Genetic Counseling* 45 at 51.

⁹³ Lori Andrews, “Gen-Etiquette: Are There Moral and Legal Responsibilities to Share Genetic Information Within Families?” in Mark Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997) at 258.

⁹⁴ Andrea Farkas Patenaude, Karine Sénécal & Denise Avard, “Whither Pediatric Research and Predisposition Genetic Testing?” (2006) 4:2 *GenEdit* 1 at 2.

cerning family information poses a serious conceptual threat to this paradigm.⁹⁵ On the one hand, it has been argued that an emphasis on individual autonomy, particularly in medical law and ethics, is paradoxical in the context of the genetic family, which has nothing to do with choice.⁹⁶ It has also been argued that an emphasis on individual autonomy as a root of moral decision-making renders the genetic family amoral because biological relationships are not freely chosen. One scholar has observed that the effect is that the moral solidarity of families has been de-emphasized as individual autonomy has flourished as an ethical value.⁹⁷ On the other hand, within theories such as Gilbar's notion of the biosocial family, there may indeed be a significant amount of choice. After all, you cannot choose with whom you are biologically related, but culture and society allow room to be selective with respect to whom one considers "family".⁹⁸ As a result, neither view of individual autonomy adequately addresses the issue of how to approach the obligation to share genetic information.

Authors have cited problems with the concept of autonomy regarding genetic information as it applies to women and their role within families. In a study by Hallowell and colleagues, women who had been diagnosed with breast cancer were motivated to undergo BRCA1/2 genetic testing to provide genetic risk information for their family members. This was done so as to facilitate relatives' autonomous decision-making around their own genetic risk, rather than so as to benefit the women themselves.⁹⁹ This sense of obligation to generate genetic information for the benefit of family members may mean that the decision to undergo genetic testing is not fully autonomous.¹⁰⁰

However, this concern may come out of an overly simplistic view of autonomy within family relationships. Theories of relational autonomy, which take relationships and context into consideration, may be better suited to the matter of genetic information-sharing within families. Susan Sherwin has argued that rather than conceiving of autonomy in abstract, absolute terms, the concept of relational autonomy takes stock of the political, social, interpersonal, and other types of factors that influence one's ability to make an autonomous decision.¹⁰¹ Emphasizing the autonomy of individuals as isolated entities, as opposed to individuals as part of relationships, fails to account for the complexities of decision-making. In the context of health care, "many decision makers, especially women, place the interests of others at the center of their deliberations."¹⁰² In so doing, these decision makers do not demonstrate a fully realized (and possibly unattainable) individual autonomy, but are still making deliberate choices that embody their agency.¹⁰³ Martha Minow argues that conceiving the patient by highlighting the importance of the patient's relationship with others does not infringe individual autonomy. Individual autonomy, she says, is rightly reconceived in light of patients' relationships with others because it *includes* interpersonal relationships, rather than existing around them or in spite of them.¹⁰⁴ Similarly, Gilbar argues that in deliberating over whether to communicate genetic information with family members, it should be recognized that decisions will affect the maintenance of relationships and the family environment and will therefore have an impact not only for relatives, but also for those who initiate communication.¹⁰⁵ To put it another way, relational autonomy locates the "costs and benefits associated with disclosure of genetic information within the context of people's everyday lives."¹⁰⁶

⁹⁵ Laurie, *supra* note 16 at 4.

⁹⁶ Kaja Finkler, Cecile Skrzynia & James P. Evans, "The New Genetics and its Consequences for Family, Kinship, Medicine and Medical Genetics" (2003) 57 *Social Science & Medicine* 403.

⁹⁷ Janet Dolgin, "Choice, Tradition, and the New Genetics: The Fragmentation of the Ideology of Family" (2000) 32 *Conn. L. Rev.* 523.

⁹⁸ Andrews, *supra* note 93 at 257.

⁹⁹ N. Hallowell *et al.*, "Balancing Autonomy and Responsibility: The Ethics of Generating and Disclosing Genetic Information" (2003) 29 *Journal of Medical Ethics* 74.

¹⁰⁰ *Ibid.* at 78.

¹⁰¹ Susan Sherwin, "A Relational Approach to Autonomy in Health Care", in Susan Sherwin, ed., *The Politics of Women's Health: Exploring Agency and Autonomy* (Philadelphia: Temple University Press, 1998) at 19.

¹⁰² *Ibid.* at 34.

¹⁰³ *Ibid.*

¹⁰⁴ Martha Minow, "Who's the Patient?" (1994) 53 *Md. L. Rev.* 1173 at 1173-74.

¹⁰⁵ Gilbar, *supra* note 11 at 72.

¹⁰⁶ d'Agincourt-Canning, *supra* note 8 at 237.

Relational autonomy may provide an adequate explanation for feelings of moral obligations toward family, but it also risks placing exclusive focus on social relationships. An ideal approach to autonomy in this context may be one where notions of individual autonomy are balanced against relational or communitarian notions.¹⁰⁷ Angela Davey has proposed “family comity”—or, considerate behavior toward family members—as an alternative guiding principle that would recognize relational autonomy and social responsibility as inhering in genetic information because of its hereditary nature.¹⁰⁸ In this way, comity is a counterbalance to autonomy and requires that individual interests be checked in order to respect the interests of others. “Family comity” may therefore be one way to balance individual and relational notions of autonomy.

C. Ownership or Control of Genetic Information

Another way of grounding intra-familial obligations to communicate genetic information focuses on who owns or controls such information and who may have access to it. There are few laws and policies that create or discuss ownership or property rights with respect to genetic information. In Canada, medical information is treated as belonging to the individual while the medical record itself belongs to the physician or hospital where it is kept. Patients have rights of access to their information except in unusual circumstances where allowing access would be inappropriate or dangerous.¹⁰⁹ Because the genetic information contained in a medical record is also “related” to the patient’s relatives, it is arguable that the relatives could also be considered to “own” the information, and as such gain access to it. Granting exclusive access rights to the patient solely because she is the *source* of knowledge unduly sidelines the relatives’ own legitimate interest in the information.¹¹⁰

Worldwide, there appears to be a wide spectrum of legislative views regarding ownership of genetic information. For example, the Icelandic government has taken the position that genetic information is a national resource and as such, there are no individual property rights with respect to it.¹¹¹ On the other hand, a few U.S. states have enacted legislation that clearly restricts ownership of genetic information to the individual tested.¹¹² Colorado legislation states that genetic information is the property of the person to whom it pertains.¹¹³ This is more ambiguous because the information could *pertain* to genetic relatives.

Policy making bodies, however, appear to favour a broad view of ownership of genetic information, one that does not place access to the information solely in the hands of the individual tested. The Human Genetics Society of Australasia puts forth that “information about the gene mutation *belongs* to all blood relatives,”¹¹⁴ and the Australian National Health and Medical Research Council creates an individual property regime with a right of access to records of the individual tested by her relatives.¹¹⁵ In this regime, records, including tissue sent for genetic testing, are the “property of the bodies that make the records or hold the tissues.” However, “[t]he presumption should be that relatives and descendants should have access to those materials for purposes of assessment of their own risk.”¹¹⁶

The approach where multiple individuals hold rights of ownership, control, or access to genetic information is embodied in the “joint account theory” of genetic information. This theory puts forth that genetic information is owned by multiple parties. As such, the conventional model of confidenti-

¹⁰⁷ Angela Davey, Ainsley Newson & Peter O’Leary, “Communication of Genetic Information Within Families: The Case for Family Comity” (2006) 3 *Bioethical Inquiry* 161 at 164.

¹⁰⁸ *Ibid.*

¹⁰⁹ *McInerney v. MacDonald*, [1992] S.C.R. 138, 93 D.L.R. (4th) 415.

¹¹⁰ Laurie, *supra* note 16 at 93.

¹¹¹ Richard A. Spinello, “Property Rights in Genetic Information” (2004) 6 *Ethics and Information Technology* 29 at 32.

¹¹² Alaska Stat. tit. 18 § 13.010(a)(2) (2004); Fla. Stat. Ann. tit. 44 § 760.40(2)(a) (1992); Ga. Code Ann. tit. 33 § 54-1(1) (1995).

¹¹³ C.R.S.A. tit. 10 § 3-1104.7(1)(a) (2002).

¹¹⁴ Laura E. Forrest *et al.*, “Communicating”, *supra* note 75 at 614, Table 1 (“Summary of Guidelines”).

¹¹⁵ Austl., National Health and Medical Research Council, *Familial Aspects of Cancer: A Guide to Clinical Practice* (Canberra: Commonwealth of Austl., 1999).

¹¹⁶ *Ibid.* at 17.

ality should be reversed and genetic information should be available to all “account holders”, or relatives to whom the information relates, unless there is sufficient reason to do otherwise.¹¹⁷ Questions remain as to what this regime would look like and what its effects would be. There is no precedent for regulating information that is both personal and shared or simply shared, other than the all-encompassing notion of the public domain. It is worth noting that the WHO has called for a revision of ownership laws to reflect the special nature of genetic information and to clear up legal obligations with respect to it.¹¹⁸ The Organization has also asserted that individuals are entitled to rights to control their genetic samples and information in a manner akin to property rights.¹¹⁹

An alternative approach that is often called upon as a counter-argument to property regulation discussions revolving around blood, tissue, organs, pituitary glands, corneal tissue, corpses, and biological tissue is to treat genetic information as *sui generis*, or in a category of its own. This would warrant the adoption of a specific regulatory regime.¹²⁰ The advantage of this approach—flexibility—is also its disadvantage. Flexibility allows the many and varied interests in genetic information to be addressed on a case-by-case basis, but it also provides very little guidance for policy makers on how to regulate in the area.¹²¹ This approach also faces the criticism of genetic exceptionalism for treating genetic information as special and severable from other forms of personal information.¹²² The criticism is apt in some regards. The purported “special characteristics” of genetic information, including its predictive quality, its relevance to family members, its potential use in discriminating against individuals and groups, and its ability to cause serious psychological harm, are in fact also true of other forms of information.¹²³ On the other hand, it is also the case that genetic information is the only form of medical information to possess *all* of these characteristics.

D. Limits of Health Care Providers’ Obligations

There is a growing body of literature, policy, and law addressing health care providers’ communication of genetic information with patients’ relatives without the patients’ consent. Several approaches to the role of health care providers in this context are discussed here, followed by an analysis of how intra-familial obligations line up, or intersect, with health care providers’ obligations.

One approach to the role of health care providers, as articulated by the American Society of Human Genetics (ASHG) is that such communication may occur at the physician’s discretion in a limited set of circumstances, as follows: where “attempts to encourage disclosure on the part of the patient have failed; where the harm is likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk.”¹²⁴ The justification for the ASHG position is that under such circumstances, the harm from failing to disclose will outweigh the harm from disclosure and thereby justify non-consensual disclosure.

The Canadian Medical Association takes a different approach, stating that health information should not be collected, used, disclosed, or accessed without patient consent except “under strict conditions” and in the “very limited circumstances” where it is “permitted or required by legislation

¹¹⁷ Anneke Lucassen, “Should Families Own Genetic Information? Yes” (2007) 335 *British Medical Journal* 22 at 22; Michael Parker & Anneke Lucassen, “Genetic Information: A Joint Account?” (2004) 329 *British Medical Journal* 165.

¹¹⁸ Wertz, Fletcher & Berg, *supra* note 63 at 51.

¹¹⁹ Graeme Laurie, “Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights—A WHO Report” (2004) 11 *Eur. J. Health L.* 87 at 88.

¹²⁰ Trudo Lemmens, Mireille Lacroix & Roxanne Mykitiuk, *Reading the Future?: Legal and Ethical Challenges of Predictive Genetic Testing* (Montreal: Éditions Thémis, 2007) at 242.

¹²¹ *Ibid.*

¹²² Thomas Murray, “Genetic Exceptionalism and ‘Future Diaries’: Is Genetic Information Different from Other Medical Information?” in Mark Rothstein, ed., *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997).

¹²³ M.J. Green & J. Botkin, “Genetic Exceptionalism in Medicine: Clarifying the Differences Between Genetic and Non-Genetic Tests” (2003) 138 *Annals of Internal Medicine* 571.

¹²⁴ American Society of Human Genetics, *supra* note 55 at 474.

or regulation” or “when ordered or decided by a court of law.”¹²⁵ The Canadian Medical Association Code of Ethics states that health professionals should only disclose patients’ personal health information to third parties “with their consent, or as provided by law, such as when the maintenance of confidentiality would result in a significant risk of substantial harm to others” and requires that the patient be informed that his or her confidentiality will be breached.¹²⁶ An interesting question with respect to the CMA documents is: Who is a “third party” in the context of genetic information? Given the relevance of the information in the eyes of genetic relatives, there may be room to argue that they are not third parties with respect to this information.

Some organizations hold that the extent of health professionals’ obligations is to ensure patients are aware of the importance of communicating test results to family members.¹²⁷ Many others appear to make an exception to their policies of non-directive genetic counseling and advise genetic counselors to actively encourage patients to inform their family members.¹²⁸ Indeed, research has shown that genetic counselors often believe that family members have a moral obligation to share genetic information.¹²⁹

Whether health professionals have a legal duty to warn relatives of genetic risk is the subject of some debate. The professional duty to warn third parties of a threat of harm first arose in a California case in the context of threats made by a psychiatric patient against a third party during sessions with his psychiatrist.¹³⁰ In that case, the key considerations triggering liability for a failure to warn included the fact that the potential harm to an identifiable party was serious and foreseeable, that there was a close connection between the conduct and the injury suffered, and that moral blame attached to the defendant’s conduct. Also, the psychiatrist should have been privy to existing policies on the prevention of future harm. Other factors that weighed against the doctor were the (minimal) extent of the burden of warning, the positive community consequences of imposing such a duty, and the availability and cost of insurance to protect against such a risk. A similar professional duty has also been recognized by a Canadian court in the context of a physician’s duty to warn third parties at risk of acquiring a sexually transmitted disease from a patient.¹³¹ Health professionals’ duty to warn has also been discussed by American courts in the genetics context¹³² and in some cases a duty to warn has been found.¹³³

The standards laid out by the ASHG and other organizations regarding health professionals’ duty to warn third parties and regarding their discretion to disclose information, are difficult to meet in the genetics context. To begin, in the psychiatric and infectious disease duty to warn cases, the threatening or infected party is herself an agent of the potential harm—a harm that may be preventable if the individual at risk is warned. In the genetics context, however, the potential harm has in a sense already been done. Either an individual has a genetic mutation as part of his or her genetic code or she does not; the patient is not a causal agent of the genetic harm. Another requirement for health professionals’ duty to warn is that the warning will be beneficial to the person warned. Although genetic risk information may, in some circumstances, be helpful to prevent or monitor the

¹²⁵ Canadian Medical Association, “CMA Health Information Privacy Code” (1998), Principle 3.4, online: Canadian Medical Association <http://www.cma.ca/index.cfm/ci_id/3216/la_id/1.htm>.

¹²⁶ Canadian Medical Association, “Code of Ethics of the Canadian Medical Association” (2004), art. 35, online: Canadian Medical Association <<http://policybase.cma.ca/PolicyPDF/PDO4-06.pdf>>.

¹²⁷ American Society of Clinical Oncology, “Policy Statement Update: Genetic Testing for Cancer Susceptibility” (2003) 21 *Journal of Clinical Oncology* 2397; Human Genetics Society of Australasia, *The Protection of Human Genetic Information* (2007) at 2–3, online: Human Genetics Society of Australasia <<http://www.hgsa.com.au/images/UserFiles/Attachments/PROTECTIONOFHUMANGENETICINFORMATION1.pdf>>.

¹²⁸ Laura E. Forrest *et al.*, “Communicating”, *supra* note 75; Knoppers, *supra* note 3; Kenneth Offit *et al.*, “The ‘Duty to Warn’ a Patient’s Family Members About Hereditary Disease Risks” (2004) 292 *Journal of the American Medical Association* 1469 at 1471.

¹²⁹ Jon Torgny R. Wilcke, “Late Onset Genetic Disease: Where Ignorance is Bliss, Is It Folly to Inform Relatives?” (1998) 317 *British Medical Journal* 744.

¹³⁰ *Tarasoff v. Regents of the University of California*, (1976) 551 P.2d 334 (Cal. Sup. Ct.).

¹³¹ *Pittman Estate v. Bain*, (1994) 112 D.L.R. (4th) 257 (Ont. Ct. Div.).

¹³² *Pate v. Threlkel*, (1995) 661 So.2d 278 (Fla. Sup. Ct.); *Safer v. Pack*, (1996) 677 A.2d 1188 (N.J. Super. Ct.) [*Safer*].

¹³³ *Safer, ibid.*

onset of a genetic condition, knowledge of genetic risk is valued differently by individuals and may not, in all cases, be experienced as a benefit.¹³⁴

Other difficulties include defining what constitutes serious harm in the genetics context,¹³⁵ and determining in which cases prevention and surveillance measures are sufficiently available and effective to give rise to the duty to warn. Finally, non-consensual disclosure to relatives involves the relative's right to know outweighing the patient's right to confidentiality. However, there is reason to be skeptical that the relative's right to know can ever outweigh the patient's right to confidentiality in the genetics context, typically because of the problem of establishing the imminence of the genetic risk. The imminence of genetic risk is typically uncertain, particularly in the context of multifactorial genetic diseases such as breast cancer, where genetic risk information is never more than probabilistic information with regards to the realization of the risk.¹³⁶

The relevance of this discussion in the context of articulating intra-familial obligations to communicate genetic information is that the limits of health care providers' obligations may implicate limits for intra-familial obligations. Would the limits of health professionals' obligations also apply to family members, or might intra-familial obligations be more robust?

Australian policy has put forth the view that patients have obligations more often than health professionals.¹³⁷ It may simply be that it takes less to trigger a patient's obligation to disclose. In that case, even where the criteria discussed above are not met, an intra-familial obligation may yet arise. This could be justified simply by reference to the fact that there is lower threshold for obligations within families as compared to that for professional-patient obligations. Another argument in favour of more robust intra-familial obligations is that relatives would gain access to important health information without health professionals breaching patient confidentiality. This respect of the duty of confidentiality is valued as a fundamental element of the medical system and is necessary to reassure those who seek testing about the protection of their privacy rights. However, there is a flipside to the strong presumption in favour of maintaining duties of confidentiality save in very special circumstances: patients have corresponding ethical responsibilities. The duty of confidentiality presupposes that patients undertake responsibility for managing their illness.¹³⁸ It is arguable that the fact that most laws and policies do not allow non-consensual disclosure by health professionals (except in limited circumstances) implies an obligation for patients to communicate where such circumstances are not met.

E. Familial Privacy Versus Individual Privacy

Confidentiality involves the prevention of the use or disclosure of information known about a person by another for unauthorized purposes, and "privacy is about an individual not being required to provide certain types of information about themselves to others."¹³⁹ Confidentiality is the duty of health professionals toward their patients. It may only be subject to exceptions in very limited circumstances. But when a third party professional is not part of the scenario, how do privacy rights play out? Can an individual have a privacy right to maintain his or her own personal information private even where the

¹³⁴ Jennifer Gold, "To Warn or Not to Warn? Genetic Information, Families, and Physician Liability" (2004) 8 McGill Journal of Medicine 72 at 76.

¹³⁵ Bartha Maria Knoppers *et al.*, "Defining 'Serious' Disorders in Relation to Genetic Services: Who Should Decide?" (1995) 57 (suppl.) American Journal of Human Genetics 296A.

¹³⁶ Gold, *supra* note 134 at 76.

¹³⁷ Anti-Cancer Society of Victoria, Cancer Genetics Ethics Committee, *Ethics and Familial Cancers: Including Guidelines on Ethical Aspects of Risk Assessment, Genetic Testing and Genetic Registers* (1996) being ch. 2 of Australia, National Health and Medical Research Council, *Clinical Practice Guidelines: Familial Aspects of Cancer: A Guide to Clinical Practice* (1999) 13 at 18, online: National Health and Medical Research Council <http://www.nhmrc.gov.au/publications/synopses/_files/cp67.pdf> [Victoria Guidelines, 1996].

¹³⁸ *Ibid.* at 17–18.

¹³⁹ Government of Canada, "Chapter 5: Human Rights Issues Related to Genetic Information and Privacy" in *A Brave New World: Where Biotechnology and Human Rights Intersect* (July 2005) at 5–9, online: Government of Canada <http://dsp-psd.pwgsc.gc.ca/Collection/Iu199-6-2005E_Biotech_CH5.pdf>.

information could help a genetic relative and/or withholding the information could result in otherwise preventable harm?

Two questions are important in this analysis. The first is whether privacy rights are an appropriate fit in the context of genetic information given its possible qualification as shared, or personal and shared. Privacy protections have emerged to prevent unfair discrimination on the basis of genetic information, particularly in the employment and insurance contexts.¹⁴⁰ However, these protections can be as effectively provided through legislation that addresses the wrongful use of genetic information, rather than through the creation of privacy rights.¹⁴¹

The second question is whether individual rights to privacy have a place within the family context. It may be that within families, individual members do not have privacy rights against other members and that families enjoy privacy protection as a unit. Individual privacy protection in Canada does not apply within the family sphere and between family members. The right to privacy has been read into the *Canadian Charter of Rights and Freedoms*¹⁴² but these protections apply to government actors and not between private citizens. They also only arise where there is a reasonable expectation of privacy, which is questionable in the context of genetic information. Individual privacy rights with respect to personal information are created in the federal *Privacy Act*¹⁴³ and *Personal Information and Electronic Documents Act*¹⁴⁴, and in provincial privacy legislation. These regimes protect the individual against privacy infringement by state actors and in some cases, in the context of commercial activities, and do not apply between private citizens or outside of the realm of commerce.

One scholar has argued that relationships within families are not well described using the language of rights. He asserts that rights are part of justice between strangers, that they are wholly procedural, and that they consequently have no place within families.¹⁴⁵ Duties, not rights, govern families.¹⁴⁶ This view of families, rights, and duties marks a move toward recognizing a duty of care between family members by simple virtue of their shared membership in a family. In this view, genetic relatives may not have a right to be informed of their genetic risk (although they may have a right to be informed by a health professional who is a stranger), but a patient nonetheless has a duty to communicate genetic information with them.

It is interesting to note that articulations of privacy in international, national, and regional normative documents include the family sphere as a protected realm of individual privacy.¹⁴⁷ If—in addition to the individual's personal privacy—the individual's private realm of the family is protected from interference by external parties, this arguably weighs against non-consensual disclosure by health professionals since this would be an infringement of the individual's private family sphere. This in turn may implicate more robust intra-familial communication obligations.

¹⁴⁰ See e.g. *Genetic Information Act*, *supra* note 36.

¹⁴¹ Skene, *supra* note 27 at 2.

¹⁴² See e.g. *Hunter v. Southam Inc.*, [1984] 2 S.C.R. 145, 11 D.L.R. (4th) 641; *R v. Dymont*, [1988] 2 S.C.R. 417, 55 D.L.R. (4th) 503.

¹⁴³ *Privacy Act*, R.S.C. 1985, c. P-21.

¹⁴⁴ *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5.

¹⁴⁵ Weijer, *supra* note 77 at 1466.

¹⁴⁶ *Ibid.*

¹⁴⁷ *Universal Declaration of Human Rights*, GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948) 71, s. 12; *International Covenant on Civil and Political Rights*, GA Res. 2200A (XXI), UN GAOR, Supp. No. 16, UN Doc. A/6316 (1966) 52, art. 17; OAS, General Assembly, *American Declaration of the Rights and Duties of Man*, OR OEA/Ser.L/V/E.23 Doc.21 (1948) ch. 1, art. 5; *American Convention on Human Rights*, 18 July 1978, O.A.S. T.S. 36, 1144 U.N.T.S. 123 at ch. 2, art 11; *European Convention for the Protection of Human Rights and Fundamental Freedoms*, 3 September 1953, 213 U.N.T.S. 222 at s. 1, art. 8.

III

THE FORMS FOR INTRA-FAMILIAL OBLIGATIONS TO COMMUNICATE GENETIC INFORMATION

Up to now, this article has focused on possible foundations for intra-familial obligations to communicate genetic risk. The following section switches gears to address the possible forms that such obligations could take. The first section is an analysis of various national and international policies that articulate a moral obligation in this context. The second section is an analysis of Canadian common law and Quebec civil law rules as they apply to intra-familial communication obligations. It also draws on the legislative approach to intra-familial communication of genetic risk enacted in France.

A. Intra-familial Communication as a Moral Obligation: An International Comparison

Some international and national policies articulate an obligation on the part of family members to disclose genetic information;¹⁴⁸ however, there are no such articulations made by Canadian policy organizations. These articulations are typically of moral obligations and they draw on the various foundations that are discussed above.

The WHO bases an obligation to communicate genetic information within families on duties to protect family members from harm¹⁴⁹ that lies at the root of the function of families. According to the WHO, kinship bonds and the principle of non-maleficence give rise to an obligation to share genetic information that may extend to distant relatives.¹⁵⁰ An alternative root for the obligation, according to a separate WHO document, is the notion that families “own” genetic information together because it is shared.¹⁵¹ The WHO also makes some effort to clarify moral obligations regarding genetic information between spouses. There is a moral obligation to disclose genetic information to one’s spouse, even where no children are planned, if the information will affect the spouse’s life.¹⁵² Where DNA has been banked, spouses should not have access to samples, but they may be informed that their spouse’s DNA has been banked.¹⁵³ When a couple is planning on having children, it is the moral obligation of the partner who has had DNA banked to disclose relevant information associated with the banking to his or her spouse.¹⁵⁴

Another international organization that has made a statement in this area, the Human Genome Organisation (HUGO), creates a moral obligation in the context of genetic information, on the basis that “shared biological risks create special interests and moral obligations.”¹⁵⁵

Several national organizations have policy statements that mention moral obligations within families in the genetic context. France has a fairly well-developed position. The French National Consultative Committee for Health and Life Sciences states that it is “morally condemnable” to withhold information that could avoid or treat illness in relatives.¹⁵⁶ This marks a retreat from an earlier statement where the patient’s interests were recognized as fundamental.¹⁵⁷ The Committee justifies this on grounds that strict observance of the principle of individual autonomy threatens to put the lives of blood relatives in danger.¹⁵⁸ Accordingly, the Committee allows one nuance. It recognizes that the complexities that mar health professionals’ disclosure of *unpreventable* and *untreatable* diseases militate against the creation of a duty to warn relatives in such cases. These complexities

¹⁴⁸ Karen Forrest, “Barriers”, *supra* note 89.

¹⁴⁹ WHO, *Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services* (1998) at 5, Table 3, online: <http://whqlibdoc.who.int/hq/1998/WHO_HGN_GL_ETH_98.1.pdf>.

¹⁵⁰ *Ibid.*

¹⁵¹ Wertz, Fletcher & Berg, *supra* note 63 at 51.

¹⁵² *Ibid.* at 54.

¹⁵³ WHO, *supra* note 149.

¹⁵⁴ *Ibid.*

¹⁵⁵ Human Genome Organization, *supra* note 60.

¹⁵⁶ *Opinion No. 76*, *supra* note 19 at 6–7.

¹⁵⁷ France, National Consultative Committee for Health and Life Sciences, *Opinion No. 70 Regarding Consent for the benefit of another person* (2001). All Opinions are available in French online: Comité Consultatif National d’Éthique <<http://www.ccne-ethique.fr/avis.php>>.

¹⁵⁸ *Opinion No. 76*, *supra* note 19 at 6–7.

include the many sources of genetic information, the psychological difficulties associated with communication and knowledge of genetic information, the existence of a right not to know, and the fact that health professionals and third parties are mediated by patients. In cases where there is no offer of therapeutic hope, the Committee states that it is unimaginable to impose a communication obligation.¹⁵⁹ Where there is no therapeutic hope, health professionals cannot disclose genetic information because doing so would rupture confidence in the patient-physician relationship and so it is preferable that the information be communicated by the patient.¹⁶⁰

The United Kingdom (U.K.) has several organizations representing professionals, patient groups, and bioethics committees with statements in this area. The Nuffield Council on Bioethics states that persons “acting responsibly” would normally want to communicate information and receive information about genetic risk,¹⁶¹ and that “the primary responsibility for communicating genetic information to a family member or other third party lies with the individual and not the doctor.”¹⁶² However, the Council contends that even where relatives have a legitimate interest in knowing genetic information, this should not always supersede patients’ privacy rights.¹⁶³ Moreover, the Council stands explicitly against legally enforceable obligations in this context: “We have difficulty in contemplating how any such legal obligation would work and how any legal right of family members (assuming that they could always be identified) could be enforced. In any event, in certain circumstances there may be perfectly good reasons why an individual would not wish to inform family members about the result of a genetic test.”¹⁶⁴

This approach is supported by the U.K. Genetic Interest Group, a patient organization that encourages patients to “act ethically”. It exhorts patients to communicate genetic information as an ethical imperative, but does not advocate in favour of punishment should a patient fail to do so.¹⁶⁵ Similarly, the British Medical Association commented that “all patients have duties of some sort, which may include voluntarily disclosing information to other people who may be affected.”¹⁶⁶ But the Association adds that consent to sharing information must not be forced.¹⁶⁷

In Australia, there are two statements about intra-familial obligations to communicate genetic information, made by two organizations. The first is the National Health and Medical Research Council (NHMRC), which recognizes both individual and familial interests: “It is generally accepted that an individual has responsibilities to his/her family as well as a right to the privacy and confidentiality of his/her genetic information.”¹⁶⁸ Although there is no legal duty to warn in family relationships recognized in Australia, the NHMRC states that in deciding whether to disclose genetic information to relatives, patients “will need to balance carefully their own right to privacy with the fact that disclosure could lead to the avoidance of substantial harm for their relatives.”¹⁶⁹ The NHMRC also states that “[u]nlike ... blood relatives ..., [spouses and partners] are not at increased risk of developing the genetic disorder, but they should be informed if their present/future children could develop/inherit the disorder.”¹⁷⁰ In a separate document that deals specifically with hereditary cancer, the NHMRC states that disclosure to spouses may not be as compelling as disclosure to genetic rela-

¹⁵⁹ *Ibid.* at 5.

¹⁶⁰ *Ibid.* at 5–6.

¹⁶¹ Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues*, (London: Nuffield Council on Bioethics, 1993) at 49, online: Nuffield Council on Bioethics <http://www.nuffieldbioethics.org/fileLibrary/pdf/genetic_screening.pdf>.

¹⁶² *Ibid.*

¹⁶³ *Ibid.*

¹⁶⁴ *Ibid.*

¹⁶⁵ Genetic Interest Group, *Confidentiality Guidelines* (London: Genetic Interest Group, 1998), ss. 2.6–2.7, online: Genetic Interest Group <http://www.gig.org.uk/docs/gig_confidentiality.pdf>.

¹⁶⁶ British Medical Association, *Human Genetics: Choice and Responsibility* (Oxford: Oxford University Press, 1998) at 12.

¹⁶⁷ *Ibid.* at 19.

¹⁶⁸ National Health and Medical Research Council, *supra* note 66.

¹⁶⁹ *Ibid.*

¹⁷⁰ *Ibid.* at 49.

tives because it is impossible to disclose to spouses without disclosing the identity of the patient and because there is no immediate risk to the health of spouses.¹⁷¹

The second policy document that deals with this issue is the Cancer Council of Victoria, which ties the moral obligation to communicate information about some familial cancers in some families to family history:

It is as members of families that [patients] are at risk, and because of a family history which they share with many others that they may end up having a genetic test. [...] Ethically speaking, [patients] should be prepared to shoulder their share of the burden, and to contribute to the benefits, [...] and this includes [patients] being ready to allow for the possibility of relations being informed of their own potential for genetic risk.¹⁷²

The Council also states that spouses may have an interest in the information, especially when children are planned who may be at risk of inheriting the mutation.¹⁷³ More broadly, the Council advocates a shift away from the language of individual rights and toward an emphasis on wider responsibility and communal concerns.¹⁷⁴

Statements of moral obligation to communicate genetic information within families are made in several other national documents. The German Society of Human Genetics articulates a moral obligation to share knowledge of genetic make-up and to inform partners insofar as it can implicate offspring.¹⁷⁵ According to the Greek National Bioethics Commission, all patients who know about their genetic risk “must [...] assume responsibility for informing any third persons involved”.¹⁷⁶ In the United States, the American Society of Clinical Oncology states that health professionals best fulfill obligations to family members by communicating relevant information to the tested patients themselves, and not to their at-risk family directly.¹⁷⁷ In Denmark, the Danish Council of Ethics states that even in serious cases, the disclosure of genetic information to family is a decision to be made by the patient tested. Genetic information is solely a family affair and the communication initiative must come from the patient.¹⁷⁸ These approaches imply that any obligation that health professionals may have to patients’ family members is passed over to the patient when the health professional communicates risk information to her.

Even where a moral intra-familial obligation is articulated, it is not entirely clear what the effect of such an articulation might be. Such obligations are not enforceable in the same way that professional ethical obligations are, such as by suspension of professional license or through other punishment. Perhaps such articulations aim merely to cause a change in public perceptions of genetic information and of the obligations that flow from it.

B. Intra-familial Communication as a Legal Obligation

Legal obligations, on the other hand, are enforceable. Although some family members owe each other legal duties of care, particularly parents and children, spouses, and guardians toward dependents, it is unlikely that a legal obligation to communicate genetic information within families can be founded on either Canadian common law or Quebec civil law rules. This section begins with a discussion of a legal regime enacted in France where legislative efforts have specifically targeted intra-familial communication of genetic information. It then moves on to investigate barriers to a finding of liability under Canadian common law and Quebec civil law rules for a failure to communicate ge-

¹⁷¹ National Health and Medical Research Council, *supra* note 115 at 18.

¹⁷² Anti-Cancer Society of Victoria, Cancer Genetics Ethics Committee, *Ethics and Familial Cancers: Including Guidelines on Ethical Aspects of Risk Assessment, Genetic Testing and Genetic Registers* (March 1997) [Victoria Guidelines, 1997].

¹⁷³ Victoria Guidelines, 1996, *supra* note 137 at 18.

¹⁷⁴ Bell & Bennett, *supra* note 2 at 135, citing Victoria Guidelines, 1997, *supra* note 172 at 38.

¹⁷⁵ German Society of Human Genetics, *Position Paper of the German Society of Human Genetics* (1998) at 6, online: http://www.medgenetik.de/sonderdruck/en/Position_paper.pdf.

¹⁷⁶ Greece, National Bioethics Commission, *Recommendation on the Collection and Use of Genetic Data* (2002), s. B.1(a), online: National Bioethics Commission <http://www.bioethics.gr/media/pdf/recommendations/recom_genetic_data_eng.pdf>.

¹⁷⁷ American Society of Clinical Oncology, *supra* note 127 at 2397.

¹⁷⁸ Danish Council of Ethics, *Ethics and Mapping the Human Genome* (Copenhagen: Danish Council of Ethics, 1993).

netic information within the family. There is no statute in Canada that outlines a legal obligation to communicate genetic information within families. Indeed, the Ontario *Report of the Provincial Advisory Committee on New Predictive Genetic Technologies* calls for the creation of legislation dealing specifically with genetic information, but states that such legislation “should not impose a duty to disclose genetic information to high-risk relatives.”¹⁷⁹

1. France’s Legislative Regime

In France, the *Loi relative à la bioéthique 2004* creates a specialized regime for intra-familial communication of genetic information. Relevant text of the regime is extracted here:

En cas de diagnostic d’une anomalie génétique grave posé lors de l’examen des caractéristiques génétiques d’une personne, le médecin informe la personne ou son représentant légal des risques que son silence ferait courir aux membres de sa famille potentiellement concernés dès lors que des mesures de prévention ou de soins peuvent être proposées à ceux-ci. L’information communiquée est résumée dans un document signé et remis par le médecin à la personne concernée, qui atteste de cette remise. Dans ce cas, l’obligation d’information à la charge du médecin réside dans la délivrance de ce document à la personne ou à son représentant légal.

La personne concernée, ou son représentant légal, peut choisir d’informer sa famille par la procédure de l’information médicale à caractère familial. Elle indique alors au médecin le nom et l’adresse des membres de sa famille dont elle dispose en précisant le lien de parenté qui les unit. Ces informations sont transmises par le médecin à l’Agence de la biomédecine qui informe, par l’intermédiaire d’un médecin, lesdits membres de l’existence d’une information médicale à caractère familial susceptible de les concerner et des modalités leur permettant d’y accéder. Les modalités de recueil, de transmission, de conservation et d’accès à ces informations sont précisées par un décret en Conseil d’Etat, pris après avis de la Commission nationale de l’informatique et des libertés.

Le fait pour le patient de ne pas transmettre l’information relative à son anomalie génétique dans les conditions prévues au troisième alinéa ne peut servir de fondement à une action en responsabilité à son encontre.¹⁸⁰

This regime outlines the responsibilities of both health professionals and patients with regard to genetic information. Health professionals must explain the implications of the information for relatives and provide a letter for patients to pass along to relatives. This absolves the health professional of his or her obligations and transfers these obligations to the patient. The patient may then decide to inform relatives directly, or use an external mechanism set up for the exchange of such information, “l’information médicale à des fins familiales.” The information passes through the patient’s physician, the Agence de la biomédecine, and the relative’s physician before it reaches the relative. These communication requirements only arise when a serious genetic anomaly is found. Finally, the law makes clear that no basis for civil liability can be made out either against a patient or against a health professional for failure to inform potentially affected relatives.

2. Negligence in Canadian common law

A finding of civil liability in Canadian common law requires proof of a breach of a duty of care, a compensable injury, and a causal link between the fault and the injury. The following discussion applies the common law rules for each stage of the civil liability analysis to the circumstances where an individual has failed to communicate genetic risk information to a potentially affected relative and that relative has developed a genetic disease, had a child affected with genetic disease, or has died.

Breach of the duty of care - With the exception of obligations between spouses and parents and their minor children, there is no special duty of care between family members for reason only of their familial relation. Family duties set out in family law demonstrate the level of care that is expected by the state between family members. They also provide a statutorily mandated duty of care for the purposes of civil liability. In the Ontario *Family Law Act*, for example, the obligations between spouses

¹⁷⁹ Ontario Provincial Advisory Committee on New Predictive Genetic Technologies, *supra* note 68 at 75 (recommendation 26(a)).

¹⁸⁰ *Loi n° 2004-800 du 6 août 2004 relative à la bioéthique*, J.O., 7 June 2004, 14040, art. L.1131-1. It is worth noting that the unique regime outlined in the *Loi relative à la bioéthique* has not been put into use as of the time of writing. The Conseil d’État must first prepare an implementation decree. See Claudine Bergoignan Esper, “En génétique, quelques propos sur l’information médicale à caractère familial” (2007) 84 *Médecine & droit* 80 at 80.

and parents and children are limited to financial support obligations¹⁸¹ and as such are unlikely to give rise to a duty to communicate genetic information.

Duties of care between family members in this context will therefore rely on common law rules, where they are established using the neighbour principle: a duty of care extends to “persons who are so closely and directly affected by my actions that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.”¹⁸² The requirements for this test are proximity (is there a sufficiently close relationship between me and the category of people to which the person affected belongs?) and reasonable foreseeability (is it reasonably foreseeable that this category of people will be affected by my actions or omissions?). An updated formulation of the test has been adopted in Canada, as follows: (1) whether the circumstances disclose a reasonable and foreseeable harm and proximity sufficient to establish a *prima facie* duty of care—proximity factors arising from the relationship between the parties—and (2) whether there exist residual policy considerations which justify denying liability.¹⁸³

Between relatives who share a genetic code, or family members who share a close relationship, there would appear to be, *de facto*, sufficient proximity between the parties for a duty of care to arise. Not only are genetic relatives close in relationship by virtue of their shared biology, it is also reasonably foreseeable that genetic relatives would be affected by a failure to inform them of the presence of a genetic risk within the family. Exceptions to this occur where the existence of genetic relatives, or the importance of the information for them, is unknown. The latter exception is likely to be rare, as guidelines for genetics professionals increasingly advise discussing the importance of genetic information for potentially affected relatives with patients.¹⁸⁴

Problems may arise however at the second stage of the analysis: whether there are policy reasons to negate the duty of care. In *Winnipeg v. G.*¹⁸⁵ and *Dobson v. Dobson*,¹⁸⁶ two cases involving the obligations of pregnant women toward their unborn children, the Supreme Court of Canada supported the following, *inter alia*, as legitimate policy reasons to negate the duty of care: difficulty of drawing a line between appropriate and inappropriate behavior;¹⁸⁷ concerns about restricting the autonomy and privacy of pregnant women;¹⁸⁸ and concern over family disharmony resulting from prenatal causes of action.¹⁸⁹ Concerns over the potential negative effects on family relationships in the context of communication of genetic information are common.¹⁹⁰ Similarly, difficulty drawing the line between appropriate and inappropriate behaviour is challenging where the family context and relationships play a significant role in the communication of genetic information. Finally, concern over the autonomy and privacy rights of individuals is also likely to be a relevant policy concern in the eyes of common law courts.

In Canadian common law, there is an increased duty of care on the part of parents with respect to their minor children since parents have fiduciary obligations to act in their children’s best interests.¹⁹¹ However, there is no consensus on whether children should be made aware of their genetic risk or undergo genetic testing for adult onset conditions. Moreover, parents acting as fiduciaries with respect to their children’s interests are given discretion to decide what is in their children’s best interests, particularly when the “right” course of action is less than clear.¹⁹² Where there is no clear consensus on the

¹⁸¹ *Family Law Act*, *supra* note 14, ss. 30–32.

¹⁸² *Donoghue v. Stevenson*, [1932] A.C. 562 at 580.

¹⁸³ *Cooper v. Hobart*, [2001] 3 S.C.R. 537.

¹⁸⁴ American Society of Clinical Oncology, *supra* note 127; Human Genetics Society of Australasia, *supra* note 127; Laura E. Forrest *et al.*, “Communicating”, *supra* note 75; Knoppers, *supra* note 3; Offit, *supra* note 128.

¹⁸⁵ *Winnipeg Child and Family Services (Northwest Area) v. G. (D.F.)*, [1997] 3 S.C.R. 925, 152 D.L.R. (4th) 193 [*Winnipeg*].

¹⁸⁶ *Dobson (Litigation Guardian of) v. Dobson*, [1999] 2 S.C.R. 753, 174 D.L.R. (4th) 1 [*Dobson*].

¹⁸⁷ *Winnipeg*, *supra* note 185.

¹⁸⁸ *Ibid.*; *Dobson*, *supra* note 186.

¹⁸⁹ *Dobson*, *ibid.*

¹⁹⁰ Gilbar, *supra* note 11.

¹⁹¹ *M.(K.) v. M.(H.)* [1992] 3 S.C.R. 6, 98 D.L.R. (4th) 289.

¹⁹² *Ibid.*

merits of communicating genetic information with children and on genetic testing for adult-onset conditions in children, it is unlikely that a breach of this duty would be found.

Injury - Injury in a case of a failure to communicate genetic information could be the onset of a disease associated with surveillance and prevention measures, such as hereditary non-polyposis colorectal cancer (HNPCC) or breast cancer, the onset of a non-preventable disease, such as Huntington's disease, death associated with one of these diseases, or the birth of a child affected by a genetic mutation or genetic disease. The injury could also be associated with the lost chance to plan one's life with knowledge of the future onset of a debilitating disease.

There are issues in Canadian common law with claims for an injury associated with the birth of a child. Such injuries are known as wrongful birth (a claim by parents against a physician for failure to inform parents that their unborn fetus was affected by disease or disability, where the parents would have aborted or avoided conceiving had they known this information), wrongful life (a claim by a diseased or disabled child against a physician or hospital for having been born affected by disease or disability), and wrongful pregnancy (a claim by parents against a physician or hospital, typically for a failed sterilization procedure that led to the birth of a healthy child).

Wrongful birth has been recognized by Canadian courts,¹⁹³ notwithstanding the fact that these cases may be problematic as creating a duty on the part of physicians to advise women to abort their unborn children and as devaluing disabled children's lives.¹⁹⁴ With the advent of reproductive technologies such as pre-implantation genetic diagnosis—which can enable individuals who are aware of their risk of having a child affected by genetic disease to prevent such a birth—the difficult issue of abortion may not be raised in a claim for wrongful birth. Rather, the issue may become the lost chance to undergo preventive reproductive procedures where, had parents been aware of their genetic risk; they would have undergone such procedures prior to conception. These cases may create an entirely new category of claims: wrongful conception. This unprecedented type of claim may share characteristics with claims for wrongful birth and for wrongful pregnancy. However, such cases would not avoid the problem of seeing courts handing down rulings that ascribed less value to the lives of children affected with genetic disease than to those of children born free of them.

Claims for wrongful life have been divided into two categories, one of which has been recognized by Canadian courts. Courts have recognized claims for wrongful life where a child was born with abnormalities that were caused by a physician's wrongful act or omission, but denied claims where "but for" the wrongful act of a physician, the child would not have been born at all.¹⁹⁵ Cases involving serious hereditary disease are likely to fall into the second category as the injury in such cases is caused by the existence of a genetic mutation and not by a wrongful act or omission.¹⁹⁶ Where a physician fails to inform the mother or parents of the possibility of having a child affected with genetic disease, he or she causes or allows the child to be conceived or born where parents would otherwise have avoided pregnancy or sought an abortion.

Wrongful pregnancy has been rejected by one court in Ontario¹⁹⁷ as well as in the U.K.¹⁹⁸ on the ground that courts cannot deem the birth of a healthy child to have constituted an injury to the child's parents. Here again, a claim for wrongful conception may arise where a couple claims that they would have taken precautions to avoid pregnancy had they been aware of the risk of having an affected child. In sum, wrongful birth, wrongful life, and wrongful pregnancy claims are problematic at the level of injury assessment in Canadian common law. Other injury claims become problematic at the level of causation.

¹⁹³ *Arndt v. Smith*, [1997] 2 S.C.R. 539, 148 D.L.R. (4th) 48.

¹⁹⁴ These were the reasons given for a rejection of such a claim in the U.K. case of *McKay v. Essex Area Health Authority*, [1982] Q.B. 1166.

¹⁹⁵ *Lacroix (Guardian of) v. Dominique* (2001), 202 D.L.R. (4th) 121; but see *Bovingdon v. Hergott* (2008), 88 O.R. (3d) 641, 290 D.L.R. (4th) 126 [*Bovingdon*] where the division of claims for wrongful life into two categories was rejected as unhelpful and the claim was decided on a civil liability analysis.

¹⁹⁶ *Bovingdon*, *ibid.*

¹⁹⁷ *Kealey v. Berezowski* (1996), 30 O.R. (3rd) 37, 136 D.L.R. (4th) 708.

¹⁹⁸ *McFarlane v. Tayside Health Board*, [1999] 3 W.L.R. 1301.

Causation - In common law, causation is established where, on a balance of probabilities, there is a direct and foreseeable link between the fault and the injury.¹⁹⁹ The test for directness is commonly articulated as the “but for” test that asks: but for the fault, would the injury have happened? The common law also sometimes asks whether the damage was a reasonably foreseeable consequence of the faulty act. Ultimately, causation can be determined based on a common sense evaluation of the facts of a case.²⁰⁰

Establishing causation between the failure to inform genetic relatives of the presence of a genetic mutation in the family and injuries such as the development of a genetic disease, death from genetic disease, or the birth of a child affected by genetic disease, is a formidable challenge. Here, the failure to communicate is not the *cause* of the injury. The injury is caused by the genetic mutation that an individual either has or does not have from the moment of conception. This is distinguishable from cases involving a duty to warn one’s sexual partner of infection with a sexually transmitted disease where the infected partner is, in a sense, an agent of the disease. In such cases, the infected person creates the risk, whereas in genetics cases the risk is already present (or absent).²⁰¹

The loss of a chance to prevent the onset of genetic disease or the birth of an affected child may be one route around causation problems. In such cases, the court must determine what might have happened had there been no failure to communicate genetic information. In cases involving a disease that has 100% penetrance and whose onset cannot be prevented, such as Huntington’s disease, the disease will manifest regardless of prior knowledge of genetic risk. There is therefore no loss of chance to prevent disease onset in the Huntington’s context, although there might be a claim for a loss of chance to plan one’s life according to the knowledge of imminent disease onset. In cases involving complex genetic conditions such as HNPCC or breast cancer, there is often a chance that undertaking prevention and surveillance measures could prevent disease onset. In the U.K., a court has rejected causation based on loss of chance where it could not be proven that with proper treatment the chance of avoiding injury was greater than 50%.²⁰² Thus, there must be more than a 50% chance that the injury would not have occurred if communication of genetic risk had taken place.

3. *Liability in Quebec civil law*

In Quebec civil law, fault, injury, and causation are the required elements for a finding of civil liability. Statutory care obligations such as those found in the Civil Code of Quebec (CCQ) go to the determination of fault, which is where this analysis begins.

Fault - In the civil law, there is no test for the duty of care. According to 1457 CCQ, a duty of care is owed to everyone. Fault is the violation of the duty to not cause injury to another. The standard is whether a reasonably prudent and diligent person in the same circumstances would have committed the act. Because the standard is that of the reasonable person, it is a socially determined norm and it can change over time.²⁰³ As we have argued elsewhere, intra-familial communication of genetic information is a highly complex and context-based process. Often, decisions not to communicate are based on careful deliberations about what is in the best interests of family members and of the family as a whole.²⁰⁴ Moreover, as discussed above, the few laws and policies that do discuss the process of communication or that encourage intra-familial communication explicitly preclude the imposition of civil liability for a failure to communicate genetic information within the family. For these reasons, making out a fault for non-communication based on a reasonable person standard would be a challenge as social norms would be unlikely to find this a fault.

¹⁹⁹ *Barnett v. Chelsea & Kensington Hospital*, [1968] 1 All E.R. 1068.

²⁰⁰ *Snell v. Farrell*, [1990] 2 S.C.R. 311, 72 D.L.R. (4th) 289.

²⁰¹ Clayton, *supra* note 8 at 377.

²⁰² *Gregg v. Scott*, [2005] 2 A.C. 176 (H.L.).

²⁰³ Jean-Louis Baudouin & Patrice Deslauriers, *La Responsabilité Civile: Principes généraux*, 7th ed. (Cowansville, Québec: Yvon Blais, 2007) at 153.

²⁰⁴ Nycum, Knoppers & Avard, *supra* note 4.

It is important to consider whether the breach of statutory obligations between family members may constitute a fault. As compared to the Ontario *Family Law Act*, the CCQ creates a broader spectrum of obligations. In Quebec, spouses “owe each other respect, succor, fidelity and assistance.”²⁰⁵ These terms are not defined and case law does not clarify them, but it is arguable that they create broader obligations than mere financial support.²⁰⁶ One could argue that the obligations of respect, succor, and assistance include the obligation to ensure that one’s spouse is fully informed of one’s genetic status, of the potential impact of that status on health and care needs, and of the potential impact on prospective or born children of the union. Moreover, “spouses together take in hand the moral and material direction of the family, exercise parental authority and assume the tasks resulting therefrom.”²⁰⁷ It could be argued that spouses cannot take on these tasks together when one spouse is aware of genetic risk information while the other is not.

As for obligations between parents and children, in Quebec “every child, regardless of age, owes respect to his father and mother.”²⁰⁸ Might this obligation of respect also form the basis of an argument in favour of an obligation to inform parents of genetic risk? Children also possess certain rights, beyond the right to alimentary support, from their parents or guardians. Children have the “right to the protection, security and attention that his parents or the persons acting in their stead are able to give to him.”²⁰⁹ Moreover, “[e]very decision concerning a child shall be taken in light of the child’s interests and the respect of his rights. Consideration is given, in addition to the moral, intellectual, emotional, and physical needs of the child, to the child’s age, health, personality, and family environment, and to the other aspects of his situation.”²¹⁰ A similar right for children is created in the *Quebec Charter of Human Rights and Freedoms (Quebec Charter)*, where it states that “[e]very child has a right to the protection, security and attention that his parents or the persons acting in their stead are capable of providing.”²¹¹ These broad rights may create a duty on the part of parents and guardians to communicate genetic information with their children. However, the list of considerations that must be taken into account in coming to such a decision to communicate could act to justify a decision not to communicate, in the child’s best interests.

Another relevant statutory duty that would apply to a larger group of genetic relatives is found in the *Quebec Charter*. Section 2(2) creates a duty to rescue: “Every person must come to the aid of anyone whose life is in peril, either personally or calling for aid, by giving him the necessary and immediate physical assistance, unless it involves danger to himself or a third person, or he has another valid reason.”²¹² This duty to rescue may create a positive duty to communicate serious genetic risk with those who may be potentially affected, regardless of their degree of relation. In the present context, it may be that concern for other family members or family harmony could be valid justifications for a decision not to communicate under this article of the *Quebec Charter*.

Injury - The assessment of injury in the civil law is similar to the determination in the common law, as discussed above. In civil law, injuries may be “bodily, moral or material”²¹³ and as such they could include loss of income, cost of care, pain and suffering, and loss of ability. All of these are associated with the development of a genetic disease, with death from genetic disease, or with the birth of a child affected with genetic disease or having a genetic mutation. Loss of chance to prevent these injuries may also be considered an injury in the civil law.

In the civil law, the wrongful birth of a healthy child has been compensated.²¹⁴ The Quebec Court of Appeal found that, in Quebec, public policy is not opposed to the birth of a healthy child constitut-

²⁰⁵ Art. 392 C.C.Q.

²⁰⁶ See e.g. Alain Roy, “Le contrat en contexte d’intimité” (2001-2002) 47 McGill L.J. 855 at 879 where the author argues that the obligation of fidelity is included in this article.

²⁰⁷ Art. 394 C.C.Q.

²⁰⁸ Art. 597 C.C.Q.

²⁰⁹ Art. 32 C.C.Q.

²¹⁰ Art. 33 C.C.Q.

²¹¹ *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12 at s. 39.

²¹² *Ibid.* at s. 2(2).

²¹³ Art. 1457 C.C.Q.

²¹⁴ *Cooke v. Suite*, [1995] R.J.Q. 2765.

ing an injury, that the right to plan family size is an important one, and that the benefits associated with the birth of a healthy child do not annul the damage suffered in losing the right to plan family size.²¹⁵ Moreover, a Quebec court has also recognized a claim for wrongful pregnancy and the wrongful birth of a child affected with a heritable condition in a case involving a failed sterilization procedure.²¹⁶ A claim for the wrongful birth of a child affected with genetic disease or a genetic mutation may therefore be easier to make out in the context of non-communication of genetic information.

Loss of chance goes to causation in the common law but in civil law it is also a consideration at the level of injury. The Supreme Court of Canada has compensated a victim for the trauma of knowledge that a chance was lost but not for the injury whose prevention the lost chance was claimed for.²¹⁷ In this case, the Court ruled that the lost chance was itself the injury, but did not go to the larger injury, death from cancer. If, on a causation analysis, it cannot be proven on a balance of probabilities that the lost chance caused an injury such as the onset of disease or death, in Quebec, the loss of chance to prevent the larger injury may itself be considered an injury.

Causation - In Quebec, causation is established if it can be shown on a balance of probabilities that the injury is a direct and immediate consequence of the faulty act.²¹⁸ Although several approaches to determining causation have been used by Quebec courts, the most common is adequate causation—an approach that separates the true cause from conditions that allowed the injury to take place.²¹⁹ It is an objective test that asks what cause truly led to the injury.²²⁰ The civil law also attaches importance in the determination of causation to reasonable foreseeability that the injury would result from the faulty act, and to breaks in the chain of causation.²²¹

The challenges to a finding of causation that arise in the common law of negligence are at issue in the civil law causation analysis as well. Given that genetic mutations are present from birth, establishing a causal link between the failure to communicate genetic information and the development of genetic disease is challenging. It may be reasonably foreseeable that not communicating genetic information could lead to the development of genetic disease that is preventable. However, the lack of such communication is not an adequate cause of the development of genetic disease. The adequate cause is rather the presence of a genetic mutation.

CONCLUSION

This article has discussed some of the many possible foundations for finding an intra-familial obligation to communicate genetic information. In defining the genetic family for the purposes of determining to whom a communication obligation may be owed, a biosocial approach that gives wide berth both to recognized interests and to social relationships will subsume biological and social relationships within the definition of family. However, it will also allow the exclusion of those family members with whom there is no relationship whatsoever. When defining and characterizing genetic information, it is important to consider whether family history information should be included in the category. It is also meaningful to ask whether such information should be treated like other medical information or whether it warrants a unique and distinct category.

Communication obligations could arise by virtue of the special obligations that go along with membership in a family. Those perforce will vary in accordance with perceptions of who is a genetic family member. Notions of individual autonomy may work to preclude communication obligations, whereas relational autonomy may facilitate recognition of communication obligations by acknowledging that decision-making takes place in the context of relationships. Theories of ownership and control that recognize genetic information as shared between family members can affect perceived

²¹⁵ *Ibid.*

²¹⁶ *Engstrom v. Courteau*, [1986] R.J.Q. 3048.

²¹⁷ *Laferrrière v. Lawson*, [1989] R.J.Q. 27.

²¹⁸ Art. 1607 C.C.Q.

²¹⁹ Baudouin & Deslauriers, *supra* note 203203 at 629.

²²⁰ *Ibid.*

²²¹ *Ibid.* at 625.

communication obligations and facilitate communication. When it comes to the limits of health care provider obligations, it may be that there are stronger obligations between family members than between health professionals and the relatives of their patients since there is no duty of confidentiality between family members mitigating communication obligations. Finally, although individual privacy rights are well protected in Canada, it is arguable that these rights do not reach inside families to protect the private information of one family member from other members.

Although it has been argued here that a legal obligation to communicate genetic information within families would be difficult to make out under Canadian common law and Quebec civil law rules, there are nonetheless several international and national normative documents that articulate an intra-familial obligation to communicate genetic information. These articulations could provide support for a court of law looking to find a legal obligation in this context. It is therefore important for policy makers to address this issue and provide sound guidance on whether there is or is not a legal obligation to communicate genetic information within families. Legislation that creates a legal obligation is ill-advised as it would likely cause difficulties for families given the context specificity of decision-making around intra-familial communication. Moreover, to the best of our knowledge, no other nation in the world has created a legislative regime that would impose this kind of obligation. In fact, the one nation that we know has taken up intra-familial communication of genetic information in a legislative regime, France, explicitly precludes the imposition of liability for a failure to communicate but provides a mechanism that facilitates such communication. Rather, such a regime should acknowledge perceived obligations and provide mechanisms for individuals and families to meet these obligations in a manner and setting that are appropriate for each family context.

THE MUD AND THE BLOOD AND THE BEER: CANADA’S PROGRESSIVE LICENSING FRAMEWORK FOR DRUG APPROVAL¹

Ron A. Bouchard & Monika Sawicka*

Canada is currently undergoing a transition in its system of public health, including major redefinition of the duties, accountabilities and risks assumed by public and private actors responsible for developing, regulating, and consuming innovative therapeutic products. This has been accompanied by increasing political rhetoric to the effect that many distinct elements of Canada’s health care system are functioning poorly or not at all, with great economic and quality of life costs for all Canadians. In particular, the nation’s proposed new drug regime, termed the “Progressive Licensing Framework”, has received considerable attention since the announcement of Bill C-51 in early 2008. Critics claim that expedited review, or so-called “flexible departure”, may lead to a lower standard for drug approval and a further increase in unsafe products directed to the market. Supporters claim that more emphasis on post-market safety will effectively recalibrate the risks, benefits, costs, and uncertainties of therapeutic product development. Ironically, the focus of both groups is on the balancing function of drug regulation, as global governments seek to integrate the wide range of competing scientific, economic, and public health interests involved in innovative product development. This article reviews developments leading up to the focus on the “lifecycle” or “real world” approach to drug regulation, including shifts in the speed and mechanism of drug approval, the growth in intellectual property and regulatory rights attached to drug products, the effects of these developments on post-market safety, and the manner in which advocates of lifecycle regulation argue it will help solve certain post-market safety problems.

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¹ The full lyric is “Kicking and a’ gouging in the mud and the blood and the beer”: from the song “A Boy Named Sue” sung by Johnny Cash, written by Shel Silverstein, and recorded on February 24, 1969 at San Quentin Prison (Columbia).

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ABBREVIATIONS²

ADR	Adverse Drug Reaction
ANDS	Abbreviated New Drug Submission
EMEA	European Medicines Agency
FDA	Food & Drug Administration
GOC	Government of Canada
HPFB	Health Products & Food Branch
IOM	Institute of Medicine
IPR	Intellectual Property & Regulatory
NDS	New Drug Submission
NOC	Notice of Compliance
NOC/c	Notice of Compliance with conditions
PDUFA	Prescription Drug User Fee Act (US)
PLF	Progressive Licensing Framework
rTPL	regulated Therapeutic Product Lifecycle
TPD	Therapeutic Products Directorate
SNDS	Supplementary New Drug Submission
SANDS	Supplementary Abbreviated New Drug Submission
WHO	World Health Organization

INTRODUCTION

The Government of Canada (GOC) announced on February 8, 2008 that the *Food and Drugs Act*³ and *Food and Drug Regulations*⁴ would be substantially amended to make room for its new “Progressive Licensing Framework” (PLF) for drug approval. While the announcement occurred after at least two years of stakeholder consultations, it nevertheless set off a media storm, with voices from newsprint, internet, and radio outlets crying foul, including those of many experts in the field.⁵ Stakeholders in the natural health product sector also opposed Bill C-51, alleging that up to three-quarters of natural health products would be unable to meet the requirements for approval under Bill C-51.⁶ By contrast, supporters of PLF claim that an increased focus on post-market safety will effectively recalibrate the balance between access and safety and mitigate the ills of the last decade of

² The following list comprises abbreviations that are used throughout this article.

³ *Food and Drugs Act*, R.S.C. 1985, c. F-27.

⁴ *Food and Drug Regulations*, C.R.C., c. 870.

⁵ Carly Weeks, “New Drug Rules Pose Grave Risks: Critics” *The Globe and Mail* (8 February 2008) L6 (Jim Wright [UBC], Joel Lexchin [York], David Juurlink [Sunnybrook], Mary Wiktorowicz [York], Judy Wasylcyia-Leis [NDP] and Michael McBane [Canadian Health Coalition] expressed concerns over the implications of PLF for patient safety); Carly Weeks, “Experts Sound Alarm on Drug-Approval Plan: Under Sweeping New Changes, Drug Companies Only Have to Prove That Benefit of Product Outweighs the Harm” *The Globe and Mail* (9 April 2008). See also “Manufacturers, Patient Groups Support Ottawa’s New Drug Safety Proposals” *CBC News* (10 April 2008), online: CBC <<http://www.cbc.ca/health/story/2008/04/09/drug-bill.html>>; “Canada to Release Trial Drugs to Patients” *New Scientist* (21 April 2008) online: New Scientist <<http://www.newscientist.com/channel/health/mg19826523.800-canada-to-release-trial-drugs-to-patients.html>>; Carly Weeks, “Drug Recalls Linked to U.S. Testing Deadlines” *Globe and Mail* (27 March 2008).

⁶ Spence Pentland, “Bill C51: Taking Away Your Right to Natural Health Products in Canada” *Acubalance Wellness Centre* (2 June 2008), online: Acubalance Wellness Centre <<http://www.acubalance.ca/content/bill-c51-taking-away-your-right-natural-health-products-canada>>; Shawn Buckley, “Bill C-51 Threatens Natural Health Products” *Health Action Network Society*, online: Health Action Network Society <<http://hans.org/magazine/366/threatens-products-natural-health>>; see also Martin Mittelstaedt, “Ottawa to Revive Supplement Safety Bill” *The Globe and Mail* (30 October 2008); Carly Weeks, “Critics Blast New Rules for Natural Remedies” *The Globe and Mail* (23 May 2008) (Some of the claims made include: “most of the herbal remedies for sale in Canada may soon be illegal” and “Canadian parents who give their children vitamins could face arrest”. However, other commentators believe that Bill C-51 will not significantly affect the way natural health products are marketed and sold in Canada, but instead may bring accountability to the unregulated industry). In response to these concerns, GOC issued a statement clarifying that “Bill C-51 will not affect the way that natural health products are regulated in Canada, [that the] *Natural Health Product Regulations*, introduced in 2004, will continue to operate the same way under the proposed Bill [and that] Bill C-51 has been drafted to complement and support current policies for natural health products”: Government of Canada, “Bill C-51 and Natural Health Products - The Facts”, online: Healthy Canadians <http://www.healthycanadians.ca/pr-rp/billc-51_e.html>.

drug regulation. As alluded to in the title of this article, the architects of PLF clearly intend to roll up their sleeves to regulate what food and drug agencies in Canada,⁷ the U.S.,⁸ and the E.U.⁹ have labelled “real world” drug safety and effectiveness. While a truism of sorts, the term is somewhat duplicious. This is because it provides a certain degree of camouflage for the carefully orchestrated disconnect, vetted by major food and drug agencies, between the health status of clinical trial populations on whom drugs are tested and that of actual individuals consuming the products once they are approved. Nevertheless, it is safe to say that greater post-market oversight by GOC will be a welcome step for all parties to drug development, regulation, and consumption.

Progressive licensing is currently enshrined in Bill C-51,¹⁰ which has had its second reading in Parliament to date. While its fate is uncertain at this moment in Canadian politics, provisions such as those encompassed by Bill C-51 are likely to come into force at some point in the near future. Parallel initiatives driven by a cascade of criticisms over existing linear models of drug approval have already been implemented in some form by other major drug agencies, including the U.S. Food and Drug Administration (FDA)¹¹ and the European Medicines Agency (EMA).¹² Consistent with its 2006 National Pharmaceutical Strategy¹³ and accompanying Smart Regulations strategy,¹⁴ GOC sees itself as a leader both in developing an “innovative drug regulation” platform and providing “unique regulatory incentives” to the pharmaceutical industry.¹⁵ In this capacity, drug regulators in Canada are no different from their American and European counterparts, all of whom claim that therapeutic prod-

⁷ Health Canada, “Real World Drug Safety and Effectiveness”, online: Health Canada <<http://www.hc-sc.gc.ca/hcs-sss/pharma/nps-snpp/securit/index-eng.php>> [Health Canada, “Drug Safety”]. See particularly the description of the “distributed” and “centralized” new drug approval models: Health Canada, “4.0 Approaches to Strengthening the Evaluation of Real World Drug Safety and Effectiveness”, online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/pharma/nps-snpp/securit/guide_4-eng.php>. See also Alan Cassels, “Institute of Medicine’s New Drug Safety Report: Implications for Canada” (2006) 175 *Canadian Medical Association Journal* 1515.

⁸ U.S., Institute of Medicine: Committee on the Assessment of the US Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Washington: National Academies Press, 2007), online: Institute of Medicine of the National Academies <<http://www.iom.edu/CMS/3793/26341/37329.aspx>> [IOM Report]. See also Gina Kolata, “The Evidence Gap—New Arena for Testing of Drugs: Real World” *New York Times* (25 November, 2008).

⁹ European Medicines Agency: Evaluation of Medicines for Human Use, *Innovative Drug Development Approaches: Final Report from the EMA/CHMP-think-tank Group on Innovative Drug Development* (London: European Medicines Agency, 2007) [EMA Innovation].

¹⁰ Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, 2nd Sess., 39th Parl., 2008 [Bill C-51].

¹¹ U.S., Food and Drug Administration, “Fast Track, Accelerated Approval and Priority Review: Accelerating Availability of New Drugs for Patients with Serious Diseases” (May 2006), online: FDA <<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessToImportantNewTherapies/ucm128291.htm>> [FDA Fast Track]. U.S., Food and Drug Administration: Department of Health and Human Services, “The Sentinel Initiative: A National Strategy for Monitoring Medical Product Safety” (May 2008), online: FDA <<http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf>> [FDA, “Sentinel”]. See also Gardiner Harris, “F.D.A. to Expand Scrutiny of Risks from Drugs after They’re Approved for Sale” *The New York Times* (23 May 2008).

¹² EC, European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), *Guideline on the Scientific Application and the Practical Arrangements Necessary to Implement Commission Regulation (EC) No 507/2006 on the Conditional Marketing Authorisation for Medicinal Products for Human Use Falling Within the Scope of Regulation (EC) No 726/2004* (Doc. Ref. EMA/509951/2006) (London: European Medicines Agency, 2006), online: EMA <<http://www.emea.europa.eu/pdfs/human/regaffair/50995106en.pdf>> [EMA CHMP 1]; EC, European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), *Report of the CHMP Working Group on Benefit-Risk Assessment Models and Methods* (London: European Medicines Agency, 2007), online: EMA <<http://www.emea.europa.eu/pdfs/human/brmethods/1540407en.pdf>> [EMA CHMP 2]; European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), *Reflection Paper on Benefit-Risk Assessment Methods in the Context of the Evaluation of Marketing Authorisation Applications of Medicinal Products for Human Use* (Doc. Ref. EMA/CHMP/15404/2007) (London: European Medicines Agency, 2008), online: EMA <<http://www.emea.europa.eu/pdfs/human/brmethods/1540407enfin.pdf>> [EMA CHMP 3].

¹³ Federal/Provincial/Territorial Ministerial Task Force on the National Pharmaceuticals Strategy, *National Pharmaceuticals Strategy: Progress Report* (Ottawa: Health Canada, 2006), online: Health Canada <http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgpps/pdf/pubs/2006-nps-snpp/2006-nps-snpp-eng.pdf> [National Pharmaceuticals Strategy].

¹⁴ External Advisory Committee on Smart Regulation, *Smart Regulation: A Regulatory Strategy for Canada* (Ottawa: External Advisory Committee on Smart Regulation, 2004), online: Privy Council Office <<http://www.pco-bcp.gc.ca/smartreg-regint/en/o8/sum.html>> [Smart Regulations].

¹⁵ Robert Peterson, “Innovation in Drug Regulation: Canada as a Leader” (Lecture delivered at Ottawa Regional Conference: “Building Excellence in Clinical Research and Clinical Trials”, 11 February 2005).

uct development is crucial for national prosperity and productivity in the global marketplace.¹⁶ It is therefore not surprising that GOC sees its role not merely as a facilitator, but an “active participant” in driving the costs and risks of medical product development.¹⁷

The sections of Bill C-51 that have sparked the most debate are those granting GOC sweeping powers for clinical trial¹⁸ and market¹⁹ authorizations, including highly complex multi-stage evidentiary thresholds for suspension²⁰ and revocation²¹ of clinical trial applications, market authorizations, and establishment licences. The Bill further gives GOC discretionary power to grant probationary approval for market authorization well ahead of approval typically granted after traditional Phase 3 clinical trials.²² This process has been appropriately referred to by Health Canada in its policy and guidance documents as “flexible departure”.²³ Another significant change from the existing approval regime is the express provision that the threshold for market authorization is where the “benefits outweigh the risks” of a new drug.²⁴ As such, the legal standard of evidence is $\geq 51\%$ benefit-risk rather than a more substantial threshold of say 85%, 75%, or even 65%. Indeed, the preamble to Bill C-51 specifically states that Parliament recognizes that the “lack of full scientific certainty is not to be used as a reason for postponing measures that prevent adverse effects on human health.”²⁵ This has led to predictions of the death, or at least the loss, of important limits imposed on regulatory decision making by reliance on the precautionary principle.²⁶ Concern has also been expressed over the reading-in of provisions incorporating strong intellectual property and regulatory (IPR) rights²⁷ and specific language contemplating incorporation into GOC policy and regulations, knowledge, documents, or information produced by industry and its trade organizations.²⁸ While it is reasonable to speculate that the latter provision is aimed at regulatory harmony and efficient incorporation into the drug approval exercise of technical information arising from global approval processes, there has been some unease that these practices are more in service of economic growth than GOC’s public health mandate.²⁹ This reading is bolstered by statements from various branches of GOC itself.³⁰

¹⁶ Ron A. Bouchard, “Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?” (2007) 13 B.U.J. Sci. & Tech. L. 120 [Bouchard, “Balancing”].

¹⁷ Peterson, *supra* note 15 at 23.

¹⁸ *Bill C-51*, *supra* note 10 at cl. 8 ss. 18.2-18.6.

¹⁹ *Ibid.* at cl. 8 ss. 18.7-19.1.

²⁰ For suspension with notice to sponsor, the threshold for clinical trial application and establishment licence is “preventing an injury” (cl. 8 ss. 15.5(1) and 19.6(1)) and for market authorization is “risks greater than benefit” (cl. 8 s. 19(1)) whereas for suspension without notice to sponsor, the threshold for clinical trial application, market authorization, and establishment licence is “serious and immanent risk of harm” (cl. 8 ss. 18.5(2), 19(2) and 19.6(2)).

²¹ For revocation with notice to sponsor, the threshold for clinical trial application, market authorization, and establishment licence is “breach of terms and condition” of authorization (cl. 8 ss. 18.6(1), 19.1(1), 19.7(1)) whereas for revocation with notice to sponsor, the threshold is “unacceptable risks” (cl. 8 s. 18.6(2)), “risks greater than benefit” (cl. 8 s. 19.1(2)) and “risk of injury to health” (cl. 8 s. 19.7(2)) for clinical trial application, market authorization, and establishment licence respectively.

²² Cl. 8 ss. 18.7-19.2, supported by powers granted cl. 8 s. 20.2, cl. 11 ss. 30(1)(s), (y), and (z.1), and 30.2(1).

²³ Health Canada, “Blueprint for Renewal: Transforming Canada’s Approach to Regulating Health Products and Food” (October 2006) at 14, 20, 38, 39, online: Health Canada <http://www.hc-sc.gc.ca/ahe-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan-eng.pdf> [Health Canada, “Blueprint”]; Health Canada, “The Progressive Licensing Framework Concept Paper for Discussion” at 20-24, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/proglic_homprog_concept-eng.pdf> [Health Canada, “Concept Paper”]. See also Neil Yeates, David K. Lee & Maurica Maher, “Health Canada’s Progressive Licensing Framework” (2007) 176 *Canadian Medical Association Journal* 1845 [Yeates].

²⁴ *Bill C-51*, *supra* note 10 cl. 8 s. 18.7(1).

²⁵ *Ibid.* at preamble, lines 20-23.

²⁶ Mike McBane, “Health Canada Proposing to Eviscerate the Food & Drugs Act” 10:8 *The CCPA Monitor* 1 (February 2004); Janice Graham, “Smart Regulation: Will the Government’s Strategy Work?” (2005) 173 *Canadian Medical Association Journal* 1469 [Graham, “Smart”]; B. Campbell & M. Lee, “Putting Canadians at Risk: How the Federal Government’s Deregulation Agenda Threatens Health and Environmental Standards” *Canadian Centre for Policy Alternative Working Paper*, online: Canadian Centre for Policy Alternatives <http://www.policyalternatives.ca/documents/National_Office_Pubs/2006/Putting_Canadians_at_Risk_summary.pdf>.

²⁷ *Bill C-51*, *supra* note 10 at cl. 11 s. 30(3).

²⁸ *Ibid.* at cl. 11 s. 30(7)(b).

²⁹ Graham, “Smart”, *supra* note 26 at 1469.

This article traces the evolution of the lifecycle approach to drug regulation and provides an overview of its advantages and disadvantages based on contemporary legal and scientific norms. First, we describe the historical roots of the existing regime enshrined in the *Food and Drugs Act* and *Food and Drug Regulations*.³¹ We then discuss several developments in drug regulation that combined have facilitated faster access to new drugs by the public. This includes the following: institution of a fee-for-service arrangement between food and drug agencies and sponsoring firms (user fees); other substantive and procedural mechanisms designed to speed access to new drugs in the presence or absence of market authorization; the evolution of the decision-making model underpinning drug approval away from the precautionary principle toward risk management principles; the accrual of domestic and global IPR rights explicitly designed to stimulate industrial pharmaceutical innovation; and the manner in which the IPR rights agenda has evolved over time to inform both limbs of the push-pull market dynamic for pharmaceutical products. We assess whether these changes, taken together, are associated with increased post-market drug safety problems such as drug withdrawals, black box warnings, and dosage form discontinuations.³² We then describe the movement toward lifecycle, or real world models of drug regulation, including the shift toward PLF. Finally, we conclude with a review of concerns expressed over the global evolution toward the lifecycle approach, including those relating to PLF in Canada.

I

EVOLVING REGULATORY LANDSCAPE

A. Historical Framework

Under the *Constitution Act, 1867*,³³ GOC has jurisdiction over matters pertaining to the approval of pharmaceuticals. The Health Products and Foods Branch (HPFB), an entity of Health Canada, is responsible for granting market authorization for drugs.³⁴ HPFB's mandate is "to take an integrated approach to managing the health-related risks and benefits of health products and food by: minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health."³⁵ As such, the benefit-risk decision making and evidentiary framework for drug regulation and approval is embedded within HPFB's regulatory mandate.

³⁰ See *e.g.* the 2005 speech accompanying the launch of the government's Implementation Plan for Smart Regulation: Reg Alcock, "Government of Canada's Implementation Plan for Smart Regulations" (24 March 2005), online: Treasury Board of Canada Secretariat <http://www.tbs-sct.gc.ca/media/ps-dp/2005/0324_e.asp>; Health Canada, "Blueprint", *supra* note 23 at 8-9; Health Canada, "Concept Paper", *supra* note 23 at 21; Peterson, *supra* note 15; Health Canada: Health Products and Food Branch, "Clinical Trials Regulatory Review—Stakeholder Workshop" (26 March 2007) at 6, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/ctrl_o_eccr_a_2007-03-26-eng.pdf> [Health Canada, "Stakeholder Workshop"]. See also Trudo Lemmens & Ron A. Bouchard, "Regulation of Pharmaceuticals in Canada" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 3d ed. (Toronto: LexisNexis, 2007) 311 [Lemmens & Bouchard].

³¹ *Food and Drugs Act*, *supra* note 3; *Food and Drug Regulations*, *supra* note 4.

³² A "black box warning" is a warning on the package insert for marketed drugs that the product may cause serious adverse reactions, or ADRs. The term arises from the black border that usually surrounds the text of the warnings. See U.S., Food and Drug Administration: Department of Health and Human Services, "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format—Draft Guidance" (Rockville, MD: Center for Biologics Evaluation and Research, 2006) at 9, online: FDA <<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075096.pdf>>.

³³ *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, s. 91 (27) reprinted in R.S.C. 1985, App. II, No. 5. The regulation of pharmaceuticals falls generally under the criminal head of power under s. 91(27) of the *Constitution Act, 1867*. Martha Jackman, "Constitutional Jurisdiction Over Health in Canada" (2000) 8 Health L.J. 95 at 96-99 (According to Jackman, the Supreme Court of Canada held in *R. v. Wetmore*, [1983] 2 S.C.R. 284 at 288, "that the provisions of the federal *Food and Drugs Act* relating to the safety of food, drugs and medical devices, were supportable under the criminal law power, inasmuch as they were directed at protecting the 'physical health and safety of the public'").

³⁴ Lemmens & Bouchard, *supra* note 30 at 319.

³⁵ Health Canada, "About Health Canada: Health Products and Food Branch", online: Health Canada <<http://www.hc-sc.gc.ca/ahe-asc/branch-dirgen/hpfb-dgpsa/index-eng.php>>.

The Therapeutic Products Directorate (TPD) is responsible for granting market authorization for pharmaceutical drugs and medical devices intended for human use.³⁶ In order for authorization to be granted, a manufacturer must present “substantive scientific evidence”³⁷ of a product’s “safety, efficacy and quality,”³⁸ as provided for under the provisions of the *Food and Drugs Act*³⁹ and *Food and Drug Regulations*.⁴⁰ As defined in the *Food and Drugs Act*,

[a] ‘drug’ includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, (b) restoring, correcting or modifying organic functions in human beings or animals, or (c) disinfection in premises in which food is manufactured, prepared or kept.⁴¹

Substances regulated by Health Canada as drugs include prescription, non-prescription, brand name, and generic pharmaceuticals; vaccines; recombinant and blood related biologics; radiopharmaceuticals; homeopathic, traditional, and herbal natural health products; disinfectants; and veterinary medications.⁴²

The process for drug approval in Canada has been divided historically into four phases: (1) pre-clinical studies; (2) clinical trials; (3) drug submission; and (4) approval and marketing. Pre-clinical studies are basic scientific studies that verify the safety of potential drugs, their potential therapeutic uses and the existence and extent of their toxic effects in animals.⁴³ They include all *in vitro*, *in vivo* and animal model experiments.⁴⁴ Based on the results of pre-clinical studies, a drug manufacturer or sponsor may apply, by virtue of a clinical trial application⁴⁵ to the TPD for approval to conduct clinical trials on humans.⁴⁶ Health Canada reviews the applications and notifies the sponsor within 30 calendar days if the application is found to be deficient; if the application is deemed acceptable, a No Objection Letter is issued within the 30-day review period.⁴⁷ A clinical trial application “contains information and documentation to support the objectives and goals of the proposed clinical trial” and “data that supports the drug product quality.”⁴⁸ “The clinical and quality components of the application are reviewed in parallel and both must be satisfactory before a No Objection Letter can be issued.”⁴⁹ The approval of local/institutional Research Ethics Boards at each institution must also be obtained before a clinical trial is initiated.⁵⁰

The existing legislation and regulations contemplate distinct categories of clinical trials,⁵¹ which will almost certainly change when PLF comes into force. These are Phases 1-4.⁵² Phase 1 trials are the first studies in which a new drug is tested in humans.⁵³ They are conducted on small populations

³⁶ Health Canada, “About Health Canada: Therapeutic Products Directorate”, online: Health Canada <<http://www.hc-sc.gc.ca/ahe-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php>>.

³⁷ Lemmens & Bouchard, *supra* note 30 at 326-28.

³⁸ Health Canada, “Drugs and Health Products: Drug Products”, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php>>.

³⁹ *Food and Drugs Act*, *supra* note 3 at s. 30.

⁴⁰ *Food and Drug Regulations*, *supra* note 4 at s. C.08.002(2)(h).

⁴¹ *Food and Drugs Act*, *supra* note 3 at s. 2.

⁴² *Ibid.*

⁴³ Lemmens & Bouchard, *supra* note 30 at 321.

⁴⁴ *Ibid.*

⁴⁵ Health Canada, “Guidance for Clinical Trial Sponsors: Clinical Trial Applications”, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/ctdcta_ctddec_e.html#3> [Health Canada, “Clinical Trial Applications”].

⁴⁶ Lemmens & Bouchard, *supra* note 30 at 321; *Food and Drug Regulations*, *supra* note 4 at s. C.05.004.

⁴⁷ Health Canada, “Food and Drugs Act and Regulations: Background”, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_background-eng.php> [Health Canada, “FDAR Background”]. See also *Food and Drug Regulations*, *supra* note 4 at s. C.05.006.

⁴⁸ Health Canada, “FDAR Background”, *ibid.* See also *Food and Drug Regulations*, *supra* note 4 at s. C.05.005.

⁴⁹ Health Canada, “FDAR Background”, *ibid.*

⁵⁰ *Ibid.*; *Food and Drug Regulations*, *supra* note 4 at s. C.05.006(1)(c).

⁵¹ *Food and Drugs Act*, *supra* note 3; *Food and Drug Regulations*, *supra* note 4 at s. C.05.004. For a definition of “clinical trial” see *Food and Drug Regulations*, *supra* note 4 at s. C.05.001.

⁵² Lemmens & Bouchard, *supra* note 30 at 321-25 and references therein.

⁵³ *Ibid.* See also Health Canada, “Clinical Trial Applications”, *supra* note 45; *Regulations Amending the Food and Drug Act Regulations (1024 - Clinical Trials)*, S.O.R./2001-203; Health Canada: Health Products and Food Branch, *Guidance for Industry: General Considerations for Clinical Trials, ICH Topic E8*, (Ottawa: Public Works and Government Services Can-

(20-80) of healthy volunteers and aim to explore the general pharmacological and pharmacokinetic properties of the drug in question. Phase 2 trials involve larger (100-300) populations of patients who suffer from the disease for which the drug has been developed. The goal of these studies is to evaluate the efficacy of the drug and its short-term side effects. Phase 3 trials typically involve randomized double-blind controlled trials on about 1000-5000 patients, the focus being to determine not only efficacy but also long-term effects, including side effects. Whereas Phase 1-3 trials are currently conducted prior to a drug's market authorization, Phase 4 trials are performed once a drug has been approved. Historically, Phase 4 trials have been aimed at assessing long-term efficacy, different routes of administration, and whether the drug in question differs significantly from other drugs of the same class already on market.⁵⁴ However, as discussed in detail below, the nature of Phase 3-4 trials and the nature of scientific evidence required for approval is almost certain to change once PLF is fully integrated into the nation's regulatory regime.

Where Phase 1-3 trials demonstrate that the potential therapeutic benefits of a given new pharmaceutical outweigh its potential risks, the drug manufacturer may file a New Drug Submission (NDS).⁵⁵ The NDS contains data on drug safety, efficacy, and quality, including data from all relevant preclinical studies and clinical trials pertaining to a drug's manufacturing, packaging, labelling, claimed therapeutic value, conditions for use, and side effects.⁵⁶ A Supplemental New Drug Submission (SNDS) may be filed by a manufacturer for changes to a drug product already marketed by that sponsor.⁵⁷ These changes often include amendments to dosage, strength, formulation, method of manufacture, labelling, route of administration, or even indication.⁵⁸ Products associated with an SNDS are typically referred to as "line-extensions" (Line Extensions) of an already marketed drug. By contrast, a "me too" (Me Too) drug is typically not the first product on market for a given indication and chemical class. While a typical Me Too drug does not necessarily offer a better benefit-risk profile than previously approved comparator(s) for that indication, it does offer a better therapeutic option.⁵⁹ By contrast, a "first in class" (First in Class) drug has no comparator at all. First in Class drugs can be either new (NDS) or supplementary (SNDS) submissions.⁶⁰

Manufacturers of generic drugs submit an Abbreviated New Drug Submission (ANDS) in order to obtain market authorization. An ANDS requires that the generic drug (e.g., sildenafil, vardenafil, and tadalafil) be pharmaceutically equivalent to the reference brand name product (e.g., Viagra, Levitra, and Cialis).⁶¹ In this context, "equivalence" means that the generic product must be the same as the reference product with regard to (a) chemistry, (b) manufacturing, (c) route of administration, (d) conditions of use, and (e) therapeutic and adverse systemic effects when given to patients under the same conditions.⁶² Similar to brand name sponsors, generic sponsors may also submit Supple-

ada, 1997), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/e8-eng.pdf>. See generally Health Canada: Health Products and Food Branch, "ICH Guidance E6: Guideline for Good Clinical Practice: Consolidated Guideline" (1997), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6_e.html>.

⁵⁴ Lemmens & Bouchard, *supra* note 30 at 321-25.

⁵⁵ *Ibid.* at 325; *Food and Drug Regulations*, *supra* note 4 at s. C.08.002(1)(a).

⁵⁶ Lemmens & Bouchard, *supra* note 30 at 325; *Food and Drug Regulations*, *supra* note 4 at s. C.08.002(2). For details, see Health Canada: Health Protection Branch, "Preparation of Human New Drug Submissions: Therapeutic Products Programme Guideline" (1991), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/prephum-eng.pdf>.

⁵⁷ *Food and Drug Regulations*, *supra* note 4 at s. C.08.003.

⁵⁸ Lemmens & Bouchard, *supra* note 30 at 326; *Food and Drug Regulations*, *supra* note 4 at s. C.08.003(2).

⁵⁹ Personal communications with David K. Lee (Director, Office of Legislative and Regulatory Modernization, Policy Planning and International Affairs Directorate [PPAID], HPFB, Health Canada), Dr. Maurica Maher (Senior Scientific Advisor, Progressive Licensing Project, TPD, Health Canada) and Ms. Lesley Brumell (Supervisor, Submissions Processing, Submission and Information Policy Division [SIPD], Health Canada) during the period April-July 2008 [Health Canada Personal Communication].

⁶⁰ The definitions of "First in Class", "Line Extension", and "Me Too" drugs employed by Health Canada are further developed in the companion article: Monika Sawicka & Ron A. Bouchard, "Empirical Analysis of Canadian Drug Approval Data 2001-2008: 'Doing More With Less'" 3 McGill J.L. & Health.

⁶¹ Lemmens & Bouchard, *supra* note 30 at 326. For definition of "Canadian reference product" and "pharmaceutical equivalent", see *Food and Drug Regulations*, *supra* note 4 at s. C.08.001.1.

⁶² Lemmens & Bouchard, *supra* note 30 at 326; *Food and Drug Regulations*, *supra* note 4 at C.08.002.1(1).

mental Abbreviated New Drug Submissions (SANDS) where certain changes are made to a generic drug that is already on the market. Consequently both brand name and generic firms can make “new” and “supplemental” submissions.

The HPFB subsequently reviews NDS, SNDS, ANDS and SANDS to assess the safety, efficacy, and quality of the drug candidates, as well as potential risks and benefits of the product.⁶³ Different classes of therapeutic products have different target times for screening and completion of reviews. For instance, the screening and review times for standard submissions by brand name firms of NDS and SNDS are 45 and 300 days respectively.⁶⁴ Conversely, with respect to generic submissions of ANDS and SANDS, the screening and review times are 45 and 180 days.⁶⁵ Once all regulatory requirements pertaining to safety, effectiveness, and quality have been met, and where the therapeutic benefits of a new drug outweigh its risks and those risks can be managed, a drug manufacturer is issued a Notice of Compliance (NOC).⁶⁶ In the case of generic drugs (ANDS and SANDS), an NOC is issued where the generic drug in question is deemed to be bioequivalent to the Canadian reference product. If a given pharmaceutical does not comply with all the necessary requirements, a Notice of Non-Compliance is issued with opportunity for appeal.⁶⁷

B. Speed of Approval

One of the most important goals of drug regulation writ large over the last two decades is the issue of “access”. One might properly ask: access to what? The question is a vital one as different actors in a complex⁶⁸ regulated Therapeutic Product Lifecycle (rTPL) innovation ecology⁶⁹ will answer it differently, with varying levels of fiduciary obligation.⁷⁰ Even so, the public, or at least certain segments of it, have demanded rapid access to “novel therapeutic products,” and they have largely gotten their way. In Canada and the U.S., considerable resources have been spent to ensure faster drug approval.⁷¹ Primary among these, the *Prescription Drug User Fee Act*⁷² (PDUFA) was enacted by U.S. Congress in 1992. PDUFA authorizes the collection of user fees by the FDA from producers of new research-based drugs and biotechnology products.⁷³ Some commentators have suggested that user fees result in a significant reduction in the standard for review and a concomitant increase in

⁶³ Lemmens & Bouchard, *supra* note 30 at 326.

⁶⁴ Health Canada: Health Products and Food Branch, *Access to Therapeutic Products: The Regulatory Process in Canada* (Ottawa: Health Canada, 2006) at 11, online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/pubs/access-therapeutic_acces-therapeutique-eng.pdf> [*Health Canada Access to TP*].

⁶⁵ *Ibid.*

⁶⁶ *Food and Drug Regulations*, *supra* note 4 at s. C.08.004(1)(a). See also Health Canada, “Notice of Compliance” *Drugs and Health Products*, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/index_e.html>.

⁶⁷ *Food and Drug Regulations*, *supra* note 4 at s. C.08.004(1)(b).

⁶⁸ John H. Miller & Scott E. Page, *Complex Adaptive Systems: An Introduction to Computational Models of Social Life* (Princeton, NJ: Princeton University Press, 2007) at 9 (“In a complicated world, the various elements that make up the system maintain a degree of independence from one another. Thus, removing one such element [which reduces the level of complication] does not fundamentally alter the system’s behavior apart from that which directly resulted from the piece that was removed. Complexity arises when the dependencies among the elements become important. In such a system, removing one such element destroys system behavior to an extent that goes well beyond what is embodied by the particular element that is removed. Complexity is a deep property of a system, whereas complication is not.”)

⁶⁹ William Wulf, “Changes in Innovation Ecology” (2007) 316 *Science* 1253; Ron A. Bouchard, “KSR v. Teleflex Part 2: Impact of U.S. Supreme Court Patent Law on Canadian and Global Systems-Based Innovation Ecologies” (2007) 15 *Health L.J.* 247 [Bouchard, “Systems”]; Ron A. Bouchard, “Reflections on the Value of Systems Models for Regulation of Medical Research and Product Development” (2008) 17 *Health L. Rev.* 28 [Bouchard, “Reflections”].

⁷⁰ Bouchard, “Balancing” *supra* note 16; Ron A. Bouchard, “Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie that Binds Obviousness and Inventiveness” (2007) 4 *University of Ottawa Law & Technology Journal* 1 [Bouchard, “Living”].

⁷¹ Lemmens & Bouchard, *supra* note 30 at 337.

⁷² *Prescription Drug User Fee Act*, 21 U.S.C. § 343-379g (2006) [PDUFA]. See generally U.S., Food and Drug Administration, “Prescription Drug User Fees”, online: FDA <<http://www.fda.gov/oc/pdufa/>>.

⁷³ David J. Cantor, “Prescription Drug User Fee Act of 1992: Effects on Bringing New Drugs to Market” *CRS Report for Congress* (12 September 1997), online: Policy Archive <https://www.policyarchive.org/bitstream/handle/10207/459/97-838_19970912.pdf?sequence=1>.

risk for the drug-consuming public.⁷⁴ Others have vigorously denied this,⁷⁵ claiming that PDUFA has provided necessary resources to expand review staff so that drug reviews can be completed within a certain time frame in the absence of revision to the standard for drug approval.⁷⁶

The purpose of levying user fees was to enable the FDA to mitigate the regulatory burden on itself and pharmaceutical firms by augmenting staff and resources in order to accelerate review and enhance access.⁷⁷ Importantly, the FDA is not formally obligated to approve drugs faster in exchange for fees.⁷⁸ Rather, the onus is on the FDA to “review and act on” drug and biological submissions, with a focus on issuance of an action letter after review of the submission file. A 2002 U.S. General Accounting Office (GAO) report found that PDUFA funds allowed the FDA to increase the number of new drug reviewers by 77% in the first eight years of PDUFA, with a drop in median approval time for non-priority new drugs from 27 months to 14 months over the same period.⁷⁹ Using an elegant statistical analysis, Berndt *et al.* found that mean approval times for new molecular entities declined continuously following the coming into force of PDUFA I (1992), II (1997) and III (2002), from 33.6 months in a 1979-1986 year bin to 28.2, 18.6, and 16.1 months in the subsequent 1986-1992, 1992-1997, and 1997-2002 bins.⁸⁰ Comparing data trends pre- and post-PDUFA, the authors estimated that approval times would have declined even in the absence of user fees by about 1.7% annually, from 30 months in 1979 to 20 months in 2002. However, the data also demonstrated that the slope of the actual decline in review times was much steeper (25%) following the coming into force of PDUFA I and II. Similarly, Rawson and Kaitin reported that the median approval time for new drugs decreased from 713 days in 1992 with a load of 62 applications to 393 days in 2001 with a load of 25 applications.⁸¹ User fees are also collected by the EMEA,⁸² with the goal of industry fees eventually accounting for 75% of agency funding.⁸³

User fees were introduced informally in Canada as early as 1995 in order to recover the bureaucratic costs associated with drug approvals and create incentives for regulators to speed up the regulatory process.⁸⁴ As in the U.S., industry requested a faster drug approval process in return for fees.⁸⁵ By 1997, approval times had decreased substantially: the median approval time was 490 days with a load of 39 applications compared with 405 days with a load of 43 applications in the U.S.⁸⁶ By 1999, it was estimated that user fees accounted for ~70% of the cost of running the TPD.⁸⁷ The Canadian

⁷⁴ Mary E. Wiktorowicz, “Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain and France” (2003) 28 *J. of Health Politics* 615; Laura Eggertson, “Drug Approval System Questioned in US and Canada” (2005) 172 *Canadian Medical Association Journal* 317; Joel Lexchin, “Drug Withdrawals from the Canadian Market for Safety Reasons, 1963–2004” (2005) 172 *Canadian Medical Association Journal* 765 [Lexchin, “Withdrawals”]; R. Horton, “The FDA and Lotronex: A Fatal Erosion of Integrity” (2001) 357 *Lancet* 1544.

⁷⁵ John Graham, “Approving New Medicines in Canada: Health Canada Needs a Dose of Competition” (June 2005) *Fraser Forum* 9 [Graham, “Dose”].

⁷⁶ Steven K. Galson, “The FDA and the IOM Report”, Letter to the Editor (2007) 357 *New Eng. J. Med.* 2520.

⁷⁷ Cantor, *supra* note 73 at 1.

⁷⁸ Ernst R. Berndt *et al.*, “Industry Funding of the FDA: Effects of PDUFA on Approval Times and Withdrawal Rates” (2005) 4 *Nature Reviews Drug Discovery* 545 at 545 [Berndt *et al.*]; Daniel Carpenter, Evan James Zucker & Jerry Avorn, “Drug-Review Deadlines and Safety Problems” (2008) 358 *New Eng. J. Med.* 1354 at 1355 [Carpenter *et al.*].

⁷⁹ U.S., General Accounting Office, *Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals and Other Agency Activities—Report to the Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate* (S. Doc. No. 02-958) (Washington, D.C.: United States Government Printing Office, 2002) at 3, 8, online: GAO <<http://www.gao.gov/new.items/do2958.pdf>> [USGAO *User Fees*].

⁸⁰ Berndt *et al.*, *supra* note 78 at 546.

⁸¹ Nigel Rawson & Kenneth Kaitin, “Canadian and US Drug Approval Times and Safety” (2003) 37 *The Annals of Pharmacotherapy* 1403 at 1404 (note, these figures are from an “industry-sponsored study” [Rx&D]).

⁸² Ines M. Vilas-Boas & C. Patrick Tharp, “The Drug Approval Process in the U.S., Europe, and Japan: Some Marketing and Cost Implications” (1997) 3 *Journal of Managed Care Pharmacy* 459. See also EU, European Medicines Agency, *Road Map to 2010: Preparing the Ground for the Future (Doc. Ref: EMEA/H/34163/03/Final)* (4 March 2005), online: EMEA <<http://www.emea.europa.eu/pdfs/general/direct/directory/3416303enF.pdf>> [EMEA *Road Map*].

⁸³ Berndt *et al.*, *supra* note 78 at 546.

⁸⁴ Graham, “Dose”, *supra* note 75 at 9.

⁸⁵ J. Lexchin, “Transparency in Drug Regulation: Mirage or Oasis” at 9, online: Canadian Centre for Policy Alternatives <<http://policyalternatives.ca/index.cfm?act=news&do=Article&call=913&pA=94761C2A&type=5>>.

⁸⁶ Rawson & Kaitin, *supra* note 81 at 1404.

⁸⁷ Lexchin, “Withdrawals”, *supra* note 74 at 765, citing: KPMG Consulting, “Review of Therapeutic Products Pro-

*User Fees Act*⁸⁸ came into force in 2004, in part due to continued complaints over the relatively slow approval process in Canada.⁸⁹ About the time the *User Fees Act* was passed, the average approval time in Canada had increased from a low of 490 days in 1997⁹⁰ to about 621 and 820 days in 2003 and 2004, respectively.⁹¹ Since then, approval times have dropped again. Review times for 2007 reported by GOC were 247, 499, and 467 days for priority, standard, and total new drug submissions and 219, 344, and 341 days for priority, standard, and total abbreviated submissions.⁹² The data reviewed thus far illustrate that user fees legislation has been successful where implemented in reducing approval times for drugs. The increase in speed of review applies to drugs and biologics entering both standard and expedited review streams. The study by Brandt *et al.* provides evidence to suggest that the decline in approval times triggered by user fee legislation is significantly steeper than the reduction in review times that may have been ongoing prior to PDUFA.⁹³

Apart from user fees, a number of other factors have combined to increase approval speed and enhance access to new drugs.⁹⁴ This includes a number of administrative and technological developments designed to streamline the review process, higher quality applications, efforts toward global regulatory harmony, enhanced focus on leveraging knowledge gained from reviews in other jurisdictions, advocacy by real and apparent patient advocacy groups, and cultural changes within agencies themselves resulting from increasing partnership between industry and regulators.⁹⁵ Perhaps the most important of these however are policies and programs aimed at making drugs available to the public in a more expedient fashion.⁹⁶ As early as 1996, Health Canada issued a policy statement entitled *Priority Review of Drug Submissions* (Priority Review).⁹⁷ This policy provided for the “fast-tracking” of eligible NDS and SNDS intended for the treatment, prevention, or diagnosis of serious, life-threatening, or severely debilitating diseases or conditions for which there existed an unmet medical need or for which a substantial improvement in the benefit-risk profile of the therapy was demonstrated.⁹⁸ Drugs intended for conditions such as HIV/AIDS, Alzheimer’s, Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig’s Disease), angina pectoris, heart failure, and cancer, among others, were targeted for Priority Review.⁹⁹ Importantly, the same safety, efficacy, and quality criteria were required for the Priority Review process as for standard drug submissions—the main difference being the accelerated review time.¹⁰⁰ Target times for screening and review of Priority Review submis-

gramme Cost Recovery Initiative” (Ottawa: Ministry of Health, 2000). Joel Lexchin has recently suggested that 50% of the budget for drug review now comes from user fees (Joel Lexchin, personal communication [22 October 2006], cited in Lemmens & Bouchard, *supra* note 30 at 318), a figure which tracks that in the US of about 53% in 2004, up from 7% in 1993: Anna W. Matthews, “Drug Firms Use Financial Clout to Push Industry Agenda at FDA” *The Wall Street Journal* (1 September 2006) A1.

⁸⁸ S.C. 2004, c. 6.

⁸⁹ Nigel S.B. Rawson, “Time Required for Approval of New Drugs in Canada, Australia, Sweden, the United Kingdom and the United States in 1996-1998” (2000) 162 *Canadian Medical Association Journal* 501; see generally Graham, “Dose”, *supra* note 75 at 9.

⁹⁰ Rawson & Kaitin, *supra* note 81 at 1404.

⁹¹ Joel Lexchin, “Drug Approval Times and User Fees: An International Perspective in a Changing World” (2008) 22 *Pharmaceutical Medicine* 1 at 8.

⁹² Health Canada: Health Products and Food Branch, *Annual Drug Submission Performance Report: Part I* (Therapeutic Products Directorate, 2007), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/docs/perform-rendement/ar-ra/tpd_dpt_annual_annuel_07-eng.php> at 11, 34. As of April 14th 2009, Health Canada has not yet released its 2008 Annual Report.

⁹³ Berndt *et al.*, *supra* note 78.

⁹⁴ See Letter to the Editor from FDA Officials and subsequent Correction by the authors: Clark Nardinelli, Michael Lanthier & Robert Temple, “Drug Review Deadlines and Safety Problems” (2008) 359 *New Eng. J. Med.* 95; Daniel Carpenter, “Reply to Letter to the Editor” (2008) 359 *New Eng. J. Med.* 96 [Carpenter, “Reply”]. See also Berndt *et al.*, *supra* note 78; Hans-Georg Eichler *et al.*, “Balancing Early Market Access to New Drugs with the Need for Benefit/Risk Data: A Mounting Dilemma” (2008) 7 *Nature Reviews Drug Discovery* 818.

⁹⁵ Bouchard, “Balancing”, *supra* note 16; Bouchard & Lemmens, *supra* note 30.

⁹⁶ For review, see Eichler *et al.*, *supra* note 94.

⁹⁷ Health Canada, “Guidance for Industry: Priority Review of Drug Submissions” (2008), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/priordr-eng.pdf> [Health Canada, “Priority Review”].

⁹⁸ *Ibid.* at 1-2.

⁹⁹ *Ibid.*

¹⁰⁰ Lemmens & Bouchard, *supra* note 30 at 328; Health Canada, “Priority Review”, *supra* note 97.

sions have now been shortened to 25 and 180 calendar days, respectively, from 45 and 300 days for non-priority submissions.¹⁰¹ In short, Priority Review ensures that drug manufacturers jump ahead of others in the approval queue.¹⁰²

In addition to Priority Review, a drug manufacturer or sponsor may be granted an NOC with conditions (NOC/c) if certain imposed requirements are satisfied.¹⁰³ According to Health Canada, “the NOC/c Policy applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (SNDS) for a serious, life-threatening, or severely debilitating disease or condition for which there is promising evidence of clinical effectiveness based on the available data that the drug has the potential to provide: effective treatment, prevention, or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventatives, or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.”¹⁰⁴ An NOC/c is essentially granted to expedite patient access to potentially life-saving drugs under circumstances of dire illness.¹⁰⁵ In addition to less onerous evidentiary requirements, the review process itself is also significantly accelerated, as targeted screening and review times for an NOC/c are 25 and 200 calendar days respectively.¹⁰⁶ The NOC/c policy grants a drug manufacturer or sponsor market authorization for the pharmaceutical in question on the condition that it performs additional studies to confirm the drug’s alleged therapeutic benefit. The HPFB has, by virtue of the *Food & Drugs Act* and regulations, nominal jurisdiction to ensure a manufacturer’s compliance through post-market surveillance.¹⁰⁷

It has been claimed that the lack of specific legislative provisions allowing for contextual pre-market and post-market decision making relating to approvals under the NOC/c and Priority Review streams is one of the main drivers for reform of the nation’s drug approval regime.¹⁰⁸ NOCs granted in accordance with NOC/c and Priority Review policies are currently issued under the general licensing provisions of the *Food and Drug Regulations*,¹⁰⁹ rather than provisions specific to either expedited review pathway. Licences are granted under the terms of C.08.004(1), modified by evidentiary requirements specific to the “conditions for use” provided for under C.08.002(1), particularly C.08.002(1)(g), and C.08.002(1)(h). Parallel provisions exist with regard to drugs used in the context of clinical trials under C.05.006(2)(a). These provisions are enabled by s. 30(o)(ii) of the *Food and Drugs Act*, which provides GOC with the jurisdiction to make regulations respecting the “sale or conditions of sale of any new drug”.¹¹⁰ If evidence or new information arises after issuance of an NOC/c, or an NOC under the Priority Review stream, to the effect that the “conditions of use” are contravened, the Minister of Health may suspend an NOC/c or NOC under the provisions of C.08.006(1) and C.08.006(2). What contextual standards and mechanisms do exist for both review mechanisms are those based on policies contained in Health Canada “guidance documents”.¹¹¹ Guid-

¹⁰¹ *Health Canada Access to TP*, *supra* note 64 at 11. See also Health Canada, “Priority Review of Drug Submissions”, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/prfs_tpf-eng.php> (“Health Canada believes it is in the best interests of Canadians to review potentially life-saving drugs as early as possible.” Therefore, “Priority Review submissions are inserted into Health Canada’s drug submission queue in accordance with a shortened review target and, as such, may be reviewed in advance of non-priority submissions.”)

¹⁰² Health Canada Personal Communication, *supra* note 59.

¹⁰³ NOC/c is granted pursuant to s. C.08.004(1), in compliance with the conditions of use stipulated in s. C.08.002(1)(g), C.08.002(1)(h), C.08.006(2)(b), C.05.006(2)(a).

¹⁰⁴ Health Canada, *Guidance for Industry: Notice of Compliance with conditions (NOC/c)* (2006), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/noccg_accd-eng.pdf> [*NOC/c Guidance Document*].

¹⁰⁵ Lemmens & Bouchard, *supra* note 30 at 329.

¹⁰⁶ *Health Canada Access to TP*, *supra* note 64.

¹⁰⁷ Lemmens & Bouchard, *supra* note 30 at 329. See also Health Canada, “Blueprint”, Health Canada, “Concept Paper”, and Yeates, *supra* note 23.

¹⁰⁸ Health Canada, “Blueprint”, and Health Canada, “Concept Paper”, *supra* note 23; Peterson, *supra* note 15.

¹⁰⁹ *Food and Drug Regulations*, *supra* note 4. See also Health Canada, “Notice of Compliance with conditions (NOC/c)” *Drugs and Health Products*, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php>>.

¹¹⁰ *Food and Drugs Act*, *supra* note 3 at s. 30(o)(ii).

¹¹¹ Health Canada, “Priority Review”, *supra* note 97; *NOC/c Guidance Document*, *supra* note 104.

ance documents are “administrative instruments” that are “meant to provide assistance to industry and health care professionals on how to comply with the policies and governing statutes and regulations.”¹¹² While they have no force of law, GOC nevertheless claims that inclusion of the regulatory mechanisms therein allows for enhanced regulatory flexibility under certain conditions.¹¹³

In addition to Priority Review and NOC/c, Health Canada also allows physicians to gain access through its Special Access Programme to non-marketed drugs and medical devices that have not yet been approved for sale in Canada, provided that a patient has a serious or life threatening condition and where conventional therapies have failed, are unavailable, or are unsuitable.¹¹⁴

C. Mechanism of Approval

Along with the time for approval, there have also been significant shifts in the mechanism of drug approval over the last decade that have potentially accelerated the approval process and promoted access. The established decision-making framework for drug approval, as provided for in the *Food and Drugs Act* and *Food and Drug Regulations*,¹¹⁵ is referred to as the “precautionary principle”. The term is often used in reference to Galen’s injunction to “first, do no harm” (*primum non nocere*). This means that, when an activity raises a significant threat of harm to human health, precautionary measures should be undertaken even if some aspects of the cause and effect relationship have not been scientifically established.¹¹⁶ As might be surmised from the fact it is about to be replaced as the primary basis for drug approval, the precautionary principle is not universally accepted, in part due to the large variation in how it is applied.¹¹⁷ Nevertheless, it is agreed to encompass three elements: the presence of scientific uncertainty, a significant threat of harm, and a set of possible precautionary actions to avoid such harm.¹¹⁸ Its supporters view the principle as proactive and anticipatory, while its detractors as an unscientific evidentiary approach that impairs economic and technological progress based on unfounded or irrational fears.¹¹⁹

The focus of the debate over the precautionary principle as it relates to drug approval is (1) how to balance scientific uncertainty with risk in the context of inherently dangerous products and (2) who should bear the burden of adducing the required evidence of safety. Both issues are highly relevant for the lifecycle approach to approval: the former through risk acceptance and reallocation among public and private actors, and the latter through the shift in both the amount and, potentially, the type of scientific evidence required for drug approval, particularly in the context of expedited approval.¹²⁰ The question is an open one as to how best to move from a strong (100% evidence of safety) or even moderate ($\geq 75\%$ evidence of safety) precautionary principle to a benefit-risk analysis that expressly balances ($\geq 51\%$ evidence of safety) the public interest in health and safety with corporate efficiency considerations. In comparison, a purely economic focus on regulation is one that is

¹¹² Health Canada, “Priority Review”, *supra* note 97 at i; *NOC/c Guidance Document*, *supra* note 104 at i.

¹¹³ *NOC/c Guidance Document*, *supra* note 104 at i (“[A]lternate approaches to the principles/practices outlined in the documents may be accepted if they are supported by adequate scientific justification”).

¹¹⁴ Health Canada, “Drugs and Health Products—Special Access to Drugs”, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/acces/index-eng.php>>.

¹¹⁵ *Food and Drugs Act*, *supra* note 3; *Food and Drug Regulations*, *supra* note 4.

¹¹⁶ Pauline Barriue & Bernard Sinclair-Desgagné, “On Precautionary Policies” (2006) 52 *Management Science* 1145 at 1147.

¹¹⁷ Currently, there are between fourteen and nineteen different versions implemented globally: P. Sandin, “Dimensions of the Precautionary Principle” (1999) 5 *Human and Ecological Risk Assessment* 889; D. VanderZwaag, “The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces” (1998) 8 *J. Envtl. L. & Prac.* 355; Barriue & Sinclair-Desgagné, *supra* note 116.

¹¹⁸ Carolyn Raffensperger & Joel Tickner, eds., *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington: Island Press, 1999).

¹¹⁹ Royal Society of Canada Expert Panel Report on the Future of Food Biotechnology, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (2001) 64 *Journal of Toxicology and Environmental Health* 1 at 194.

¹²⁰ Health Canada, “Blueprint”, and Health Canada, “Concept Paper”, *supra* note 23.

geared toward licensing products that meet minimum quality standards (e.g., positive benefit-risk ratio), rather than licensing products that are absolutely safe.¹²¹

In strong formulations of the precautionary principle, absolute proof of safety is necessary before allowing a certain activity. Pharmaceutical firms carry the legal burden of proof to introduce necessary and sufficient evidence of drug safety in their drug submissions. While this formulation accords with a government gate-keeping function, it is nevertheless parochial in nature and presents a significant hurdle for drug development and approval seen through the eyes of newer systems biology frameworks. As discussed in the context of regulated innovation ecologies,¹²² systems-based mental models and analytical frameworks acknowledge the non-linear and uncertain nature of clinical research, even that which is conducted under the most controlled circumstances. The acceptance of uncertainty and risk in the context of medical product development and regulation clearly breaches the requirement in strong articulations of the principle for absolute proof *ex ante*. By contrast, weak articulations of the principle allow activities to be undertaken in the absence of any scientific proof at all¹²³ which also presents obvious and serious risks to human health. Moderate articulations of the principle open the door to some type of benefit-risk analysis while avoiding pitfalls associated with extremes of both positions.

The moderate position has been implicitly supported by the U.S. Institute of Medicine (IOM) in its *Future of Drug Safety* report.¹²⁴ The IOM expressly adopted a position that respects uncertainties involved in scientific investigation,¹²⁵ acknowledging that even the best drug safety system in the world will not prevent serious adverse reactions to marketed pharmaceuticals due in part to the complexity of their mechanisms of action. Probing the connection between post-market withdrawals and the effectiveness of drug regulation more generally, IOM noted that

[s]ome observers believe that drug withdrawals (which are only one potential indicator of drug safety) represent de facto failures of the drug regulatory system, or that newly identified unusual and serious adverse events indicate that someone made a mistake in approving the drug. This is not so. FDA approval does not represent a lifetime guarantee of safety and efficacy, and what is newest is not always the best. For several related reasons, even the best drug safety system would not prevent adverse reactions to pharmaceuticals on the market. It is impossible to know everything about a drug at the point of approval because drugs' mechanisms of action are complex, and because the clinical testing that happens before approval is generally conducted in controlled settings in defined, carefully selected populations that may not fully represent the wide range of patients who will use the drug after approval, some chronically, and in combination with other drugs. Thus, the understanding of a drug's risk-benefit profile necessarily evolves over the drug's lifecycle. CDER staff who review regulatory submissions, such as new drug applications, must strike a delicate balance in judging the drug's risks and benefits, and whether the need for more study to increase certainty before approval warrants delaying the release of the drug into the marketplace and into the hands of health care providers and their patients.¹²⁶

The FDA reformulated the nexus between the uncertainties of drug development and those of regulation, suggesting that the answer to the problem of post-marketing drug safety was the emerging "science of safety."¹²⁷ FDA clearly views this field as providing quantitative risk management methods not only to target drug use to specific patients but to provide a critical method to "prevent adverse effects by rapidly identifying drug safety problems before they can cause injury."¹²⁸ From the report, one might also surmise that FDA envisions a roping in of the uncertainties of drug development as

¹²¹ Louis P. Garrison Jr., Adrian Towse & Brian W. Bresnahan, "Assessing a Structured, Quantitative Health Outcomes Approach to Drug Risk-Benefit Analysis" (2007) 26 *Health Affairs* 684 at 687.

¹²² Bouchard, "Systems", and Bouchard, "Reflections", *supra* note 69.

¹²³ Kenneth R. Foster, Paolo Vecchia & Michael H. Repacholi, "Risk Management: Science and the Precautionary Principle" (2000) 288 *Science* 979 at 979.

¹²⁴ *IOM Report*, *supra* note 8.

¹²⁵ *Ibid.* at S-2; For general references regarding the role of uncertainty in scientific systems and daily life, see Gunther S. Stent, *Paradoxes of Progress* (San Francisco: W.H. Freeman, 1978); John L. Casti, *Searching For Certainty: What Scientists Can Know About the Future* (New York: William Morrow & Co., 1990); Paul W. Glimcher, *Decisions, Uncertainty and the Brain: The Science of Neuroeconomics* (Cambridge, MA: MIT Press, 2003).

¹²⁶ *IOM Report*, *supra* note 8 at S-3.

¹²⁷ U.S., Food and Drug Administration: Department of Health and Human Services, "The Future of Drug Safety—Promoting and Protecting the Health of the Public: FDA's Response to the Institute of Medicine's 2006 Report" (January 2007) at 3 (website on file with author) [FDA, "Response"].

¹²⁸ *Ibid.*

the key to “the trade-off between safety and access” or indeed that between safety, access and industrial development. Mitigation of uncertainty via development of new quantitative tools is therefore seen by FDA as a legitimate tool for the agency to achieve its goals of “personalized, predictive, [and] preventive” medicine.¹²⁹ Contrary to first impression, FDA’s position on the “science of safety” does not veer toward a stronger precautionary stance, notwithstanding the scientific, quantitative, or otherwise objective discourse in which it is embedded. This is because of FDA’s explicit purpose to support its pharmaceutical partners and stimulate industrial innovation using corporate risk management tools, including the scenario where the “Agency’s efforts to improve drug safety must not dampen the process of innovation that could itself enable safer approaches to drug development and drug use.”¹³⁰ At no point does FDA stipulate or define what constitutes an acceptable or even desirable level of “innovation” from a societal perspective, let alone how the goal of facilitating innovation relates to the degree of acceptable risk tolerance by a technologically naïve drug-consuming public.

IOM’s approach (if not that of FDA) is consistent in a number of respects to the work of the EMEA on benefit-risk assessment models.¹³¹ Importantly, both advocate a “hybrid” or “semi-quantitative” benefit-risk assessment framework that incorporates objective evidence-based and subjective expertise-based decision-making methods. However, the EMEA Committee for Medicinal Products for Human Use (CHMP) has stipulated quite clearly that “quantitative benefit-risk assessment is not expected to replace qualitative evaluation” as the cornerstone of the drug approval process.¹³² Rather, “expert judgment is expected to remain the cornerstone of benefit-risk evaluation for the authorization of medicinal products” for the foreseeable future. CHMP noted that to date none of the main global regulatory agencies have issued a list of benefit and risk criteria and that “there is no agreed approach on the methodology to estimate the overall benefit risk, and how to describe the way evidence is weighed and balanced.”¹³³ Moreover, over-reliance on quantitative numerical models had the potential to skew benefit-risk calculations, because many quantitative models do not adequately reflect the “intellectual process of assessing the empirical evidence, accommodating risks and balancing risks and benefits.”¹³⁴ After reviewing a number of quantitative, qualitative, and hybrid models, including the Number Needed to Treat (NNT), Number Needed to Harm (NNH), Principle of Three, Transparent Uniform Risk Benefit Overview (TURBO), and Multi-Criteria Decision Analysis (MCDA) models, CHMP concluded that hybrid models represented the best available decision-making approach to drug regulation based on their ability to balance objective risk assessment with expert judgment. In its follow-on report¹³⁵ the committee elaborated further on its reasons, highlighting the fact that MDCA and other hybrid models were best able to combine objective and subjective factors by allowing for uncertainties inherent to drug development and drug regulation as well as different stakeholder interests while minimizing the dangers of oversimplified quantitative models.¹³⁶ The committee called for enhanced transparency in regulatory decision-making,¹³⁷ largely via pressure on experts to explicitly document their reasons for subjective judgments and their selection of certain quantitative criteria over others and to recognize and account for differing stakeholder interests in approval.

In a recent review of emerging regulatory models, Eichler *et al.* also underscored the importance of various types of uncertainty in developing, regulating, and consuming novel therapeutic products.¹³⁸ Particular attention was drawn to the inherently unpredictable nature of these risks and their

¹²⁹ *Ibid.* at 4, 6, 8.

¹³⁰ *Ibid.* at 3.

¹³¹ EMEA CHMP 2 and EMEA CHMP 3, *supra* note 12. See also EMEA Innovation, *supra* note 9; EMEA Road Map, *supra* note 82. As noted in EMEA CHMP 3 (at 3), the threshold for approval pursuant to Article 26 of Directive 2001/83 is that “market authorisation shall be refused if the benefit-risk balance is not considered to be favourable or if therapeutic efficacy is insufficiently substantiated.”

¹³² EMEA CHMP 2, *supra* note 12 at 7.

¹³³ *Ibid.* at 3.

¹³⁴ *Ibid.* at 7.

¹³⁵ *Ibid.* at 4-6.

¹³⁶ *Ibid.* at 5.

¹³⁷ *Ibid.* at 7, 13; EMEA CHMP 3 at 2, 4, 5.

¹³⁸ Eichler *et al.*, *supra* note 94.

relation to idiosyncratic, rare, or otherwise unexpected adverse drug reactions (ADRs). The authors stated that “ADRs are not likely to become a thing of the past, do not necessarily indicate failure of the regulatory process and have to be accepted in any model of drug approval - early or late.”¹³⁹ Indeed, the notion that consumption of pharmaceutical products inevitably involves some form of risk and the public must assume a significant fraction of this risk, constitutes the main driver of emerging risk management models of drug regulation. Given the public outcry over drugs that have been withdrawn from the market for safety considerations,¹⁴⁰ it is not surprising that some drug agencies, including Health Canada, have come to an understanding that they must strike a delicate balance between providing the public with timely access to new drugs and adjudicating the risks and benefits of drug development under conditions that are uncertain and continually changing. Complicating this scenario is the information asymmetry that exists with regards to ADRs even when that information is available. The pervasive nature of the uncertainties combined with knowledge asymmetry has prompted numerous jurisdictions, including Canada,¹⁴¹ the E.U.,¹⁴² and the U.S.,¹⁴³ to base the regulatory exercise on both objective and subjective metrics rather than solely on objective evidence and quantitative models. For this reason, it seems reasonable to conclude that hybrid decision-making models embrace the more moderate articulation of the precautionary principle, even if it is reformulated in benefit-risk terms. Consequently, while the precautionary principle will no longer form the exclusive basis for drug approval, it seems premature to sound its death knell just yet.

D. IPR Rights Associated with Approval

In addition to changes in the speed and mechanism of review, there are subtle global and domestic economic forces driving the lifecycle debate that have attracted less attention.¹⁴⁴ For example, since 1993, there has been a substantial shift in the relationship between intellectual property rights associated with pharmaceutical products and regulatory approval of the drugs these patents were intended to protect. As part of Canada's obligations under NAFTA¹⁴⁵ and TRIPS,¹⁴⁶ provisions for compulsory licensing of pharmaceuticals in the *Patent Act*¹⁴⁷ were repealed and replaced with “linkage regulations” referred to as *NOC Regulations*.¹⁴⁸ These regulations tie patent protection for marketed pharmaceuticals to the drug approval process by enabling brand name pharmaceutical firms to list as many patents as are relevant to a marketed product on a patent register. For a generic firm to receive market authorization for that product, each patent on the register must be shown in litigation to be either invalid or not infringed. In this way, the number and scope of patents registered for a given Canadian reference product control entry of generic drugs into the market. Linkage regulations create a bifurcated role for government,¹⁴⁹ potentially constitutional in nature,¹⁵⁰ as public health

¹³⁹ *Ibid.* at 821.

¹⁴⁰ For book-length treatments, see Philip J. Hilts, *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* (New York: Alfred A. Knopf, 2003); Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* (New York: Alfred A. Knopf, 2004); Sheldon Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Lanham, MD: Rowman & Littlefield, 2003); Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What To Do About It* (New York: Random House, 2004); Jay S. Cohen, *Overdose: The Case Against the Drug Companies* (New York: Penguin, 2001).

¹⁴¹ Health Canada, “Blueprint”, *supra* note 23.

¹⁴² *EMEA CHMP 2* and *EMEA CHMP 3*, *supra* note 12; *EMEA Innovation*, *supra* note 9.

¹⁴³ *IOM Report*, *supra* note 8.

¹⁴⁴ Bouchard, “Balancing”, *supra*, note 16; Ron A. Bouchard & Trudo Lemmens, “Privatizing Biomedical Research—A Third Way” (2008) 26 *Nature Biotechnology* 31 [Bouchard & Lemmens, “Biomedical”].

¹⁴⁵ *North American Free Trade Agreement (NAFTA)*, 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (between the Governments of Canada, Mexico, and the United States; entered into force 1 January 1994).

¹⁴⁶ *Trade Related aspects of Intellectual Property (TRIPS) 1994*, 30 October 1947, 58 U.N.T.S. 187, Can. T.S. 1947 No. 27 (negotiated as part of the Uruguay Round (1986-1994) of the World Trade Organization's General Agreement on Tariffs and Trade [GATT]).

¹⁴⁷ R.S.C. 1985, c. P-4.

¹⁴⁸ *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133. For a review of the history of the NOC Regulations, see Gunars K. Gaikis, “Pharmaceutical Patents in Canada: An Update on Compulsory Licensing” (1992) 42 *Patent World* 19; Edward Hore, “A Comparison of US and Canadian Laws as They Affect Generic Pharmaceutical Drug Entry” (1992) 55 *Food & Drug L.J.* 373.

¹⁴⁹ See generally Rebecca S. Eisenberg, “Patents, Product Exclusivity, and Information Dissemination: How Law Directs

agencies are simultaneously charged with ensuring the safety and efficacy of pharmaceutical products while protecting the competitive advantage of firms. Patenting is seen to be critical in order for firms to innovate, and the quid pro quo accepted by domestic governments in this bargain appears to be the hope of new and useful products for consumers. The substance and procedure of the *NOC Regulations* were based on analogous legislation and policy in the U.S.¹⁵¹ Prior to this point, patent protection and regulatory approval of pharmaceuticals were governed by two completely different statutes as well as different policy goals and objectives.¹⁵² In addition to patent protection per se, new provisions were added to the *Food and Drug Regulations* pertaining to data, market and pediatric exclusivity. These exclusivity periods refer to periods of time, in addition to the patent monopoly, during which brand name sponsors are granted market monopolies linked to data submitted to Health Canada in the context of regulatory submissions.¹⁵³ Via amendments to C.08.004.1 of the *Food and Drug Regulations* in June 2006,¹⁵⁴ Canada provided for a guaranteed minimum period of 8.5 years of market exclusivity in order to implement its perceived NAFTA and TRIPS obligations. This includes six years of protection for regulatory submission data (data exclusivity), an additional two years of exclusivity (market exclusivity) during which an NOC cannot be issued to a generic manufacturer and an additional six months of protection to drugs that have been the subject of clinical trials in children (pediatric exclusivity). Hence, drugs approved by GOC are given substantial IPR rights which translate into multiple layers of market exclusivity.

Why the focus on IPR rights? To start with, it has long been understood that “large scale” commercialization¹⁵⁵ and appropriability¹⁵⁶ regimes are crucial for firms working within innovation-intensive industries.¹⁵⁷ This is particularly true for public policy having as its objective enhancement of national competitiveness and productivity via commercialization of publicly funded research,¹⁵⁸ which often singles out biomedical and life sciences sectors as fertile policy targets.¹⁵⁹ Indeed, it has been suggested that commercialization-based science and technology policies, legislation, and initia-

Biopharmaceutical Research and Development (Edited version of Robert L. Levine Distinguished Lecture)” (2003) 72 *Fordham L. Rev.* 477; Bouchard, “Living”, *supra* note 70.

¹⁵⁰ Ron A. Bouchard, “Should Scientific Research in the Lead-up to Invention Vitiolate Obviousness Under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not to Test?” (2007) 6 C.J.L.T. 1 [Bouchard, “Test”].

¹⁵¹ *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 USC § 355 (2000)), commonly known as the *Hatch-Waxman Act*.

¹⁵² *AstraZeneca Canada Inc. v Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at para. 12 [*Astra-Zeneca*].

¹⁵³ Lemmens & Bouchard, *supra* note 30 at 352. See also Regulations Amending the Patented Medicines (Notice of Compliance), C. Gaz. 2004.I.3719 (*Patent Act*); Regulations Amending the Patented Medicines (Notice of Compliance), C. Gaz. 1993.II.1388; and Regulations Amending the Patented Medicines (Notice of Compliance), C. Gaz. 2006.I.1611 (*Patent Act*).

¹⁵⁴ Regulations Amending the Food and Drug Regulations (Data Protection), C. Gaz. 2006.I.1598.

¹⁵⁵ Commercialization being the process of introducing a new product into the market; the actual launch of which is the final stage and the invention of which is the beginning.

¹⁵⁶ Appropriability being a party’s ability to capture profits generated from their own inventions, or those of others, as governed and shaped by prevailing legal, regulatory, technological, and social capital factors.

¹⁵⁷ See generally David J. Teece, “Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy” (1986) 15 *Research Policy* 285.

¹⁵⁸ Institute for Competitiveness & Prosperity, *Reinventing Innovation and Commercialization Policy in Ontario*, Working Paper No. 6 (Toronto: Institute for Competitiveness & Prosperity, 2004) [*ICP Reinventing*]; Brian Guthrie & Trefor Munn-Venn, *Six Quick Hits for Canadian Commercialization: Leaders’ Roundtable on Commercialization* (Ottawa: Conference Board of Canada, 2005) [*Guthrie & Munn-Venn*]; Government of Canada: Expert Panel on Commercialization, *People and Excellence: The Heart of Successful Commercialization* (Ottawa: Public Works and Government Services Canada, 2006) [*EPC Heart*]; Erika Fitzpatrick, *Innovation America: A Final Report* (Washington: National Governors Association, 2007) [*TCC Innovate*]; The Council on Competitiveness, *Innovate America: Thriving in a World of Challenge and Change* (Washington: The Council on Competitiveness, 2007); The Council on Competitiveness, *Five for the Future* (Washington: The Council on Competitiveness, 2007) [*TCC Five*].

¹⁵⁹ Elias Zerhouni, “The NIH Roadmap” (2003) 302 *Science* 63; Alan Bernstein, “Toward Effective Canadian Public-Private Partnerships in Health Research” (2003) 168 *Canadian Medical Association Journal* 288; U.S., Food and Drug Administration: Department of Health and Human Services, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* (2004), online: FDA <<http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf>> [*NIH Innovation or Stagnation*]; Health Canada, “Blueprint”, *supra* note 23; *EMA Road Map*, *supra* note 82.

tives were responsible for stimulating the global biotechnology revolution.¹⁶⁰ Over the years however, this narrative has morphed from being focused on stimulating private innovation to discussions of publicly funded medical research and drug regulation. For example, intellectual property rights and pharmaceutical innovation comprise two of the five “pillars” of the nation’s pharmaceutical policy¹⁶¹ - three if one reasonably counts IPR rights as part of Canada’s “international trade policy.” The importance of IPR rights along with minimal intrusion into the drug regulation sphere also permeate Canada’s National Pharmaceutical Strategy and Smart Regulations initiative,¹⁶² both of which are intended to lay the policy grounds for enhancing national productivity and prosperity through commercialization of innovative medical research. Canada is not alone in this regard. Since the passage of the U.S. *Bayh-Dole Act*,¹⁶³ private IPR rights have evolved into a fundamental policy lever¹⁶⁴ for the entire rTPL innovation ecology;¹⁶⁵ a claim supported by the reading in of TRIPS rights into Bill C-51¹⁶⁶ and associated policy discussions.¹⁶⁷ Indeed, IPR rights have been touted increasingly throughout the E.U. as a linchpin not only for national science and technology policies, but also as a fundamental policy lever for governments to fulfill their public health mandate.¹⁶⁸

Considerations such as these form a critical, though not widely understood, element of the “push-pull” dynamic in the pharmaceutical marketplace, which affects the number, quality and innovative nature of new drugs. A push-pull market system refers to movement of potential and realized therapeutic products between two poles, with “pull” referring to the various mechanisms by which consumers and agents of consumers enhance demand for a given product, and “push” referring to the mechanisms by which suppliers, and agents of suppliers, direct products toward consumers. It is by no means clear just how distinct and separate the various segments of government, public and pharmaceutical players are from one another and their respective agendas. In the context of drug regulation, the term “access” is theoretically an excellent proxy for consumer pull, while push largely refers to the regulatory mechanisms underpinning the production and market protection of products that are “safe and efficacious”. However, depending on the degree of overlap and interrelation of

¹⁶⁰ Bhavan N. Sampat, “Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole” (2006) 35 *Research Policy* 772 at 777; Bouchard, “Test”, *supra* note 150.

¹⁶¹ According to GOC, the five “pillars” of federal pharmaceutical policy are the following: (1) intellectual property, (2) pharmaceutical research and development, (3) international trade policy, (4) health care and (5) consumer protection: Barbara Oullet, “Pharmaceutical Management and Price Control in Canada” (Presentation to the North American Pharmaceutical Summit, 31 March 2006) at 7.

¹⁶² *National Pharmaceuticals Strategy*, *supra* note 13; *Smart Regulations*, *supra* note 14; Government of Canada, “Cabinet Directive on Streamlining Regulation” (2007), online: Government of Canada <<http://www.regulation.gc.ca/directive/directive00-eng.asp>> (Specifically, the National Pharmaceutical Strategy states [at 39] “Governments recognize the crucial role the innovative pharmaceutical industry plays in the development of breakthrough drugs and that intellectual property protection is key to encouraging and supporting innovation”).

¹⁶³ *Bayh-Dole Act*, 35 U.S.C. §§ 200-212 (1994). See also *Stevenson-Wydler Technology Innovation Act of 1980*, 15 U.S.C. §§ 3701-3715 (2000); *Federal Technology Transfer Act of 1986*, 15 U.S.C. §§ 3710a-3710d (2000).

¹⁶⁴ Dan L. Burk & Mark A. Lemley, “Policy Levers in Patent Law” (2003) 89 *Va. L. Rev.* 1575 at 1591. See also Sampat, *supra* note 160; Donald E. Stokes, *Pasteur’s Quadrant: Basic Science and Technological Innovation* (Washington: Brookings Institution Press, 1997).

¹⁶⁵ See both Wulf, and Bouchard, “Systems”, *supra* note 69.

¹⁶⁶ *Bill C-51*, *supra* note 10 at cl. 11 s. 30(3).

¹⁶⁷ Peterson, *supra* note 15.

¹⁶⁸ For example, the *EMEA Road Map* (*supra* note 82 at 2, 36) stipulates that the agency uses a “two-pillar approach” to make safe and effective therapeutic products available to the public. They are to (1) facilitate more rapid access to safe and effective medicines via amendment to the existing regulatory licensing framework and to (2) facilitate industrial innovation. While EMEA does not provide a definition of “innovation” nor a “map” of how it will facilitate innovative drug development in its road map or follow-up report (European Medicines Agency, *Second Status Report on the Implementation of the EMEA Road Map* (Doc. Ref. EMEA/359050/2007) [22 October 2007]), it can be plausibly assumed at the main economic drivers for this process will be a combination of intellectual property and regulatory rights. Citing *EMEA Road Map*, Eichler *et al.* (*supra* note 94 at 2) point out that “regulators acknowledge the need to facilitate innovation and the fact that a lack of efficacious therapies is a public health issue” [Emphasis added]. For a review of how drug development is seen to be necessarily contingent on the nexus between technology commercialization and IPR rights, see generally *NIH Innovation or Stagnation*, *supra* note 159; Mark Ratner, “Looking for Solid Ground Along the Critical Path” (2006) 24 *Nature Biotechnology* 885; S. Buckman, S.M. Huang & S. Murphy, “Medical Product Development and Regulatory Science for the 21st Century: The Critical Path Vision and Its Impact on Health Care” (2007) 81 *Clinical Pharmacology & Therapeutics* 141 [Buckman *et al.*]; “NIH at the Crossroads”, Editorial, (2003) 425 *Nature* 545; R.L. Woosley & J. Cossman “Drug Development and the FDA’s Critical Path Initiative” (2007) 81 *Clinical Pharmacology & Therapeutics* 129; Zerhouni, *supra* note 159; Bernstein, *supra* note 159.

consumers, government, and industry actors, the economic and public policy levers underpinning access to and the production of safe and efficacious drugs will be fundamentally intertwined. As a result, the desire for strong IPR rights permeates the entire push-pull dynamic, particularly since both patent and regulatory rights are now seen to constitute critical economic levers in the global production of innovative therapeutic products. One implication of the global nature of emerging models of drug legislation is that multinational firms seeking to market innovative products might see Canada in a negative light to the extent that domestic IPR rights are out of line with those more globally.¹⁶⁹ This implies the rTPL-IPR rights nexus will only tighten as GOC shifts from its current drug approval framework to the PLF lifecycle model, in turn strengthening market penetration by pharmaceutical/biotechnology players that have learned to master both linkage regulation loopholes¹⁷⁰ and invention by investment portfolio strategies.¹⁷¹

The result of this scenario is that arguments about “access,” particularly those that are contingent on claims for strong IPR rights, are less about *demand* for safe and efficacious drugs than they are about market *push* mechanisms. This raises the specter of post-marketing safety and whether inclusion of yet further grounds for expedited review in emerging lifecycle models will, or even can be counter-balanced by appropriate post-marketing surveillance. GOC has been reasonably transparent about the priority of this balancing function in its policy documents¹⁷² and legislative package,¹⁷³ going so far as to say in its PLF Concept Paper that under certain circumstances the potential benefits of bringing a drug to market may be “deemed to outweigh the relatively increased uncertainty regarding the safety and efficacy.”¹⁷⁴

E. Post-Approval Safety

There is varying evidence as to whether the shifts in the speed and mechanisms underpinning regulatory approval are positively correlated with increased post-marketing safety problems,¹⁷⁵ in particular drug withdrawals.¹⁷⁶ Several reports have claimed that there is no significant increase in the incidence of withdrawals, dosage form discontinuations, or black-box warnings before and after initiation of user fees in the U.S.,¹⁷⁷ while others have demonstrated a significant¹⁷⁸ or even substan-

¹⁶⁹ Ron A. Bouchard, “KSR v. Teleflex Part 1: Impact of U.S Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape” (2008) 15 Health L.J. 222.

¹⁷⁰ *AstraZeneca*, *supra* note 152.

¹⁷¹ William Kingston, “Intellectual Property’s Problems: How Far is the U.S. Constitution to Blame?” (2002) 4 Intellectual Property Quarterly 315 at 323.

¹⁷² Of the five objectives of the 2001 regulatory reform of the Food and Drug Regulations respecting clinical trials, three were aimed at reducing the costs of regulatory approval and facilitating innovation in the pharmaceutical industry. The objectives were to (i) shorten application review times without endangering health and safety, (ii) remove obstacles to firm research and development, (iii) improve access to innovative therapies, (iv) increase involvement of the regulator in clinical trials and follow-up, and (v) improve safety mechanisms for research subjects. See Health Canada, “Stakeholder Workshop”, *supra* note 30.

¹⁷³ *Bill C-51*, *supra* note 10 at cl. 11 s. 30(3) and cl. 13 30(7)(b).

¹⁷⁴ Health Canada, “Concept Paper”, *supra* note 23 at 20-1. The full quotation is “When a manufacturer is considering departing from the baseline requirement for substantial evidence of efficacy and safety for initial market authorization, a more flexible approach regarding the underlying efficacy and safety evidence is envisaged when there is a compelling reason. While the regulatory requirement for a favourable benefit-risk profile for the drug’s use under the proposed conditions would remain, initial requirements for substantial evidence of efficacy and safety may be counterbalanced against other, important evidence concerning contextual benefit-risk considerations. For example, the potential benefits of bringing the drug to market are deemed to outweigh the relatively increased uncertainty regarding the safety and efficacy.”

¹⁷⁵ For review, see the following at *supra* note 140: Hiltz; Avorn; Krinsky; Angell; and Cohen.

¹⁷⁶ These studies are difficult to compare directly owing to substantial differences in methodologies used. Some authors use only data from industry organizations (Rx&D, PhRMA), while others use government and other publicly available databases, literature comparisons, commercial databases or reports, personal communications, or some combination of the above. In addition, some studies are long-term while others are short-term, and still others review withdrawals in the same or longer test period as approvals were issued. The situation has not been helped by the recalcitrance of federal drug agencies to provide withdrawal data in an easy to access form: Lexchin, “Withdrawals”, *supra* note 74; Carpenter *et al.*, *supra* note 78.

¹⁷⁷ USGAO *User Fees*, *supra* note 79 at 4, 24-26; Olav M. Bakke *et al.*, “Drug Safety Discontinuations in the United Kingdom, the United States and Spain from 1974 through 1993: A Regulatory Perspective” (1995) 58 *Clinical Pharmacology & Therapeutics* 108; Amalia M. Issa *et al.*, “Drug Withdrawals in the United States: A Systematic Review of the Evidence and Analysis of Trends” (2007) 2 *Current Drug Safety* 177; M.K. Olson, “Pharmaceutical Policy Change and the Safety of New

tial¹⁷⁹ increase. Independent of the literature, however, is the high level of publicly reported mortality and morbidity associated with safety withdrawals in vulnerable segments of the population. For this reason, the withdrawal of Vioxx has been described by *Nature* as the “biggest drug safety catastrophe in the history of the United States.”¹⁸⁰ One might argue that even the COX-2 scenario pales to the damage done by SSRIs to vulnerable children and adolescents, which the *Lancet* referred to as a “disaster” for evidence-based medicine.¹⁸¹

Implementation of a fee-for-service basis for drug approval has been argued to affect drug safety in several ways.¹⁸² First, many drugs are approved on the basis of surrogate rather than therapeutic end-points, including the wide use of biomarkers.¹⁸³ A biomarker is “a laboratory measurement that reflects the activity of a disease process,”¹⁸⁴ whereas a surrogate marker is “a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and is expected to predict the effect of the therapy.”¹⁸⁵ The difference between the two is that a biomarker is a candidate surrogate marker, whereas a surrogate marker is a demonstrably testable and thus relatively more practical measure of the effects of a specific treatment.¹⁸⁶ Even so, a surrogate endpoint still represents a secondary measure of the effect of an experimental treatment which *may* correlate with an actual, or primary endpoint but does not necessarily have a guaranteed relationship with it (think the difference between a desired and likely endpoint of a year in the gym). Given the uncertainties involved in the use of surrogate markers it is not surprising that dependence on secondary rather than primary endpoints is claimed to enhance post-marketing risk for consumers.¹⁸⁷ Indeed, some have gone so far as to say the history of wide surrogate marker use is a “troubled one.”¹⁸⁸ A second manner in which user fees are said to be problematic is the narrow employment thereof by regulators largely in the pre-market phase. Although the restriction of utilizing user fees to fund post-marketing safety as-

Drugs” (2002) 45 J.L. & Econ. 615 [Olson, “Change”]; Rawson, *supra* note 89; Berndt *et al.*, *supra* note 78; U.S., Food and Drug Administration, *Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications* (November 2005) at 6, online: FDA <<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119253.htm>>; M. McClellan, “Drug Safety Reform at the FDA—Pendulum Swing or Systematic Improvement?” (2007) 356 *New Eng. J. Med.* 1700.

¹⁷⁸ Carpenter *et al.*, *supra* note 78.

¹⁷⁹ Diane K. Wysowski & Lynette Swartz, “Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969-2002” (2005) 165 *Archives of Internal Medicine* 1363; Andrea Clarke, Jonathan J. Deeks & Saad A.W. Shakir, “An Assessment of the Publicly Disseminated Evidence of Safety Used in Decisions to Withdraw Medical Products from the UK and US Markets” (2006) 29 *Drug Safety* 175 [Clarke, Deeks & Shakir]; Carpenter *et al.*, *supra* note 78.

¹⁸⁰ M. Wadman, “Drug Safety Special: The Safety Catch” (2005) 434 *Nature* 554 at 556.

¹⁸¹ “Depressing Research”, editorial (2004) 363 *The Lancet* 1341.

¹⁸² Horton, *supra* note 74; Avorn, *supra* note 140; P. Lurie & L.D. Sasich, “Safety of FDA-Approved Drugs” (1999) 282 *Journal of the American Medical Association* 2297; John Abraham & Courtney Davis, “A Comparative Analysis of Drug Safety Withdrawals in the UK and the US (1971-1992): Implications for Current Regulatory Thinking and Policy” (2005) 61 *Social Science & Medicine* 881; USGAO *User Fees*, *supra* note 79 at 2, 4, 26-27; U.S., Office of Inspector General, *FDA’s Review Process for New Drug Applications: A Management Review*, (Washington: Department of Health and Human Services, March 2003); S. Okie, “What Ails the FDA?” (2005) 352 *New Eng. J. Med.* 1063; Sheila Weiss Smith, “Sideline Safety—The FDA’s Inadequate Response to the IOM” (2007) 357 *New Eng. J. Med.* 961.

¹⁸³ Eichler *et al.*, *supra* note 94 at 825. Aloka G. Chakravarty, “Surrogate Marker and its Role in the Regulatory Decision Process” (Powerpoint presentation) online: American Statistical Association <<http://amstat.org/meetings/fdaworkshop/presentations/2004/ParallelSession6/ParallelSession6B.ppt>> (Dr. Chakravarty, Deputy Director, Division of Biometrics III defines a “biomarker” as a “characteristic that is objectively measured and evaluated as an indicator of normal biologic or pathogenic processes or pharmacological responses to a therapeutic intervention”).

¹⁸⁴ Russell Katz, “Biomarkers and Surrogate Markers: An FDA Perspective” (2004) 1 *NeuroRx* 189 at 189.

¹⁸⁵ *Ibid.* at 189; Robert Temple, “Are Surrogate Markers Adequate to Assess Cardiovascular Disease Drugs?” (1999) 282 *Journal of the American Medical Association* 790. See also J.N. Cohn, “Introduction to Surrogate Markers” (2004) 109 *Circulation* IV-20.

¹⁸⁶ Katz, *supra* note 184 at 189.

¹⁸⁷ Weiss Smith, *supra* note 182 at 961.

¹⁸⁸ Eichler *et al.*, *supra* note 94 at 3, 8. The authors state (at 8): “While we are optimistic about the impact of new biomarkers for drug candidate selection, theranostic purposes or safety screening, we do not predict wider use of biomarkers as surrogate end points to accelerate marketing authorization ...” The term “theranostic” refers to treatment modalities combining a diagnostic test with targeted therapy based on results from individual tests. The term is usually invoked in discussions of developing tailored therapies for individual patients in the context of personalized medicine.

assessments was lifted in 2002, this route continues to be used only in very limited circumstances,¹⁸⁹ to the potential detriment of end-users. Finally, the requirement for expedited approval for a drug candidate to be “potentially life-saving” has been very broadly interpreted in the context of expedited review, in turn giving rise to faster access for drugs intended to treat a variety of common chronic conditions, many of which were subsequently withdrawn for safety reasons.¹⁹⁰ As such, expedited review may not be a viable option for drugs intended to treat chronic conditions, which should have safety standards that tolerate minimal uncertainty.

The nuances of the debate over access are clouded by the fact that firms themselves are the primary capital sources for clinical trials, a situation that may lend itself to systemic bias in trial interpretation.¹⁹¹ Firms own data obtained from clinical trials,¹⁹² which is in any event deemed to be confidential information under domestic and international regulatory instruments.¹⁹³ Indeed, the pharmaceutical industry has gone to great lengths to protect the proprietary nature of such information.¹⁹⁴ For this reason, and in light of the scope of injury linked to recent safety withdrawals, there have been growing calls for enhanced transparency and independent review of pre-market and post-market drug efficacy and safety studies.¹⁹⁵ Indeed, the current emphasis on post-market surveillance has largely grown out of this debate. Moreover, various types of domestic and international patient advocacy groups now receive substantial funding from industry. It is therefore not surprising that concerns over transparency have been expressed in the U.S., Canada, Britain, Ireland, Italy, Germany, and elsewhere.¹⁹⁶ Typical of this type of conflict of interest is the recent “Patient Declaration on Medical Innovation and Access” submitted to the WHO with regard to its efforts to meet the public health needs of developing nations. Over half (61/110) of the document’s signatories had financial ties with industry, including in Canada.¹⁹⁷ The biggest question, however, remains whether the reduction in approval times is correlated with the recent spate of high profile drug withdrawals.

¹⁸⁹ Weiss Smith, *supra* note 182 at 961-62.

¹⁹⁰ *Ibid.* at 961.

¹⁹¹ Joel Lexchin *et al.*, “Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review” (2003) 326 *British Medical Journal* 1167. See also A.J.J. Wood, C.M. Stein & R. Woosley, “Making Medicines Safer: The Need for an Independent Drug Safety Board” (1998) 339 *New Eng. J. Med.* 1851; Krinsky, *supra* note 140 at 229; Angell, *supra* note 140 at 244-47; Wayne A. Ray & C. Michael Stein, “Reform of Drug Regulation—Beyond an Independent Drug-Safety Board” (2006) 354 *New Eng. J. Med.* 194 [Ray & Stein]; Cohen, *supra* note 140 at 198-211.

¹⁹² Thomas O. McGarity & Sidney A. Shapiro, “The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies” (1980) 93 *Harvard L. Rev.* 837; Jeffery M. Drazen, “Who Owns the Data in a Clinical Trial?” (2002) 8 *Science and Engineering Ethics* 407.

¹⁹³ In Canada, data submitted by pharmaceutical companies is deemed to be “commercially sensitive” and as such constitutes confidential information under the federal *Access to Information Act* (R.S.C. 1985, c. A-1). Under section 20(6), disclosure can only be made where it is in the public interest and relates to public health and safety. The TPD will not however release information where public interest in disclosure is outweighed by financial loss or prejudice to the competitive position of the disclosing party. See also Article 1711 of NAFTA, *supra* note 145, and Article 39 of TRIPS, *supra* note 146, pertaining to data and market exclusivity, which deem commercially sensitive information to be confidential. See generally Regulatory Impact Analysis Statement, C. Gaz. 2004.II.3718 (Regulations Amending the Food and Drug Regulations [1390 - Data Protection]), as modified by Regulatory Impact Analysis Statement, C. Gaz. 2006.I.1598 (Regulations Amending the Food and Drug Regulations [Data Protection]).

¹⁹⁴ For a detailed history of litigation over public disclosure of pharmaceutical R&D costs, see generally: U.S., Congress Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards* (Washington: U.S. Government Printing Office, 1993) at ii, 66, 284-288. The U.S. Supreme Court, in the seminal *Bowsher v. Merck* decision (*Bowsher v. Merck & Co. Inc.*, 460 U.S. 824 at 843, 103 S. Ct. 1587 at 1598 (1983)) held that pharmaceutical R&D, and related costs, constituted confidential information and thus that federal government did not have authority to compel disclosure of such information. For a more recent discussion of pharmaceutical R&D costs, see: U.S. National Institutes of Health, *NIH Response to Conference Report Request for Plan to Ensure Taxpayer’s Interests are Protected* (Bethesda, MD: National Institutes of Health, 2001).

¹⁹⁵ Weiss Smith, *supra* note 182; Bruce M. Psaty & Alta Charo, “FDA Responds to Institute of Medicine Drug Safety Recommendations—In Part” (2007) 297 *Journal of the American Medical Association* 1917; Ray & Stein, *supra* note 191.

¹⁹⁶ See generally (and references therein): Daniel Carpenter, “The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy” (2004) 23 *Health Affairs* 52; Barbara Mintzes, “Should Patient Groups Accept Money From Drug Companies? No” (2007) 334 *British Medical Journal* 935.

¹⁹⁷ Sarah Rimmington & Robert Weissman, News Release, “Signers of ‘Patient Declaration’ for WHO Talks Financially Tied to Big Pharma” (28 April 2008), online: Essential Information <<http://www.essentialaction.org/access/index.php?archives/141-News-Release-Signers-of-Patient-Declaration-for-WHO-talks-financially-tied-to-Big-Pharma.html>>.

Despite the severity of recent withdrawals, a number of influential studies have found evidence to support the conclusion that serious post-market safety metrics, including drug withdrawals, dosage form discontinuations, and black-box warnings have not increased significantly following PDUFA. For example, Berndt *et al.*¹⁹⁸ conducted a detailed statistical analysis of the impact of PDUFA on approval times and withdrawal rates. Going beyond proportion comparisons to include Kaplan-Meier survival analysis,¹⁹⁹ they found that new molecular entities submitted to FDA before PDUFA (365; 1980-1992) had a 98% survival rate (2% withdrawal) compared with post-PDUFA I submissions (351; 1992-2003), which had a 97.1% survival rate (2.9% withdrawn). These data compare favourably with those of GAO²⁰⁰ demonstrating that 3.10% of new medical entities approved between 1985 and 1992 were withdrawn for safety considerations compared to 3.47% during the period 1993-2000, a result that was not statistically different. Data from GAO and the Berndt study are consistent with other reports demonstrating a lack of change in the frequency of post-market black-box warnings (1981-2006)²⁰¹ and withdrawal rates (1993-2006)²⁰² before and after PDUFA I-III. While faster review did not, at least according to these reports, impact significantly on drug withdrawals or black-box warnings, there is evidence to support the conclusion that post-PDUFA withdrawals are occurring more rapidly.²⁰³ A potential explanation for this trend is that pharmaceutical sales have “accelerated forward” in time, which may also explain the apparent increase in mortality and morbidity associated with high profile withdrawals in light of the disconnect between the characteristics of clinical trial populations and the consuming public. Other studies focusing on post-market safety issues such as withdrawal rates²⁰⁴ and adverse effects²⁰⁵ found no substantial change before and after the institution of user fees, with one study demonstrating a transient increase in withdrawal rates during the 1990s that tailed off following the year 2000.²⁰⁶

However, not all reports agree with the conclusion that PDUFA has had no significant effect on post-market safety metrics. A recent empirical study by Carpenter, Zucker, and Avorn²⁰⁷ suggested that PDUFA-imposed decision deadlines were associated with an increased incidence of black-box warnings, discontinuation of at least one dosage form and subsequent drug withdrawals for safety reasons, particularly for approvals in the 2 months prior to the deadline. Of the 11 drugs withdrawn for safety reasons in the period 1993-2004 (average, 0.92.yr or 3.5% of 313 new molecular entities), 7 were for drugs approved just before the PDUFA-imposed deadline. In a reply,²⁰⁸ FDA disputed these data, stipulating that only 5 of 11 approvals were withdrawn close to the deadline. In their response,²⁰⁹ the authors argued that FDA used data never before reported, but even so that their conclusions were not altered. They further concluded that PDUFA-imposed deadlines rather than the speed of approval per se were responsible for the increase in observed withdrawals,²¹⁰ pointing out that their data were consistent with reports from FDA

¹⁹⁸ Berndt *et al.*, *supra* note 78 at 552.

¹⁹⁹ Berndt *et al.* (*ibid.* at 558) state that the Kaplan-Meier survival function utilized in their study measures “the percentage of subjects in a cohort that survive from one time period to the next.” As pointed out by the authors, the Kaplan-Meier method takes into account “censored” data, referring to the loss or censoring of data from the sample prior to finalization of the data set. This outcome is very useful where, as can often be the case for large and complex data sets such as those involving drug approvals or post-market safety metrics such as drug withdrawals, black box warnings or dosage form discontinuations, not all data is reliably reported by regulators (see for example, the report on drug withdrawals by Carpenter *et al.*, the FDA’s response to it, and the authors’ subsequent reply: Carpenter *et al.* *supra* note 78; Nardinelli *et al.*, *supra* note 94; Reply to Letter to Editors, *supra* note 94).

²⁰⁰ USGAO *User Fees*, *supra* note 79 at 25-26.

²⁰¹ Allan Begosh *et al.*, “Black Box Warnings and Drug Safety: Examining the Determinants and Timing of FDA Warning Labels” (2006) NBER Working Paper 12803; Henry G. Grabowski & Y. Richard Wang, “The Quantity and Quality of Worldwide New Drug Introductions 1982–2003” (2006) 25 *Health Affairs* 452.

²⁰² Issa *et al.*, *supra* note 177.

²⁰³ Berndt *et al.*, *supra* note 78 at 553.

²⁰⁴ Michael A. Friedman *et al.*, “The Safety of Newly Approved Medicines: Do Recent Market Removals Mean There is a Problem?” (1999) 281 *Journal of the American Medical Association* 1728.

²⁰⁵ Henry G. Grabowski & Y. Richard Wang, “Do Faster Food and Drug Administration Drug Reviews Adversely Affect Patient Safety? An Analysis of the 1992 Prescription Drug User Fee Act” (2008) 51 *J.L. & Econ.* 377.

²⁰⁶ Tufts Center for the Study of Drug Development, “Drug Safety Withdrawals in the US Not Linked to Speed of FDA Approval” (2005) 7 *Tufts CSDD Impact Report* 1 at 2 [Tufts Center].

²⁰⁷ Carpenter *et al.*, *supra* note 78.

²⁰⁸ Nardinelli *et al.*, *supra* note 94 at 95.

²⁰⁹ Carpenter “Reply”, *supra* note 94 at 97-98.

²¹⁰ Carpenter *et al.*, *supra* note 78 at 1357-58.

scientists²¹¹ that PDUFA has reduced the agency's focus on risks and refocused it on benefits.²¹² The data of Carpenter *et al.* are consistent with the results of a large-scale study by Abraham and Davis²¹³ comparing drug withdrawals in the U.K. and U.S. during the period 1971-1992. The conclusion of this study was that acceleration of review times, rather than several other alternatives, was correlated with increased drug safety withdrawals in the U.K. (22/21 years, or 1.05/yr) compared to the U.S. (9/22 years, or 0.43/yr) before PDUFA. A recent study by Olson,²¹⁴ controlling for the influence of drug utilization, patient conditions, drug novelty, black-box warnings, foreign drug launch, U.S. launch lags, as well as patient age and gender, found a positive correlation between faster review times and serious ADRs during the period 1990-2001, particularly for more novel drugs. A reduction in review time by a single standard deviation was estimated to result on average in a ~20% increase in serious ADRs, ADR-related hospitalizations, and ADR-related deaths. Other studies have demonstrated higher average withdrawal rates in the years following PDUFA²¹⁵ compared to those in preceding years.²¹⁶

In Canada, Lexchin reported a total of 41 withdrawals for safety reasons over the period 1963-2004,²¹⁷ amounting to an average withdrawal rate of about 1/year. Hepatotoxicity, cardiac problems, and blood dyscrasias (arrhythmias, vascular disorders, hemolytic anemia, and agranulocytosis) were the leading causes for withdrawal. Withdrawals in 10 year bins for the period 1963-2004 were 10, 6, 7, and 16, respectively,²¹⁸ with a further 8 in the greatly abbreviated 2004-2007 bin.²¹⁹ While it is tempting to speculate that there is a positive correlation between the sharp increase in withdrawals post-PDUFA I, other data from the author suggest there has actually been a *decrease* in withdrawals expressed as 5 year bins between 1985-2007 when graphed against the number of new active substances (NAS) approved.²²⁰ This parallels recent data from Issa *et al.*²²¹ demonstrating an average withdrawal rate of 1.5/year between 1993-2006 and a lack of change in average withdrawals before and after PDUFA I and II (1975-1992 v. 1993-2006), though the data do appear to show trends toward escalating withdrawal rates between 1995-2000 and 2001-2006 expressed either as absolute values or as a percentage of approved drugs.²²² The average withdrawal rates in these two studies compares favourably with those from similar longer-term analyses in the U.K. (1.05/yr, 1971-1992;²²³ 1.0/yr 1970-1992²²⁴), Germany (1.3/yr, 1970-1992²²⁵) and France (1.35/yr, 1970-1992) that were conducted prior to PDUFA. Other studies, however, reported comparatively lower U.S. withdrawal rates over the same or similar timeframes (0.3/yr, 1970-1992;²²⁶ 0.43/yr, 1971-1992;²²⁷ 0.5, 1978-1992;²²⁸ 0.64/yr, 1975-1999²²⁹).

²¹¹ Union of Concerned Scientists, "Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science" (Cambridge, MA: Union of Concerned Scientists, 2006), online: Union of Concerned Scientists <http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf>; David B. Ross, "The FDA and the Case of Ketek" (2007) 356 *New Eng. J. Med.* 1601. See also Okie, *supra* note 173; Gardiner Harris, "FDA Scientists Accuse Agency Officials of Misconduct" *New York Times* (18 November, 2008) (describing a letter sent by FDA scientists on October 14, 2008 to Congress alleging FDA is engaged in "serious misconduct" by approving unsafe or ineffective medications) at A15 [Harris, "Accuse"].

²¹² Weiss Smith, *supra* note 182; PDUFA, *supra* note 72.

²¹³ Abraham & Davis, *supra* note 182.

²¹⁴ Mary K. Olson, "The Risk We Bear: The Effects of Review Speed and Industry User Fees on New Drug Safety" (2008) 27 *Journal of Health Economics* 175 [Olson, "Risk"]. See also Olson, "Change", *supra* note 177.

²¹⁵ Wysowski & Swartz, *supra* note 179; Rawson & Kaitin, *supra* note 81; Issa *et al.*, and Olson, "Change", *supra* note 177; Clarke, Deeks & Shakir, *supra* note 179.

²¹⁶ Sidney M. Wolfe, "Differences in the Number of Drug Safety Withdrawals: United States, United Kingdom, Germany, France 1970-1992" Public Citizen, Health Research Group Paper (2 February 1995); Abraham & Davis, *supra* note 182; Wysowski & Swartz, *supra* note 179 (see also Tables 3 and 4 therein at 1366-67); Karen E. Lasser *et al.*, "Timing of New Black Box Warnings and Withdrawals for Prescription Medications" (2002) 287 *Journal of the American Medical Association* 2215 [Lasser *et al.*].

²¹⁷ Lexchin, "Withdrawals", *supra* note 74 at 765.

²¹⁸ *Ibid.*

²¹⁹ Joel Lexchin, Personal Communication (September 24, 2008).

²²⁰ Joel Lexchin, Personal Communication (October 2, 2008).

²²¹ Issa *et al.*, *supra* note 177.

²²² *Ibid.* at 180-182 (particularly, Figs. 1-3).

²²³ Abraham & Davis, *supra* note 182.

²²⁴ Wolfe, *supra* note 216.

²²⁵ *Ibid.*

²²⁶ *Ibid.*

These findings contrast somewhat with data reported by Rawson and Kaitin,²³⁰ who found that there were about 2.4x more drug withdrawals in the U.S. compared with Canada during the period 1992-2001 assessed either as the average number of withdrawals per year (0.6/yr v. 1.2/yr) or as a per cent of total approvals (1.7% of 295 approvals v. 3.56% of 337 approvals). U.S. regulators approved 15% more new chemical entities, 82% of which were also approved in Canada, and approved them about 30% faster than their Canadian counterparts.²³¹ Moreover, and perhaps accounting (along with a much shorter and more recent test period)²³² for differences in their data and those of Lexchin, there were 2.2x more priority reviews in the U.S. than in Canada over the test period. The authors concluded that Canadian regulators may have avoided potential dangers owing to longer approval times, a conclusion applied earlier under opposite conditions to U.S. regulators in a comparative study of drug withdrawals in the U.S. and U.K. during the two decades leading up to PDUFA I.²³³

Despite the strength of the statistical methods brought to bear on the analyses discussed above, one must nevertheless be cautious in relying on differences in average withdrawal or black-box warning rates, as these will be subject to variation owing to stochastic noise in the approval processes from one year to the next. In addition, pre-market decisions are based on benefit-risk calculations where a drug's benefits need only "outweigh" its risks and even then in an artificially narrow clinical trial population that has been selected to hit desired safety or efficacy signals. For the same reason, "off-label use" for example, physicians prescribing for non-approved uses, is also problematic. Moreover, as discussed by Lexchin,²³⁴ and more recently by Berndt,²³⁵ Carpenter,²³⁶ and others,²³⁷ adverse effects that are rare, idiosyncratic, or even unpredictable (and thus difficult or impossible to control under typical clinical trial constraints) can nevertheless be found to cause profound adverse effects under post-market scrutiny,²³⁸ as observed with selective cyclooxygenase isoenzyme (e.g., COX-2) inhibitors, selective serotonin reuptake inhibitors (SSRIs), cisapride, rosiglitazone, statins, tegaserod, gefitinib, terfenadine, and telithromycin, among others. In light of the confusion over how to interpret the consequences of high profile withdrawals of drugs that appear to be consumed by an increasing percentage of the public at an increasing rate, the question we are left with is how to balance the obvious need for an approval regime that will minimize consequences such as these with the need for caution in its implementation. From the above discussion, the factors that need to be balanced and weighed in evolving regulatory models include those in Table 1 below.

TABLE 1. FACTORS BALANCED IN EMERGING MODELS OF DRUG REGULATION

o Public Health Protection	o Innovation and Economic Development
o Government as Fiduciary	o Government as Facilitator of Choice
o Safety and Efficacy	o Access
o Certainty	o Uncertainty
o Objectivity	o Subjectivity
o Formal Decision-Making Model	o Contextual Decision-Making Model
o Precautionary Principle	o Risk Management
o Transparency	o Black-Box
o Publicly-Funded Medical Research	o Private IPR Rights

²²⁷ Abraham & Davis, *supra* note 182.

²²⁸ Wysowski & Swartz, *supra* note 179.

²²⁹ Lasser *et al.*, *supra* note 216.

²³⁰ Rawson & Kaitin, *supra* note 81 at 1404.

²³¹ *Ibid.* Re-calculated as the mean of data reported by Rawson and Kaitin for the years 1993, 1997, and 2000.

²³² A review of the reported literature suggests that studies with shorter test periods that are closer to the present date tend to yield much higher average withdrawal rates per year compared to test periods that are longer in length and prior to PDUFA I.

²³³ Abraham & Davis, *supra* note 182.

²³⁴ Lexchin, "Withdrawal", *supra* note 74 at 766.

²³⁵ Berndt *et al.*, *supra* note 78 at 551.

²³⁶ Carpenter *et al.*, *supra* note 78.

²³⁷ Eichler *et al.*, *supra* note 94; Issa *et al.*, *supra* note 177; Olson, "Risk", *supra* note 214. For an earlier discussion of the same problem, see: USGAO *User Fees*, *supra* note 79 at 26.

²³⁸ See also Issa *et al.*, and Olson, "Change", *supra* note 177; Olson, "Risk", *supra* note 214.

F. Lifecycle Approach

1. Canada

It has become the role of the “lifecycle approach” to drug regulation to balance the opposing factors listed in Table 1, particularly the tension between access and safety.²³⁹ As reviewed *supra*, one of the largest problems facing drug regulators, acknowledged expressly by GOC in light of escalating high profile post-market withdrawals,²⁴⁰ is that not enough focus is placed on the safety and efficacy of pharmaceuticals following market authorization. In its progressive licensing framework Concept Paper, GOC states that “while the traditional pre-market evaluation of a drug has worked dependably as a system for many years, it does not identify all the significant information about drug benefits and risks.”²⁴¹ Despite the requirement by GOC for drug manufacturers to adhere to certain obligations following a drug’s market authorization (reporting of adverse events, updating safety information, maintaining drug quality to appropriate standards, and application for further authorization for significant changes to the product), the existing *Food and Drugs Act* and regulations provide limited jurisdiction and very few regulatory tools to ensure compliance with even these minimal obligations. Moreover, outside of the NOC/*c* stream, there are no legal grounds to impose additional systematic long-term safety and efficacy studies as a condition of continued marketing or when new information suggests that additional research is warranted.²⁴² As such, the current regulatory regime is strongly front-loaded²⁴³ in that the vast majority of regulatory resources are spent before initial market authorization, when very little information is known, and almost none following market entry when the vast majority of information pertaining to drug safety and efficacy becomes available.²⁴⁴

The circumstances involving Vioxx, the COX-2 inhibitor rofecoxib, illustrate this dilemma. Rofecoxib, a non-steroidal anti-inflammatory drug (NSAID), was developed to treat osteoarthritis, acute pain, and dysmenorrhoea. The drug was heavily marketed and successful in a very short period of time.²⁴⁵ On September 30, 2004, Merck voluntarily withdrew the drug from the market because of increased risk of cardiovascular disease, mainly myocardial infarction and stroke.²⁴⁶ FDA and Health Canada approved the drug in May and October of 1999,²⁴⁷ respectively, despite evidence in pre-

²³⁹ For review, see Eichler *et al.*, *supra* note 94. See also, the discussion of the “trade-off between access and safety” in FDA, “Response”, *supra* note 127, and Weiss Smith, *supra* note 182).

²⁴⁰ Health Canada, “Blueprint”, and Health Canada, “Concept Paper”, *supra* note 23.

²⁴¹ *Ibid.* at 3.

²⁴² Lemmens & Bouchard, *supra* note 30 at 337; Health Canada, “Concept Paper”, *supra* note 23 at 9; Health Canada, “Blueprint”, *supra* note 23 at 7.

²⁴³ J.B. Rühl, “Regulation by Adaptive Management—Is it Possible?” (2005) 7 *Minnesota Journal of Law Science & Technology* 21 at 30, citing Sydney A. Shapiro & Robert L. Glicksman, “The Missing Perspective” (2003) *March/April The Environmental Forum* at 42 (for comparative pros and cons of “front end” and “back end” policy). See also Bouchard, “Systems” and Bouchard, “Reflections”, *supra* note 69.

²⁴⁴ Lemmens & Bouchard, *supra* note 30 at 336. While there is limited power to ensure that manufacturers conduct post-marketing activities, it is noteworthy that s. 23 of the *Food and Drugs Act* regarding the powers of inspectors are very broad. The inspector has the power to do the following: enter into, at any time, a pharmaceutical manufacturing, preparation, preservation or packaging facility (s. 23(1)); examine any pharmaceutical or anything used in its manufacture, preparation, preservation, packaging or storing (s. 23(1)(a)); examine and make copies of any documents/records found in the facility regarding the pharmaceutical (s. 23(1)(c)); and seize and detain any article in relation to which the inspector believes on reasonable grounds that the provisions of the *Food and Drugs Act* or *Regulations* have been contravened (s. 23(1)(d)). These broad powers may be brought into effect in the event that a manufacturer does not comply with its post-marketing obligations. However, even if this is a mechanism by which regulators may enforce post-authorization commitments, it would likely not be used, as “Health Canada has limited tools at its disposal for ensuring continued compliance with the regulations once a drug is on the market”: Health Canada, “Concept Paper”, *supra* note 23 at 9. Health Canada’s “authorities for compliance and enforcement ... are outdated, ... which limits the range of actions that can be taken, including appropriate sanctions and incentives”: Health Canada, “Blueprint”, *supra* note 23 at 7.

²⁴⁵ “Vioxx: Lessons for Health Canada and the FDA”, Editorial, (2005) 172 *Canadian Medical Association Journal* 5 [Vioxx, “Lessons”]. See also IMS Health Canada, “New Arthritis Medication Achieves Fastest Adoption Ever Recorded in Canada” *News Release* (2000), online: Longwoods Publishing <http://www.longwoods.com/articles/images/news-Rapid_uptake_new_drugs.pdf> [IMS, “Arthritis”].

²⁴⁶ Barbara Sibbald, “Rofecoxib (Vioxx) Voluntarily Withdrawn From the Market” (2004) 171 *Canadian Medical Association Journal* 1027.

²⁴⁷ U.S., Food and Drug Administration, “Vioxx (Rofecoxib) Questions and Answers: What Did FDA Know About the Risk of Heart Attack and Stroke When it Approved Vioxx?” *Center for Drug Evaluation and Research*, online: FDA

approval clinical trials of a non-statistically significant increase in risk of cardiovascular events.²⁴⁸ In January 1999,²⁴⁹ prior to FDA's market approval of Vioxx, Merck launched the Vioxx Gastrointestinal Outcomes Research (VIGOR) study in order to assess side-effects in greater detail.²⁵⁰ The results of the study, submitted to FDA in June 2000, showed that patients taking Vioxx had fewer stomach ulcers and bleeding than patients taking naproxen, another NSAID; however, the number of serious adverse cardiovascular effects increased.²⁵¹ In retrospect, it has been acknowledged that neither agency took into account the fact that these risks might reasonably have been magnified once the drug came into general use,²⁵² and thus that a need existed for more post-market surveillance. Had more substantial post-market surveillance of safety and efficacy been implemented, it is possible that a significant percentage of serious ADRs could have been reduced, depending on the speed and force of regulatory response.²⁵³ Nevertheless, while three COX-2 selective NSAIDs (celecoxib, rofecoxib, and valdecoxib) have been demonstrated to be associated with increased incidence of serious cardiovascular events,²⁵⁴ and while Vioxx (rofecoxib) and Bextra (valdecoxib) have been withdrawn for safety reasons, Celebrex (celecoxib) remains on the market.²⁵⁵

In its *Blueprint for Renewal*,²⁵⁶ GOC acknowledges the existing regulatory system is overloaded by tensions emanating from diverse social, economic, scientific, and technological developments such as those enumerated in Table 1, *supra*. Health Canada's goal is to achieve an "adaptable and sustainable regulatory system that: helps Canadians improve their health outcomes through timely access to safe, effective and high-quality health products and food; strengthens safety oversight through a product lifecycle approach; sustains and improves regulatory efficiency and predictability, while maintaining high standards for safety; is accountable, open and transparent to stakeholders and the public; and contributes to better aligned regulatory and reimbursement decision making."²⁵⁷ The approach is therefore one which recognizes that health products have a lifecycle that encompasses all stages of a drug's development and use.²⁵⁸

In a presentation in Ottawa in early 2005,²⁵⁹ about the time the *Blueprint* was being readied for release to the public, Robert Peterson, then Director General of TPD, used a cartoon to explain why GOC saw the lifecycle approach to be critical—the current regime enshrined in the existing *Food and Drug Act* was seen to be a piano falling from the sky onto an unsuspecting (and it must be said, con-

<<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106290.htm>> [FDA, "Vioxx"]; Health Canada, "Vioxx: Notice of Compliance Information", online: Health Canada <<http://205.193.93.51/NocWeb/viewnoce.jsp?noc=diif>>. See also Health Canada, "Frequently Asked Questions—Vioxx® Recall by Merck: When was Vioxx® approved for use in Canada?" online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2004/2004_50bk2-eng.php>.

²⁴⁸ Vioxx, "Lessons", *supra* note 245.

²⁴⁹ Snigdha Prahash & Vikki Valentine, "Timeline: The Rise and Fall of Vioxx" *National Public Radio*, online: NPR <<http://www.npr.org/templates/story/story.php?storyId=5470430>>.

²⁵⁰ FDA, "Vioxx", *supra* note 247.

²⁵¹ *Ibid.*

²⁵² *Ibid.*

²⁵³ *Ibid.*; Carpenter *et al.*, *supra* note 78.

²⁵⁴ Memorandum from John K. Jenkins, Paul J. Seligman & Steven Galson, U.S., Food and Drug Administration: Center for Drug Evaluation and Research, "Analysis and Recommendations for Agency Action Regarding Non-Steroidal Anti-Inflammatory Drugs and Cardiovascular Risk" (6 April 2005) online: FDA <<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106201.pdf>>.

²⁵⁵ With the caveat that the label include a boxed warning highlighting the potential for increased risk of CV events: U.S., Food and Drug Administration: Center for Drug Evaluation and Research, "Cox-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)", online: FDA <<http://www.fda.gov/cder/drug/infopage/cox2/>>; Health Canada, "Updated Safety Information on Increased Cardiovascular Risk with Celebrex (celecoxib)", online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2004/2004_67-eng.php>. For literature referencing presence (or absence) of adverse CV events due to celecoxib see Nadir Aber *et al.*, "Celecoxib for the Prevention of Colorectal Adenomatous Polyps" (2006) 355 *New Eng. J. Med.* 885; Monica M. Bertagnolli, "Celecoxib for the Prevention of Sporadic Colorectal Adenomas" (2006) 355 *New Eng. J. Med.* 873; James M. Brophy, Letter to the Editor, "Cardiovascular Risk Associated with Celecoxib", 352 *New Eng. J. Med.* 2648.

²⁵⁶ Health Canada, "Blueprint", *supra* note 23 at 1.

²⁵⁷ *Ibid.* at 1-2.

²⁵⁸ *Ibid.* at 3.

²⁵⁹ Peterson, *supra* note 15.

fused looking) person, representing the consuming public. This caricature obviously follows the well described controversies over post-marketing safety whereby the public trusted both their physician and their government to protect them from unsafe drugs. Given these controversies, and their apparent chilling effect on the pharmaceutical industry, the goals of regulatory reform were articulated as follows: facilitating biomedical innovation; creating incentives for drug development when the market itself does not do so; allowing earlier access to new drugs; creating an informed consumer; and increasing the threshold for post-market drug safety. The emphasis on providing incentives to industry to support innovation follows numerous reports from GOC and its consultants over the last number of years on the growing productivity gap in Canada relating to new drug submissions,²⁶⁰ a trend supported by data in the companion paper.²⁶¹ A shift of the balance toward more post-market surveillance was seen to grow naturally out of the scope and depth of injuries suffered from drug controversies of the 1990s and the early years of the following decade, premised on the regulatory observation that traditional pre-market Phase 1-3 clinical trials are powered primarily to assess efficacy rather than safety.²⁶² By 2005, the question to be answered by global drug regulators was seen as such: Given the bulk of safety information will be gathered predominantly post-market, *when is the right time to release the drug to the public?*

A central component of the answer to this question, debated concomitantly in the U.S.²⁶³ and E.U.²⁶⁴, is the acceptance, and subsequent reallocation, of uncertainties and risks that are inherent to the entire spectrum of drug development, regulation, and consumption. Based on a growing appreciation of these uncertainties, GOC proposed that there is nothing inventive in acknowledging that safety is not, and indeed cannot, be completely or even strongly quantified at the time of drug approval using current clinical trials best practices.²⁶⁵ The next logical step is that the “real world” risks of drug consumption be better assessed and addressed in the post-marketing phase.²⁶⁶

Other confounding factors were seen to be that Phase 3 studies were too often “fishing expeditions”, overly expensive and overly risky for firms, artificial in nature, rarely comparative in nature, commercially oriented rather than therapeutically driven, and highly secretive in nature,²⁶⁷ all to the detriment of the drug consuming public. Moreover, even when post-marketing obligations were mandated, GOC lacked the jurisdiction to enforce compliance.²⁶⁸ A lifecycle approach was therefore seen as the preferred vehicle to move products into the marketplace in a probationary manner following “strong Phase 2 clinical trials” under circumstances where GOC “participates in decisions, shares risk and costs in drug development.”²⁶⁹ Risk reallocation does not, however, end there. As noted by Health Canada in its *Real World Drug Safety and Effectiveness* guidance document,²⁷⁰ successful implementation of the lifecycle approach requires “collaboration of many stakeholders - regulators and policy makers, drug plan managers, health care providers, patients, the pharmaceutical industry, researchers, and private insurers - so that patients experience better health outcomes and fewer adverse events.”

According to GOC, a so-called real world drug lifecycle involves all relevant research and development, clinical trial studies, regulatory approval, market authorization, and normative post-market prescribing and use by physicians and the general population.²⁷¹ The unique aspect of the lifecycle approach is that there is a continuous accumulation of valuable knowledge about a product that oc-

²⁶⁰ See the following at *supra* note 158: *ICP Reinventing*, *Guthrie & Munn-Venn*, *EPC Heart*, *TCC Innovate*, and *TCC Five*.

²⁶¹ Sawicka & Bouchard, *supra* note 60.

²⁶² Peterson, *supra* note 15. For an EU perspective, see Eichler *et al.*, *supra* note 94.

²⁶³ *IOM Report*, *supra* note 8.

²⁶⁴ *EMA CHMP 2* and *EMA CHMP 3*, *supra* note 12.

²⁶⁵ Eichler *et al.*, *supra* note 94.

²⁶⁶ Peterson, *supra* note 15.

²⁶⁷ *Ibid.*

²⁶⁸ Health Canada, “Blueprint”, *supra* note 23.

²⁶⁹ Peterson, *supra* note 15.

²⁷⁰ *Real World Drug Safety*, *supra* note 7.

²⁷¹ Health Canada, “Blueprint”, *supra* note 23 at 16.

curs over its lifecycle, especially with respect to the details of its benefit-risk profile.²⁷² This progression has obvious ramifications for safety problems arising following market penetration. The tacit assumption is that as a drug's benefit-risk profile changes with time, so too should its approval status²⁷³ as, for example, ADRs not detected during initial clinical trials increase in incidence or severity²⁷⁴ and drug-drug or other drug interactions become apparent.²⁷⁵ GOC acknowledges and accepts that the progression in knowledge with the passage of time allows for an opportunity for regulators to adapt to changing conditions over time in order to manage evolving benefit-risk conditions.²⁷⁶ The lifecycle approach is an example of adaptive,²⁷⁷ or back-loaded,²⁷⁸ regulation in that a large percentage of resource allocation is aimed at evaluating drug safety and efficacy following initial market authorization. As discussed in the *Blueprint* and elsewhere,²⁷⁹ development and rigorous adherence to a kind of "best practices" for (a) physician prescribing, informed by the terms and conditions of market authorizations and (b) ADR reporting by physicians and other health care providers would be critical for success of the regime in the context of real world post-market use given the comparative dearth of pre-market safety (or efficacy) data.

Canada now formally seeks to integrate the lifecycle approach into the nation's drug regulation regime in the form of Bill C-51,²⁸⁰ which has had its second reading to date. Under the terms of the progressive licensing framework,²⁸¹ post-market studies, monitoring, safety surveillance, and risk management plans will be required when a sponsor files its submission.²⁸² The standard for initial market authorization is a "positive or favourable benefit-risk profile,"²⁸³ with maintenance of market authorization requiring a continuing favourable benefit-risk profile throughout the product's life span.²⁸⁴ According to Health Canada, this standard requires that, when used as intended by the in-

²⁷² *Ibid.* at 4.

²⁷³ *Ibid.* at 11, 15, 17.

²⁷⁴ *Ibid.* at 14-15.

²⁷⁵ *Ibid.*

²⁷⁶ *Ibid.* at 12.

²⁷⁷ Robert Jervis, *System Effects: Complexity in Political and Social Life* (Princeton, NJ: Princeton University Press 1997); Neil E. Harrison, ed., *Complexity in World Politics: Concepts and Methods of a New Paradigm* (Albany, NY: State University New York Press, 2006); David H. Guston, "Innovation Policy: Not Just Jumbo Shrimp" (2008) 454 *Nature* 940.

²⁷⁸ Ruhl, *supra* note 243.

²⁷⁹ Peterson, *supra* note 15.

²⁸⁰ *Bill C-51*, *supra* note 10. See also Health Canada, "Concept Paper", *supra* note 23.

²⁸¹ Health Canada, "Concept Paper", *supra* note 23 at 3.

²⁸² *Ibid.* at 5.

²⁸³ The notion of "favourable benefit-risk" is elaborated substantially in the Health Canada, "Concept Paper", *supra* note 23. At 14, it states that "[a] drug must have a positive benefit-risk profile to be marketed; this means that for the intended use in the intended population the drug's likelihood of causing a benefit outweighs the likelihood of causing a harm. Harm can include treatment failure or an adverse event. Benefits and risks are inherently linked concepts because there are no risks that are acceptable in the absence of benefits". Later (at 19) it states that "the demonstration of efficacy, safety and quality for the proposed conditions of use (e.g. authorised indication, target population, dosing regimen, duration of use)" will be retained as "the baseline requirement for initial market authorisation." And "[i]t will be important, however, to articulate that *safety evidence at time of initial market authorisation would be limited to identifying the most commonly occurring adverse drug reactions.*" [emphasis added]. At 20, it is underscored that favourable benefit-risk ratio may be required throughout the lifecycle in order to maintain product licensure: "In keeping with the proposed life-cycle approach, maintenance of market authorisation could require a continuing favourable benefit-risk profile for the authorised conditions of use throughout the product's lifespan. The favourable benefit-risk profile would be based on the same elements required for initial market authorisation with some possible additions, i.e., substantial evidence of efficacy, safety, and quality; substantial evidence for a favourable overall benefit-risk profile regarding the product and evidence of other important benefit-risk considerations relating to the impact of market authorisation on external decision-makers." Further context for what constitutes a favourable benefit-risk profile is given at 11, which states that "[a]ll drugs have positive and negative effects. The positive effects, known as benefits, happen when the drug works as intended to prevent, treat, or diagnose an illness. The negative effects, called risks, happen when a drug does not work as intended or it causes an adverse effect. An adverse effect can be a self-limited event like a headache, or a serious life-threatening event such as a heart attack." It could be argued that Health Canada's definition of favourable benefit-risk profile does not take into account the clinical importance of the positive or negative effect. For example, a drug for cancer that causes mild transient nausea in 100% of people would still have a positive benefit-risk profile despite that it only decreases mortality by 2%. Thus, a positive benefit-risk profile would still be found despite that risks, however trivial, outweigh the benefit. This issue would be considered by Health Canada as a "contextual benefit-risk consideration" (i.e. is the drug intended for a serious/debilitating condition?) and the potential benefits of bringing the anti-cancer drug to market may be deemed to outweigh even a high risk of nausea.

²⁸⁴ Health Canada, "Concept Paper", *supra* note 23 at 20.

tended population, the drug's likelihood of causing a benefit or positive effect outweighs the likelihood of causing a harm or negative effect.²⁸⁵ Benefits occur when a drug works as intended to prevent, treat or diagnose an illness or medical condition.²⁸⁶ Conversely, risks occur when a drug does not work as intended or if it causes an adverse effect.²⁸⁷

Under the lifecycle framework, the benefit-risk assessment for initial market authorization has two broad requirements. The first requirement is scientific evidence of substantial safety, efficacy, and quality for the proposed conditions of use (i.e. authorized indication, target population, dosing regimen, and duration of use) and information that "contextualizes" that evidence (i.e. availability and performance of other therapies, domestic and international clinical practice environments, anticipated use patterns that may lie outside the conditions of use studied in pre-market trials, and anticipated manageability of risks including potential therapeutic impact of remaining uncertainties regarding the drug). The second requirement is information regarding important contextual benefit-risk considerations (i.e. considerations relating to ethics, society, public and/or individual health, and risk acceptance).²⁸⁸ Maintenance of a market authorization past the initial, or probationary, licensing stage would require a continuing favourable benefit-risk profile throughout the remainder of the drug's lifecycle.²⁸⁹ The post-market benefit-risk assessment would be based on the same baseline elements as are required for initial market authorization, but with some possible additions²⁹⁰ such as substantial evidence for a favourable overall benefit-risk profile and evidence of other important benefit-risk considerations relating to the impact of market authorization on external decision makers.²⁹¹ Even so, safety evidence at the time of initial market authorization would only be limited to the most commonly occurring adverse drug reactions.²⁹² The trade-off under PLF is therefore a reduction in the threshold for initial drug approval in exchange for higher monitoring standards post-authorization as a condition for continuing market authorization.²⁹³

Further allowances for real world use include potential oversight by GOC in the design of post-marketing trials with defined controlled placebo requirements, comparator selection, blinding, and randomization, "structured" release into the market following Phase 2 studies (presumably to reduce risk for the first wave of consumers who will almost certainly have a much greater risk of safety problems than would be the case had Phase 3 studies been performed), determination of data requirements during probationary approval, detailed scrutiny of real-time active data collection, and subsequent modification of labelling as warranted by this data.²⁹⁴ A critical consideration is that under the terms of Bill C-51, GOC has jurisdiction to attach terms and conditions to an issued licence,²⁹⁵ including probationary licences, which may include certain field reporting commitments or that further safety and efficacy studies be completed.²⁹⁶ In this respect, PLF, at least as captured by the provisions of Bill C-51, parallels GOC's existing NOC/c policy.

Unlike the general licensing provisions of C.08.004(1) modified by the "conditions of use" under C.08.002(1),²⁹⁷ Bill C-51 contains specific language directed to licence "terms and conditions". While the provisions of Bill C-51 provide GOC with the desired jurisdiction to grant probationary approval and thus to be more involved in post-market surveillance, they also allow for considerable flexibility on the details and timing of licence issuance, suspension and revocation.²⁹⁸ Policy grounds for ex-

²⁸⁵ *Ibid.* at 14.

²⁸⁶ *Ibid.* at 11.

²⁸⁷ *Ibid.*

²⁸⁸ *Ibid.* at 18-20.

²⁸⁹ *Ibid.* at 20.

²⁹⁰ *Ibid.*

²⁹¹ *Ibid.*

²⁹² *Ibid.* at 19.

²⁹³ Paul C. Hébert, "Progressive Licensing Needs Progressive Open Debate" (2007) 176 *Canadian Medical Association Journal* 1801.

²⁹⁴ Peterson, *supra* note 15.

²⁹⁵ *Bill C-51*, *supra* note 10. See also sections of the Bill enumerated, *supra* notes 20-22.

²⁹⁶ Health Canada, "Concept Paper", *supra* note 23 at 6.

²⁹⁷ See Section I.B above.

²⁹⁸ Specific provisions in *Bill C-51* directed to terms and conditions for clinical trial applications are found in cl. 8 ss.

licit licence terms are contained in the 2006 *Blueprint*,²⁹⁹ 2007 Concept Paper,³⁰⁰ and 2007 amendments to the NOC/c policy,³⁰¹ all of which focus on the acute need for specific terms and conditions for drugs that qualify for expedited review or flexible departure under conditions where additional safety, efficacy, or effectiveness studies are recommended as a condition of continued marketing authorization.³⁰² Parallel to the current NOC/c policy,³⁰³ there is broad discretion in the provisions of Bill C-51 directed to issuance, revocation, and suspension of market authorizations under conditions where post-marketing safety signals might be accruing rapidly for example, following the first-time exposure of the drug to the general population.³⁰⁴ This flexibility is linked to the “contextual” benefit-risk mechanism for approval which, despite its “evidence-based” nature,³⁰⁵ does not provide a guarantee that drugs associated with increasing safety signals will be withdrawn from the market any faster or more efficiently than would take place under the current regime. As acknowledged by regulators elsewhere,³⁰⁶ this will continue to depend on a semi-quantitative decision-making process that encompasses both objective evidence-based and subjective context-based factors.

2. Other Jurisdictions

Canada is not alone in its efforts to legislate PLF and other lifecycle approaches. Indeed, the seeds of the lifecycle model of drug regulation appear to have been sown in an emergent manner³⁰⁷ in a number of jurisdictions in response to post-marketing safety controversies over the final quarter of the last century.³⁰⁸ Both FDA³⁰⁹ and IOM³¹⁰ recognized early that drug safety was better served by lifecy-

18.2(2), 18.2(3) and 18.4(1); for market authorizations in cl. 8 ss. 18.7(2), 18.7(3), 18.7(4), 19.1(b) and 19(1)(b); and for establishment licences in cl. 8 ss. 19.2(2), 19.2(3), 19.2(4), 19.6(1)(b) and 19.7(1)(b).

²⁹⁹ Health Canada, “Blueprint”, *supra* note 23.

³⁰⁰ Health Canada, “Concept Paper”, *supra* note 23.

³⁰¹ *NOC/c Guidance Document*, *supra* note 104.

³⁰² Health Canada, “Concept Paper”, *supra* note 23 at 8, 17-19, 26.

³⁰³ *NOC/c Guidance Document*, *supra* note 104. For example, under the NOC/c policy (at 15, 21, 23, 28), the sponsor is required to submit periodic safety reports semi-annually “until such time as the conditions have been fulfilled and removed.” Information provided includes, *inter alia*, commitments regarding enhanced post-market surveillance, including reporting of ADRs and active surveillance responsibilities. We note there are no universal evidence-based rules or standards governing the details of post-market surveillance under the policy, which are to be determined on a “case-by-case basis following discussions between GOC and sponsors.” The policy further stipulates that “enhanced post-market surveillance procedures” are mandated for products licensed the NOC/c stream, including regular monitoring of the conditions associated with an NOC/c and active surveillance. If these enhanced surveillance procedures fail to confirm the safety and efficacy claims made in the original submission, reflected in the relevant conditions of use, the policy stipulates only that “appropriate regulatory action will be taken to ensure the safety of the patients treated.” Failure of a sponsor to fulfill the conditions of an NOC/c may provide GOC with reason to suspect the product is unsafe or ineffective at that time, with the result that GOC may conclude there is insufficient evidence to establish the effectiveness of the drug for the conditions of use attached to market authorization. For example, under C.01.013 of the *Food and Drug Regulations*, GOC may issue a stop-sale letter or advise that the drug be recalled from the market. The product may however remain available through the SAP or under other conditions authorized under the discretion of the Minister. Whether and how frequently sponsors fulfill conditions attached to NOC/c licences is described in detail in the companion article: *Sawicka and Bouchard*, *supra* note 60, at Fig. 10, Table 5, and discussion thereof.

³⁰⁴ IMS, “Arthritis”, *supra* note 245; Carpenter *et al.*, *supra* note 78.

³⁰⁵ Health Canada, “Concept Paper”, *supra* note 23 at 5, 19, 20; Health Canada, “Blueprint”, *supra* note 23 at 4, 22; Yeates, *supra* note 23 at 1845-46.

³⁰⁶ *IOM Report*, *supra* note 8; *EMEA CHMP 2* and *EMEA CHMP 3*, *supra* note 12. See also *EMEA Innovation*, *supra* note 9; *EMEA Road Map*, *supra* note 82.

³⁰⁷ Peter A. Corning, “The Re-Emergence of ‘Emergence’: A Venerable Concept in Search of a Theory” (2002) 7 *Complexity* 18 (Emergence refers to the birth of novel structures and institutional functions, including patterns in law and regulation, resulting from the adaptive process of self-organization in complex systems). See also M. Mitchell Waldrop, *Complexity: The Emerging Science at the Edge of Order and Chaos* (New York: Simon & Schuster, 1992).

³⁰⁸ See the following at *supra* note 140: Hiltz; Avorn; Krinsky; Angell; and Cohen. See Ray Moynihan & Alan Cassels, *Selling Sickness: How the World's Biggest Pharmaceutical Companies Are Turning Us All Into Patients* (New York: Nation Books, 2005). For a review of the scope of pre-1980 regulatory controversies, see McGarity & Shapiro, *supra* note 192.

³⁰⁹ Food and Drug Administration: Centre for Drug Evaluation, “Concept Paper: Premarketing Risk Assessment (Draft)” (3 March 2003), (on file with author); Federal and Drug Administration: Centre for Drug Evaluation, “Concept Paper: Risk Management Programs (Draft)” (3 March 2003), (on file with author); Food and Drug Administration: Centre for Drug Evaluation “Concept Paper: Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (Draft)” (3 March 2003), (on file with author).

cle-based regulatory models, including early articulations of flexible departure and the need to regulate therapeutic products in light of real world drug use. In particular, IOM's *Future of Drug Safety* report is analogous in spirit and precedes the Canadian PLF regime. FDA requested that IOM "convene an ad hoc committee of experts to conduct an independent assessment of the current system for evaluating and ensuring drug safety post-marketing and make recommendations to improve risk assessment, surveillance, and the safe use of drugs."³¹¹ FDA's request was prompted by growing concern over the health risks approved drugs posed to an unsuspecting public.³¹²

IOM identified a number of serious problems inherent in FDA's approval process, including a lack of clear regulatory authority, chronic under-funding, organizational difficulties and a scarcity of post-approval data.³¹³ Psaty and Burke claimed that FDA not only lacks a systematic approach to identifying pre-marketing drug safety issues but is also deficient in following up on recommended post-marketing studies.³¹⁴ Indeed a number of independent sources have reported that post-marketing commitments requested by FDA are fulfilled poorly or not at all by pharmaceutical product sponsors once approval has been granted.³¹⁵ This situation is enabled by the fact that FDA has no jurisdiction to compel sponsors to complete agreed-upon post-marketing studies or initiate new ones.³¹⁶ In fact, the completion rate for these studies has declined from 62% in 1970 to 1984 to only 24% during the period 1998-2003.³¹⁷ FDA's current system of post-market surveillance has been strongly criticized in light of its reliance on an ADR reporting system which "collects information on suspected cases and offers only the weakest type of evidence about their association with drug use."³¹⁸

In light of such problems, IOM suggested FDA improve its transparency and credibility through the creation of a culture of safety based on the lifecycle approach to benefit and risk.³¹⁹ The committee recommended FDA assure performance of timely and scientifically-valid evaluations, especially where the assessment of benefit-risk continued following market authorization.³²⁰ FDA was mandated to implement an "ongoing systematic effort to monitor safety during the entire market life of a drug,"³²¹ which in both pith and substance is synonymous with the Canadian PLF regime. IOM further recommended that Congress provide FDA with jurisdiction to mandate post-marketing risk assessment and risk management programs and impose conditions before and after drug approval that reflect the specific safety concerns and benefits presented by the drug.³²² Proposed risk assessment and risk management pro-

³¹⁰ Institute of Medicine of the National Academies: Committee on Data Standards for Patient Safety, Board on Health Care Services, "Patient Safety: Achieving a New Standard of Care", online: National Academies Press <<http://www.nap.edu/openbook.php?isbn=0309090776>> [Board on Health Care Services]. See also Institute of Medicine of the National Academies: Committee on Quality of Health Care in America, "To Err is Human: Building a Safer Health System", online: National Academies Press <<http://www.nap.edu/openbook.php?isbn=0309068371>> [Committee on Quality of Health Care].

³¹¹ *IOM Report*, *supra* note 8 at S-3. See also *FDA Fast Track*, *supra* note 11.

³¹² *Ibid.* at S-3.

³¹³ Bruce M. Psaty & Sheila P. Burke, "Protecting the Health of the Public—Institute of Medicine Recommendations on Drug Safety" (2006) 355 *New Eng. J. Med.* 1753 at 1754.

³¹⁴ *Ibid.* at 1754.

³¹⁵ *IOM Report*, *supra* note 8; U.S., Government Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-Making and Oversight Process* (Washington: Government Accountability Office, 2006). See also Jerry Avorn, "Paying for Drug Approvals—Who's Using Whom?" (2007) 356 *New Eng. J. Med.* 1697; Psaty & Burke, *supra* note 313 at 1754; Psaty & Charo, *supra* note 195 at 1917; Tufts Center, *supra* note 206; U.S., Food and Drug Administration, "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies" (2005) 70 *Federal Register* 8379; U.S., Food and Drug Administration, "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies" (2006) 71 *Federal Register* 10978; U.S., Food and Drug Administration, "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies" (2007) 72 *Federal Register* 5069; Public Citizen, "Study of the Drug Industry's Performance in Finishing Required Postmarketing Research (Phase IV) Studies", HRG Publication #1520 (13 April 2000), online: Public Citizen <<http://www.publiccitizen.org/publications/release.cfm?ID=6721>> [Public Citizen, "Study"].

³¹⁶ *IOM Report*, *supra* note 8. See also Weiss Smith, *supra* note 182; Psaty & Charo, *supra* note 195; Carpenter *et al.*, *supra* note 78.

³¹⁷ Psaty & Charo, *supra* note 195 at 1917. See also Public Citizen, "Study", *supra* note 315.

³¹⁸ Psaty & Charo, *ibid.*

³¹⁹ *IOM Report*, *supra* note 8 at S-5.

³²⁰ *Ibid.* at S-7.

³²¹ Psaty & Charo, *supra* note 195 at 1917.

³²² *IOM Report*, *supra* note 8 at S-11.

grams included the following: (a) compliance with agency-initiated changes in drug labels; (b) specific warnings to be incorporated into all promotional materials; (c) a moratorium on direct-to-consumer advertising; (d) restriction to certain facilities, pharmacists, or physicians with special training or experience; (e) the performance of specified additional clinical trials or other studies; and (f) the maintenance of an active adverse event surveillance system.³²³

In 2007, FDA responded to the IOM.³²⁴ Its response received a mixed review. Some believed the response is consistent with the spirit of IOM report,³²⁵ whereas others claimed it fell far short of what the public deserves in that it demonstrated an overwhelming lack of understanding of the magnitude of the changes recommended by the IOM to create a culture of safety.³²⁶ It was argued that FDA's response offered at best incremental progress, which in and of itself offers a glimpse into the future of drug safety.³²⁷ FDA offered a detailed response to many of the IOM's recommendations (e.g., plans for reviewing the adverse effect reporting system, increasing access to study data from large automated health care databases, evaluating risk minimization plans, developing and systematically improving risk-benefit analyses, creating a new advisory committee on communication with patients and consumers, and developing risk communication plans).³²⁸ Even so, some commentators suggested that the road map offered by FDA appeared to be constrained in certain respects by a lack of resources while other aspects of its response appeared to reflect the culture, visions, and values of an FDA badly in need of change.³²⁹ Indeed, Psaty and Charo³³⁰ and Weiss Smith³³¹ charge that, when viewed in its entirety, the FDA's response demonstrates its failure to understand the nature of the threats outlined in the IOM Report, namely, those directing FDA to carefully balance public and private interests in drug development: the transparency and independence of the review process; the need to balance pre-approval (access) and post-approval (safety) activities of the agency; and the need to generally keep an arm's length relationship with industry.

On May 9, 2007, the U.S. Senate passed Bill S. 1082, the *Food and Drug Revitalization Act*.³³² In response to the recommendations set out in the IOM report, the Bill enhanced FDA's authority to conduct post-market drug monitoring.³³³ On May 22, 2008, shortly after GOC announced Bill C-51, the FDA launched its "Sentinel Initiative" aimed at achieving a national, integrated, and electronic system for monitoring medical product safety.³³⁴ According to FDA, the Sentinel Initiative "will enable FDA to query multiple, existing data sources, such as electronic health record systems and medical claims databases, for information about medical products" and "to query data sources at remote locations, consistent with strong privacy and security safeguards."³³⁵ The ultimate goal of the Sentinel Initiative is to strengthen FDA's ability to monitor medical products throughout their entire lifecycle, consistent with its mandate to enhance the protection and promotion of public health.³³⁶

The lifecycle approach has also found strong support in the E.U.³³⁷ In a series of detailed and thoughtful reports, EMEA stipulated that "drug development should be considered as a 'continuum' throughout the lifecycle of the product, including post-approval risk management plans with real-life use of the drug" and further that "enhanced post-marketing safety follow-up should be considered to

³²³ *Ibid.* at S-9-10.

³²⁴ FDA, "Response", *supra* note 127.

³²⁵ Galson, *supra* note 76.

³²⁶ J.K. Jones, "The Institute of Medicine's Report on Drug Safety: Constructive and Ambitious, But Does it Go Far Enough?" (2007) 81 *Clinical Pharmacology & Therapeutics* 156; Weiss Smith, *supra* note 182 at 962.

³²⁷ Psaty & Charo, *supra* note 195 at 1917, 1919.

³²⁸ *Ibid.* at 1917-18.

³²⁹ *Ibid.* at 1917, 1919.

³³⁰ *Ibid.* at 1919.

³³¹ Weiss Smith, *supra* note 182 at 962. But see Letter to the Editor by Steven K. Galson, former Director of CDER: Galson, *supra* note 76, and Reply to Letter to the Editor by Weiss Smith (2007) 357 *New Eng. J. Med.* 2521.

³³² Bill S. 1082, *Food and Drug Administration Revitalization Act*, 110th Cong., 2007, (not yet referred to a House Committee) online: GovTrack.us <<http://www.govtrack.us/congress/bill.xpd?bill=s110-1082>>.

³³³ Hébert, *supra* note 293.

³³⁴ FDA, "Sentinel", *supra* note 11.

³³⁵ *Ibid.*

³³⁶ *Ibid.*

³³⁷ For a recent review, see Eichler *et al.*, *supra* note 94.

complement and strengthen the safety during the lifecycle of the product, but could not substitute for what needs to be known before placing the product on the market.”³³⁸ EMEA clearly acknowledges the importance of uncertainty and risks of drug development, regulation, and consumption, and the relevance thereof to pre- and post-market safety and efficacy monitoring,³³⁹ conditional marketing authorization, and active post-marketing surveillance.³⁴⁰ In addition, EMEA clearly recognizes that the danger of expediting approval under conditions of limited information can be balanced to some degree by aggressive post-market surveillance. Allocating resources to both ends of the access-safety balance is seen to provide the benefits of faster approval while mitigating the dangers of marketing a drug too quickly.³⁴¹

II

UPWARDS OR DOWNWARDS ON FOUCAULT’S PENDULUM?

Analogizing concerns over the lifecycle approach to Foucault’s pendulum resonates for several reasons. First is the idea of drug development, regulation, and consumption as a constantly moving 360° pendulum that is highly sensitive to *both* its initial starting conditions and to changes in dynamic conditions occurring over time. We can extend this analogy beyond physicist Leon Foucault’s work to encompass that of philosopher Michel Foucault, through the convergent nexus of social institutions, power, knowledge, post-structuralism (here, “post” linear regulatory models),³⁴² and a “thick” moral reading³⁴³ of the diverse motivations of public and private actors making up the rTPL ecology. The exclamation point is Umberto Eco’s novel of the same title, with its layers of intricate conspiracies, the likes of which have been invoked almost neurotically as an essential element of drug regulation by many commentators in the last decade. A question at the point of convergence of all these paths might be this: Does the lifecycle approach to drug approval represent a legitimate contextual effort to rebalance pre-market and post-market drug safety, efficacy and effectiveness considerations, or yet a further swing toward the upper reaches of pro-industry regulation?

Given the persistence of concerns relating to post-marketing drug safety,³⁴⁴ it is perhaps not surprising that a range of criticisms have been leveled at the lifecycle approach despite some of its fairly clear advantages. The thrust of this critique is that the focus of PLF will be on industrial development rather than public protection, including a continued preference for access, faster review times, private IPR rights, and minimal post-marketing obligations. According to its critics, the result of this scenario is that post-market safety withdrawals will remain significant or even increase in light of flexible departure and that the public will be treated to yet more secondary Me Too and Line Extension products rather than first-of-kind breakthrough therapies.

One of the most contentious aspects of PLF is that it provides GOC with increased “flexibility” to grant faster market authorization for drugs intended for extraordinary circumstances,³⁴⁵ including those for conditions that are urgent, rare, serious, life-threatening, or where there is an otherwise unmet medical need.³⁴⁶ PLF allows flexibility in granting initial authorization where promising drugs have a very limited amount of safety and efficacy information available at the time of licensing;³⁴⁷ for

³³⁸ *EMEA Innovation*, *supra* note 9 at 17-18. See also the following *EMEA CHMP 1*, *EMEA CHMP 2*, and *EMEA CHMP 3*, *supra* note 12; *EMEA Road Map*, *supra* note 82.

³³⁹ *EMEA Innovation*, *supra* note 9 at 6.

³⁴⁰ *Ibid.* at 7-8.

³⁴¹ *Ibid.* at 16.

³⁴² Benoit Godin, “The Linear Model of Innovation: The Historical Construction of an Analytical Framework” (2006) 31 *Science, Technology & Human Values* 639; Bouchard, “Reflections”, *supra* note 69.

³⁴³ Michael Walzer, *Thick and Thin: Moral Argument at Home and Abroad* (Notre Dame: University of Notre Dame Press, 1994).

³⁴⁴ For a detailed description of safety and efficacy issues in the period leading up to 1980, see: McGarity & Shapiro, *supra* note 192.

³⁴⁵ See generally *supra* notes 20-21.

³⁴⁶ *Bill C-51*, *supra* note 10 at cl. 8 ss. 18-19. See also Yeates, *supra* note 23 at 1845; Health Canada, “Concept Paper”, *supra* note 23 at 10.

³⁴⁷ Health Canada, “Concept Paper”, *supra* note 23 at 15.

instance, emergency use drugs that cannot be ethically tested in humans.³⁴⁸ Health Canada appropriately refers to mechanisms for early approval in face of potentially less safety and efficacy evidence as “flexible departure”.³⁴⁹ However, while the mechanism for increased post-market surveillance has been appropriately lauded, flexible departure has garnered significant criticism given its capacity to depart from the usual evidentiary requirements for safety and efficacy.³⁵⁰ To “depart” from the baseline means that while a positive benefit-risk profile for the particular pharmaceutical product constitutes an important element of the standard for approval, other “contextual” evidence may counterbalance and indeed offset the requirement of substantial safety and efficacy evidence imposed under normal circumstances.³⁵¹ Contextual evidence can be evidence showing that potential benefits of marketing the drug will outweigh the relatively increased uncertainty regarding the drug’s safety and efficacy.³⁵²

As discussed *supra*, the terms of flexible departure have been incorporated into Bill C-51, which expressly states that “a lack of full scientific certainty is not to be used as a reason for postponing measures that prevent adverse effects on human health if those effects could be serious or irreversible.”³⁵³ However, given the importance of both objective and contextual factors in most emerging lifecycle models of drug regulation,³⁵⁴ it seems reasonable to speculate that this portion of the Bill is not expressly intended to justify regulatory risk-taking. For example, a “lack of full scientific certainty” could be used to justify withdrawal of a product from the market following a sufficient increase in the frequency of relevant safety signals. This would be consistent with the so-called flexible nature of the proposed regulatory scheme, which presumably would lend itself equally well to both “flexible departure” and “flexible withdrawal.”

It is also unknown whether GOC will focus more on Priority Review and NOC/c-type approvals once PLF comes into force, thus continuing the post-user fee trend of favouring access over safety. A related issue is a potential reduction in the standard for approval for drugs that depart the pre-approval stage earlier, although federal drug agencies vigorously deny this.³⁵⁵ Similarly, a shift from the precautionary principle to benefit-risk as the mechanism of flexible departure may conduce to post-market withdrawals, as with earlier observations of shifts in regulatory practices following a change in the political culture underpinning drug approval.³⁵⁶ Additional concerns have been expressed over whether federal drug agencies will have the required arm’s length separation in pre-market and post-market authorization capacity and jurisdiction.³⁵⁷ A related issue is that GOC may not actually suspend or revoke market authorization once approval has been granted given the increasing partnership between drug regulators and industry over the last two decades.³⁵⁸ Certainly the multi-stage thresholds for suspension and revocation of clinical trial applications, market authorizations, and establishment licences discussed above allow enormous flexibility and discretion on the part of GOC under the terms of Bill C-51. It would be invaluable in this regard to have data pertaining to historical trends in drug approval by Health Canada as it leads up to its lifecycle approach, particularly data comparing the number of approvals in standard and expedited review streams (Pri-

³⁴⁸ *Ibid.*

³⁴⁹ *Ibid.* at 21.

³⁵⁰ *Ibid.* at 20-21.

³⁵¹ *Ibid.* at 21.

³⁵² *Ibid.*

³⁵³ *Ibid.* at 20.

³⁵⁴ See generally Section I.C. An additional consideration is that the statement regarding scientific uncertainties is found in the bill’s preamble rather than in a specific substantive clause. Typically, a legislative or constitutional preamble is intended to explicate the purpose and underlying philosophy of legislation prior to providing a specific statutory framework, rather than having any real force and effect in law. See *e.g.* Elmer Driedger, *The Composition of Legislation* (Ottawa: The Queen’s Printer, 1957) at 93-94.

³⁵⁵ Health Canada, “Blueprint”, *supra* note 23; FDA, “Sentinel”, *supra* note 11; EMEA CHMP 2 and EMEA CHMP 3, *supra* note 12. See also Eichler *et al.*, *supra* note 94.

³⁵⁶ Abraham & Davis, *supra* note 182; Carpenter *et al.*, *supra* note 78.

³⁵⁷ Weiss Smith, *supra* note 182; Psaty & Charo, *supra* note 195; Eichler *et al.*, *supra* note 94.

³⁵⁸ See generally *NIH Innovation or Stagnation*, *supra* note 159; Ratner, *supra* note 168; Buckman *et al.*, *supra* note 168; Woosley & Cossman, *supra* note 168; Zerhouni, *supra* note 159; Bernstein, *supra* note 159; FDA, “Response”, *supra* note 127; Wiktorowicz, *supra* note 74.

ority Review and NOC/c) and in relation to expedited approvals that do (NOC/c) and do not (Priority Review) require further evidence of safety to be submitted following initial market authorization.

A growing concern relating to domestic and global drug approval models is the increasing strength and scope of IPR rights associated with therapeutic products. This is a particularly important consideration in light of the increasing privatization of the medical research enterprise and rTPL ecology.³⁵⁹ A relevant issue is whether the lifecycle approach will continue the trend initiated by NAFTA, TRIPS, and linkage regulations of favouring development of Me Too and Line Extension drugs over development of truly breakthrough products.³⁶⁰ Data demonstrating trends in the types of drug approvals on which GOC has focused in the lead-up to PLF would be valuable in predicting the types of products to which the public is likely to gain access in a PLF context. Particularly useful would be data relating to the number and per cent of total approvals that were First in Class, Me Too, and Line Extensions, as well as the number and per cent of total approvals that were associated with brand name and generic pharmaceutical firms.

On the other end of a shifting evidentiary balance, the evolution toward lifecycle regulation is clearly motivated by and intended to rectify errors that led to post-marketing safety controversies over the last decade. In this light, GOC deserves credit for pushing the system toward a state of robustness and away from a state where the system was clearly not working.³⁶¹ In this light, a critical issue is that this shift in the regulatory approval machinery and leadership are perceived publicly to be occurring in response to calls from industry and apparent patient advocacy groups, under conditions where material information pertaining to drug safety is becoming available exponentially and sometimes for the first time. It is also occurring, however, in response to pleas by Health Canada, and its partner agencies in the U.S. and E.U., to close the gap between the need for enforcement of post-market obligations and agency jurisdiction to do just that. Hence, the idea of dynamic balance in favour of a public health mandate is central to all iterations of the lifecycle approach to drug regulation.³⁶²

Given the already substantial movement toward faster access in all three jurisdictions, there can be little question that the post-market compliance and enforcement gap is the linchpin for the lifecycle or real world approach to drug regulation. While this gap is set to be remedied by the provisions of Bill C-51 (or future legislation), only the future will reveal how hard a line drug regulators will take when faced with evidence of acute safety problems. As experience with conflicted FDA drug reviewers has shown amply,³⁶³ it will take strongly principled action on the part of agency and government leadership to ensure the delicate balance sought to be effected by PLF is maintained. If put into practice with the teeth the public deserves, PLF and other lifecycle approaches should provide a mechanism to appropriately balance the tangible and intangible costs, benefits and risks of drug development, drug regulation, and drug consumption.³⁶⁴ If not, it is not inconceivable that we will see even further movement toward post-marketing safety controversies, particularly given GOC's stated goal to move away from traditional Phase 3 studies toward some system of probationary approval follow-

³⁵⁹ *Ibid.*; Bouchard & Lemmens, "Biomedical", *supra* note 144.

³⁶⁰ Joel Lexchin, "Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?" (2005) 35 *International Journal of Health Services* 237; "Drugs in 2001: A Number of Ruses Unveiled" (2002) 11 *Prescribe International* 58; Song Hee Hong *et al.*, "Product-Line Extensions and Pricing Strategies of Brand Name Drugs Facing Patent Expiration" (2005) 11 *Journal of Managed Care Pharmacy* 746; Domenico Motola *et al.*, "An Update on the First Decade of the European Centralized Procedure: How Many Innovative Drugs?" (2006) 62 *British Journal of Pharmacology* 610. See generally Patented Medicine Prices Review Board, *Annual Report 2000*, online: Patented Medicine Prices Review Board <<http://www.pmprb-cepmb.gc.ca/CMFiles/ar00e812NPN-482003-6735.pdf>>.

³⁶¹ Robustness refers to the quality of being able to withstand stresses, pressures, or other changes in environment as a result of the ability to learn and adapt to changing conditions with minimal damage or loss of functionality.

³⁶² For review, see Eichler *et al.*, *supra* note 94.

³⁶³ See both Union of Concerned Scientists, and Harris, "Accuse", *supra* note 211.

³⁶⁴ Health Canada, "Blueprint", and Health Canada, "Concept Paper", *supra* note 23; FDA, "Response", *supra* note 127. See also Campbell & Lee, *supra* note 26; McBane, *supra* note 26; Ann Silversides, "Transparency and the Drug Approval Process at Health Canada (2005)", online: Women and Health Protection <<http://www.whp-apsf.ca/pdf/transparency.pdf>>; Graham, "Smart", *supra* note 26.

ing Phase 2 investigations.³⁶⁵ In light of the self-interest of all other actors in an rTPL ecology, it will be up to government and agency leadership to balance competing interests and protect the public. Details as to the operation of Bill C-51 will wait until the accompanying regulations are tabled and come into force.³⁶⁶

III SUMMARY & CONCLUSIONS

The first part of the article described how the historical drug regulation regime, informed strongly by the Thalidomide crisis of the 1960s, focused on strong pre-market review with little, if any, post-market safety surveillance. The pivot around which the system revolved was a combination of scientific evidence from Phase 1-3 clinical trials and a decision-making matrix that was strongly informed by the relatively risk-averse precautionary principle. A tacit assumption of drug regulation over the last several decades was that, given enough time and resources, regulators could obtain necessary and sufficient evidence regarding a drug's safety and efficacy profile such that that post-marketing problems could be avoided or at least substantially mitigated.

Over time, a host of regulatory subsystems coevolved to affect a substantial increase in the speed of drug review, which in turn resulted in enhanced "access" by the public to newly approved drugs. As reviewed in Section I, these include the institution in all major jurisdictions of user fees, a slow but sure migration from the precautionary principle to risk management principles as the primary basis for regulatory decision making, incentives favouring pharmaceutical innovation revolving around a growing platform of intellectual property and regulatory rights, and a growing number of pathways for expedited approval, some involving market entry before completion of traditional Phase 3 clinical trials.

However, along with enhanced access came a spate of serious and widespread post-marketing drug safety disasters. The sheer persistence and severity of these controversies, including numerous tragedies relating to the morbidity and mortality of children and adolescents due to hiding and otherwise selective reporting of clinical trial data, was mind boggling. This led to widespread public criticism of drug regulators and the means at their disposal to protect the public, if not their intent in doing so. Reports of corporate malfeasance escalated to such an extent that regulators in all major jurisdictions spent substantial resources seeking efficient and effective alternatives to existing drug regulatory regimes. About the same time came a growing recognition by regulators and scholars of the complexity and uncertainties inherent to large scale drug development, regulation and consumption. Thus, was born the lifecycle, or "real world," approach to drug regulation.

Concerns persist, however, as to whether regulatory agencies have the best interests of private firms in mind, or whether lifecycle-based legislation and regulations are truly aimed at rebalancing public and private interests in therapeutic product development. There is no question that Bill C-51 privileges a risk management approach rather than one dominated by the precautionary principle. Moreover, GOC drafted Bill C-51 such that it retains substantial discretion at numerous points in the approval process. This discretion could easily be used to facilitate even more rapid entry of certain drugs into the market despite concerns by regulatory scientists and public commentators with regard to post-marketing safety. Indeed, the legislation provides for highly convoluted multi-stage evidentiary thresholds for suspension and revocation of clinical trial applications, market authorizations and establishment licences. GOC has made it clear that it seeks to replace a system it sees as broken with a system geared toward probationary approval balanced by stronger post-marketing compliance and enforcement measures.

Rebalancing of the regulatory framework is entirely workable in theory. What remains to be seen is whether GOC will bring the same level of tenacity and principled leadership to the post-marketing side of a recalibrated regulatory balance that it has thus far brought to reducing barriers to regula-

³⁶⁵ Peterson, *supra* note 15.

³⁶⁶ Clause 11 section 30 of *Bill C-51*, *supra* note 10, provides jurisdiction for the Governor in Council to make regulations respecting the operational details of the PLF regime.

tory approval and encouraging innovation via IPR rights. In light of the resources it has put into nurturing, articulating, publicly consulting over, and finally proposing tentative legislation, it would be highly discouraging if more of an effective balance of pre-market and post-market regulatory oversight was not struck when viewed with appropriate hindsight and scale.

Finally, given the pronounced emphasis in developed nations on personal autonomy and choice,³⁶⁷ and the marketplace as a preferred vector for exercising these rights,³⁶⁸ it is reasonable to assume that both pharmaceutical firms and the consuming public will continue to act as self-interested and quasi-rational actors more often than not. It therefore falls to government to aggressively referee and balance these interests while serving the goals of making available safe and efficacious products to the public and facilitating innovation in the biomedical sciences in a manner constrained by prevailing legal rights and norms. As acknowledged for some time,³⁶⁹ it is not knowledge, but action, that lies at the heart of an efficient and effective regulatory regime.

³⁶⁷ Janice Gross Stein, *The Cult of Efficiency* (Toronto: House of Anansi Press, 2001).

³⁶⁸ Joseph Heath, *The Efficient Society: Why Canada Is As Close To Utopia As It Gets* (Toronto: Penguin, 2001).

³⁶⁹ *IOM Report*, *supra* note 8. See also Board on Health Care Services, *supra* note 310 and Committee on Quality of Health Care, *supra* note 310, citing Goethe to the effect that “Knowing is not enough; we must apply. Willing is not enough; we must do.”

EMPIRICAL ANALYSIS OF CANADIAN DRUG APPROVAL DATA 2001-2008: ARE PHARMACEUTICAL PLAYERS “DOING MORE WITH LESS”?

Monika Sawicka & Ron A. Bouchard*

Canada’s proposed new drug regime, termed the “Progressive Licensing Framework” (PLF), has received considerable attention since the announcement of Bill C-51 in 2008. On the one hand, its critics claim that “flexible departure”, or expedited approval prior to completion of traditional Phase 3 clinical trials, may lead to a lower standard for drug approval and an increase in unsafe products on the market. Supporters, on the other hand, claim that more emphasis on post-market safety will effectively recalibrate the risks, benefits, and uncertainties of therapeutic product development. We developed a novel empirical model to analyze Canadian drug approval data during the term 2001-2008. Our objectives were to (1) determine the types of candidates that might qualify for flexible departure under PLF and (2) assess the rate and direction of innovative activity by the Canadian pharmaceutical system. The data demonstrate that new drug submissions declined over the test period, whereas follow-on supplementary submissions from both brand name and generic firms increased in a strongly time-dependent manner. New “First in Class” and “Me Too” submissions remained relatively constant over the test period, whereas First in Class and Me Too supplementary submissions increased steeply. Priority reviews, which have the same or similar evidentiary requirements as standard new submissions, declined slightly over the test period, while NOC/c submissions, which have either the same or lower evidentiary requirements as standard submissions with additional post-market obligations, increased steeply. Analysis of withdrawal data reveals that very few substantive NOCs issued over the test period (2,122) were withdrawn to date (0.66%), with no withdrawals for either expedited review stream. Our findings show that concerns expressed over PLF pushing Canada in a new direction with regard to the workings and output of its drug regulatory regime may be misguided in that the existing approval regime has already been anticipating the lifecycle approach for several years. The data also show that the rate and direction of innovative activity by pharmaceutical firms has shifted significantly over time, implying that the domestic pharmaceutical industry, as a whole, is “doing more with less” with existing technologies.

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ABBREVIATIONS¹

ANDS	Abbreviated New Drug Submission
GOC	Government of Canada
IPR	Intellectual Property & Regulatory
NAS	New Active Substance
NCE	New Chemical Entity
NDS	New Drug Submission
NOC	Notice of Compliance
NOC/c	Notice of Compliance with conditions
PLF	Progressive Licensing Framework
R&D	Research and Development
rTPL	regulated Therapeutic Product Lifecycle
S&T	Science and Technology
SNDS	Supplementary New Drug Submission
SANDS	Supplementary Abbreviated New Drug Submission

INTRODUCTION

As discussed in detail in the accompanying article,² the Government of Canada (GOC) announced on February 8, 2008 that it would substantially amend the existing *Food and Drugs Act*³ and *Food and Drug Regulations*⁴ to make room for its new “Progressive Licensing Framework” (PLF) for drug approval in the form of Bill C-51.⁵ Notwithstanding the nation’s state of political upheaval during the time Bill C-51 was tabled, provisions such as those encompassed by Bill C-51 are almost certain to come into force at some point in the near future. This follows the development of a critical mass favouring regulatory reform in Canada, the United States (U.S.), and the European Union (E.U.), spurred in large part by well described post-marketing drug safety controversies. Indeed, Health Canada has invested considerable resources in its lifecycle-based PLF platform over the last several years, which it views as demonstrating global leadership in innovative drug regulation and as a platform for providing strong incentives to pharmaceutical firms to produce innovative products under conditions where the market does not.⁶

A range of concerns have been expressed over newer regulatory models such as PLF that seek to reallocate the risks and benefits of drug development. The concern is that lifecycle models of this nature will in fact yield a lower threshold for initial market authorization, resulting in potentially dangerous drugs slipping through regulatory cracks.⁷ Scholars, politicians, public interest groups, and media have argued that recasting drug regulation in this manner will turn the public into “guinea pigs” for drugs that have not been adequately tested,⁸ particularly under conditions where post-market studies

¹ The following list comprises abbreviations that are used throughout this article.

² Ron A. Bouchard & Monika Sawicka, “The Mud and the Blood and the Beer: Canada’s New Progressive Licensing Framework for Drug Approval” (2009) 3 McGill J. of L. & Health.

³ *Food and Drugs Act*, R.S.C. 1985, c. F-27 [*Food and Drugs Act*].

⁴ *Food and Drug Regulations*, C.R.C., c. 870 [*Food and Drug Regulations*].

⁵ Bill C-51, *An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts*, 2nd Sess., 39th Parl., 2008 [*Bill C-51*].

⁶ Robert Peterson, “Innovation in Drug Regulation: Canada as a Leader” (Lecture delivered at the Ottawa Regional Conference: “Building Excellence in Clinical Research and Clinical Trials” 11 February 2005) [Peterson, “Innovation”].

⁷ Paul C. Hébert, “Progressive Licensing Needs Progressive Open Debate” (2007) 176 Canadian Medical Association Journal 1801; James M. Wright, “Progressive Drug Licensing: An Opportunity to Achieve Transparency and Accountability?” (2007) 176 Canadian Medical Association Journal 1848. See also Hans-Georg Eichler *et al.*, “Balancing Early Market Access to New Drugs with the Need for Benefit/Risk Data: A Mounting Dilemma” (2008) 7 Nature Reviews Drug Discovery 818, citing Sir David Cooksey, *A Review of UK Health Research Funding* (London: Her Majesty’s Stationary Office, 2006); Ismail Kola & John Landis, “Can the Pharmaceutical Industry Reduce Attrition Rates?” (2004) 3 Nature Reviews Drug Discovery 711.

⁸ Carly Weeks, “New Drug Rules Pose Grave Risks: Critics” *The Globe and Mail* (8 February 2008) L6 [Weeks, “Critics”].

recommended by regulators are not conducted by sponsors once approval has been given.⁹ Fears of this nature are well grounded in light of over two decades of poor decisions by pharmaceutical firms to design, cover-up, or otherwise report clinical trial data selectively.¹⁰ A second important concern relating to PLF and other lifecycle approaches is the linking of flexible approval procedures to a benefit-risk profile that is “favourable” to the drug rather than to the more conservative, and some say more evidence-based, precautionary principle.¹¹ Canada is not alone in this stance, as parallel criticisms have been voiced over provisions for accelerated¹² and conditional¹³ approval in the U.S. and E.U.

The twin arguments by drug agencies in support of the lifecycle approach is that it will help to (1) recalibrate the balance of pre-market and post-market safety and efficacy considerations and (2) stimulate innovation in the pharmaceutical industry, with a concomitant increase in new therapeutic products for the consuming public. In this light, it would be important to have data pertaining to historical trends in drug approval by Health Canada as it leads up to its lifecycle approach, particularly data comparing the number of approvals in the standard and expedited review streams (Priority Review and

⁹ See generally U.S., Institute of Medicine: Committee on the Assessment of the US Drug Safety System, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (Washington: National Academies Press, 2007), online: Institute of Medicine of the National Academies <<http://www.iom.edu/CMS/3793/26341/37329.aspx>> [IOM Report]. See also U.S., Government Accountability Office, *Drug Safety: Improvement Needed in FDA’s Postmarket Decision-making and Oversight Process* (Washington: Government Accountability Office, 2006); Jerry Avorn, “Paying for Drug Approvals—Who’s Using Whom?” (2007) 356 *New Eng. J. Med.* 1697; Bruce M. Psaty & Sheila P. Burke, “Protecting the Health of the Public—Institute of Medicine Recommendations on Drug Safety” (2006) 355 *New Eng. J. Med.* 1753 at 1754; Bruce M. Psaty & R. Alta Charo, “FDA Responds to Institute of Medicine Drug Safety Recommendations—In Part” (2007) 297 *Journal of the American Medical Association* 1917 at 1917; Tufts Center for the Study of Drug Development, “FDA Requested Postmarketing Studies in 73% of Recent New Drug Approvals” (2004) 6:4 *Impact Report* 1; U.S., Food and Drug Administration, “Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies” (2005) 70 *Federal Register* 8379; U.S., Food and Drug Administration, “Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies” (2006) 71 *Federal Register* 10978; U.S., Food and Drug Administration, “Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies” (2007) 72 *Federal Register* 5069.

¹⁰ Craig J. Whittington *et al.*, “Selective Serotonin Reuptake Inhibitors in Childhood Depression: Systematic Review of Published versus Unpublished Data” (2004) 363 *Lancet* 1341; Jeffrey R. Lisse *et al.*, “Gastrointestinal Tolerability and Effectiveness of Rofecoxib versus Naproxen in the Treatment of Osteoarthritis: A Randomized, Controlled Trial” (2003) 139 *Annals of Internal Medicine* 539; Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, “Expression of Concern: Bombardier *et al.*, ‘Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis’” (2005) 353 *New Eng. J. Med.* 2813; Gregory D. Curfman, Stephen Morrissey & Jeffrey M. Drazen, “Expression of Concern Reaffirmed” (2006) 354 *New Eng. J. Med.* 1193; Bruce M. Psaty *et al.*, “Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis” (2004) 292 *Journal of the American Medical Association* 2622; Bruce M. Psaty & Curt D. Furberg, “COX-2 Inhibitors: Lessons in Drug Safety” (2005) 352 *New Eng. J. Med.* 1133; Bruce M. Psaty & Noel S. Weiss, “NSAID Trials and the Choice of Comparators: Questions of Public Health Importance” (2007) 356 *New Eng. J. Med.* 328; Bruce M. Psaty, Noel S. Weiss & Curt D. Furberg, “Recent Trials in Hypertension: Compelling Science or Commercial Speech?” (2006) 295 *Journal of the American Medical Association* 1704.

¹¹ Sheila Weiss Smith, “Reply to Galson” (2007) 357 *New Eng. J. Med.* 2521 [Weiss Smith, “Reply to Galson”] (elaborates on this approach (at 2521), stating that drug-approval decisions are based on a relatively narrow “evidence-based” interpretation of benefit-risk: “Benefits are defined according to the intended effect and intended population, as proposed by the sponsor. These factors are measured in efficacy studies performed in a modest number of carefully selected patients, who may or may not reflect the characteristics of the broader population likely to receive the drug. Furthermore, benefits may be extrapolated from surrogate markers ...” and “[t]he approval question becomes ‘are there persons for whom the potential benefits could outweigh the known risks?’ This standard is reasonable in limited circumstances, particularly for drugs for imminently fatal conditions ... otherwise, such a narrow interpretation of risks and benefits, which tends to favour industry over public health, has resulted in many of the FDA’s most prominent failures”). See also Sheila Weiss Smith, “Sidelining Safety—The FDA’s Inadequate Response to the IOM” (2007) 357 *New Eng. J. Med.* 960 [Weiss Smith, “Sidelining”]; Steven K. Galson, “The FDA and the IOM Report”, Note to Editor (2007) 357 *New Eng. J. Med.* 2520.

¹² U.S., Food and Drug Administration, “Fast Track, Accelerated Approval and Priority Review: Accelerating Availability of New Drugs for Patients with Serious Diseases” (May 2006), online: U.S. Department of Health & Human Services <<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccessstoImportantNewTherapies/ucm128291.htm>> [FDA, “Fast Track”].

¹³ European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), “Guideline on the Scientific Application and the Practical Arrangements Necessary to Implement Commission Regulation (EC) No 507/2006 on the Conditional Marketing Authorisation for Medicinal Products for Human Use Falling Within the Scope of Regulation (EC) No 726/2004” (London: European Medicines Agency, 2006) online: EMEA <<http://www.emea.europa.eu/pdfs/human/regaffair/50995106en.pdf>> [EMA, “CHMP Guideline”].

Notice of Compliance with conditions, or NOC/*c*) as well as expedited approvals that do (NOC/*c*) and do not (Priority Review) require further evidence of safety to be submitted following initial market authorization. In addition, data demonstrating trends in the types of drug approvals issued in the lead-up to PLF would be invaluable in predicting the types of products to which the public is likely to gain access in a post-PLF context. Particularly useful would be data relating to the number and percent of total approvals that were “First in Class”, “Me Too”, and “Line Extensions,”¹⁴ as well as those granted to brand name and generic pharmaceutical firms. Data of this nature would help clarify the influence of drug regulation on the rate and direction of innovative activity by the domestic pharmaceutical industry.

Considerations such as those expressed above led to the current study. One of our goals was to develop an independent empirical methodology and synthetic model to investigate what types of drug candidates might qualify for flexible departure under Bill C-51 or related PLF legislation and assess the post-market fate of these candidates. A second and related goal was to use this model to identify patterns in the rate (how much) and direction (what kind) of innovative activity by Canadian brand name and generic pharmaceutical firms and analyze this data in relation to GOC’s proposed policy goals respecting lifecycle regulation. We empirically analyzed 2,122 substantive Notices of Compliance (NOCs) granted by GOC during the period 2001-2008 to assess meta-trends in the pattern of drug approvals, particularly with regard to submissions for “new” drugs and how these compared with data on “supplemental” Me Too and Line Extension submissions using classifications provided by Health Canada. We found that GOC is already approving drugs with PLF in mind, that there is a significant and potentially growing proportion of drugs entering the market with evidence of safety still required to be met through post-marketing studies, and that very few of the drugs approved during the period of analysis, including those via the two expedited streams, have been withdrawn to date. The data also speak to the strength of the functional relationship between two supposed independent “silos” in a regulated Therapeutic Product Lifecycle (rTPL) innovation ecology¹⁵ e.g., drug regulation and the national science and technology (S&T) policies designed to enhance domestic competitiveness via intellectual property and regulatory (IPR) rights. We conclude that PLF has already been incorporated into the nation’s drug regulation framework and that the domestic pharmaceutical industry, as a whole, is focused more on leveraging and extending the value of existing technologies and IPR rights rather than on the production of novel first-of-kind “breakthrough” technologies.

I ANALYSIS

A. General

On its website, Health Canada posts a listing¹⁶ of all drugs that have received an NOC since 1991. The listing is divided by year and according to the following headings: Biologic products for human use; Non-prescription products for human use; Products for veterinary use, and Prescription products for human use.

Biologics¹⁷ are defined as “drug products derived from biological sources that are listed on Schedule D of the *Food and Drugs Act*. The list includes blood products, cells and tissues, gene therapies, vaccines, radiopharmaceuticals, and therapeutic products derived through biotechnology.”¹⁸ Schedule

¹⁴ Working definitions are provided in Section I.B for “First in Class,” “Me Too,” “Line Extension”, and “New Active Substance”.

¹⁵ For discussion of innovation ecology in the basic and medical sciences, see William A. Wulf, “Changes in Innovation Ecology” (2007) 316 *Science* 1253; Ron A. Bouchard, “KSR v. Teleflex Part 2: Impact of U.S. Supreme Court Patent Law on Canadian and Global Systems-Based Innovation Ecologies” (2008) 15 *Health L.J.* 247 [Bouchard, “Systems”]; Ron A. Bouchard, “Reflections on the Value of Systems Models for Regulation of Medical Research and Product Development” (2008) 17 *Health L. Rev.* 28 [Bouchard, “Reflections”].

¹⁶ Health Canada, “Drugs and Health Products—Notice of Compliance Listings”, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/list/index-eng.php>>.

¹⁷ Health Canada, “Biologics, Radiopharmaceuticals and Genetic Therapies”, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/brgtherap/index-eng.php>>.

¹⁸ Eileen McMahon & Teresa A. Reguly, “Canada: Follow-on Biologics in Canada” (2008) 3 *Update* 43 at 43, online: Mondaq: Pharmaceutical, Healthcare & Life Sciences <<http://www.mondaq.com/article.asp?articleid=61359>>.

D also includes: allergenic substances used for the treatment or diagnosis of allergic or immunological diseases; drugs obtained by recombinant DNA procedures; drugs other than antibiotics prepared from micro-organisms; monoclonal antibodies, their conjugates, and derivatives; snake venom; and other products.¹⁹ Non-prescription products include over-the-counter medications²⁰ and natural health products such as vitamins, minerals, and herbal remedies.²¹ Products for veterinary use, as the name suggests, are those therapeutic products intended for use in animals. Prescription products for human use include those products that contain as medicinal ingredients any of the compounds listed in Part I and II of Schedule F of the *Food and Drug Regulations*. The remainder of the paper will be directed at pharmaceutical products for human use.

NOCs can be granted in an “expedited” fashion in one of two ways.²² One is through Priority Review,²³ which refers to the fast-tracking of eligible NDS and SNDS intended for the treatment, prevention, or diagnosis of serious, life-threatening or severely debilitating diseases or conditions wherein there exists an unmet medical need or for which a substantial improvement in the benefit-risk profile of the therapy is demonstrated.²⁴ Evidentiary requirements for safety, efficacy, and quality parallel those for non-priority submissions; the main difference being an accelerated review time.²⁵ In addition to Priority Review, sponsors may also be granted an NOC with conditions (NOC/c)²⁶ for eligible NDS or SNDS submissions directed to serious, life-threatening, or severely debilitating diseases or conditions for which there is promising evidence of clinical effectiveness based on available data.²⁷ In addition to less onerous evidentiary requirements, the review process for NOC/c approval is significantly accelerated.²⁸ The main difference compared to Priority Review is that licensure is granted on the “condition” that the sponsor perform additional studies to confirm the drug’s alleged therapeutic benefit. Even so, GOC has nominal jurisdiction to ensure a manufacturer’s compliance through post-market surveillance.²⁹ Table 1 shows examples of NOC/c approvals recently granted by GOC.

¹⁹ *Food and Drugs Act*, *supra* note 3 at Sch. D.

²⁰ For a listing of non-prescription pharmaceuticals given a Notice of Compliance from 1991 to the present date see Health Canada, “Drugs and Health Products—Notice of Compliance Listings”, online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/list/index-eng.php#2008>>.

²¹ For a comprehensive description of natural health products see Health Canada, “Drugs and Health Products—Natural Health Products”, online: <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>>.

²² For a detailed discussion of expedited review pathways in Canada, see Bouchard & Sawicka, *supra* note 2 at Section I.B.

²³ Health Canada, “Guidance for Industry: Priority Review of Drug Submissions”, online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/priordr-eng.pdf> [Health Canada, “Priority Review Guidance Document”].

²⁴ *Ibid.* at 1-2.

²⁵ Trudo Lemmens & Ron A. Bouchard, “Regulation of Pharmaceuticals in Canada” in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 3rd ed. (Toronto: LexisNexis, 2007) 311 at 328; Health Canada, “Priority Review Guidance Document”, *supra* note 23.

²⁶ NOC/c is granted pursuant to s. C.08.004(1), in compliance with the conditions of use stipulated in s. C.08.002(1)(g), C.08.002(1)(h), C.08.006(2)(b), and C.05.006(2)(a).

²⁷ Health Canada, *Guidance for Industry: Notice of Compliance with conditions* (Ottawa: Public Works and Government Services Canada, 2007), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/noccg_accd-eng.pdf>. A candidate for NOC/c must have the potential to provide an effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada or a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies, preventative or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

²⁸ Health Canada, “Access to Therapeutic Products: The Regulatory Process in Canada—Target Review Times”, online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php#6.2>.

²⁹ Lemmens & Bouchard, *supra* note 25 at 329.

TABLE 1. EXAMPLES OF RECENTLY ISSUED NOC/C APPROVALS

NOC/c	Active Ingredient	Date	Indication	Significance	Priority	NAS
Isentress®	Raltegravir Potassium	2007-11-27	HIV integrase strand transfer inhibitor	HIV/AIDS	YES	YES
Duodopa®	Levodopa Carbidopa monohydrate	2007-03-01	Parkinson's	Parkinson's Disease	NO	NO
Lyrica®	Pregabalin	2007-11-09	Analgesic	Neuropathic pain	NO	NO
Atriance®	Nelarabine	2007-09-22	Anti-neoplastic	Adult & child T-cell acute lymphoblastic leukemia/T-cell lymphoblastic lymphoma	NO	YES

A statistical analysis of NOCs issued in Canada from January 1st 2001 to December 31st 2008 inclusive was conducted. For each year, Health Canada's "Prescription Products for Human Use" NOC listing (listing) was analyzed. A listing for a given year encompasses NOCs issued from January 1st of that year to December 31st. With respect to each NOC issued, the listing provides the following information: (a) the brand name of the prescription product that received the NOC; (b) the source of the prescription product (i.e. manufacturer or company name); (c) the active ingredient of the prescription product; (d) the date the NOC was granted; (e) the drug identification number (DIN) assigned to the prescription product upon granting of the NOC; (f) the therapeutic class of that product (i.e. the specific indication or condition for which that prescription product is intended to be used); and (g) any additional comments such as the dosage requirement, route of administration, and whether the NOC was granted due to the manufacturer and/or product's name change among other things. The listing explicitly states whether an NOC was issued under the NOC/c policy. Figure 1 illustrates how an NOC is presented in the listing.

Brand Name:	Cialis
Source:	Eli Lilly Canada Inc.
Active Ingredient:	Tadalafil
Comments:	Manufacturer name change; TAB (2.5mg, 5mg, 10mg, 20 mg) ORL
Date:	2007-09-11
DIN:	0229688, 02296896, 02248088, 02248089
Therapeutic Class:	cGMP-Specific Phosphodiesterase Type 5 Inhibitor / Treatment of Erectile Dysfunction

Brand Name:	Isentress ISSUED UNDER THE NOC/C POLICY
Source:	Merck Frosst Canada Ltd., Merck Frosst Canada Ltée
Active Ingredient:	Raltegravir (supplied as Raltegravir potassium)
Comments:	TAB (400mg)ORL
Date:	2007-11-27
DIN:	02301881
Therapeutic Class:	HIV integrase strand transfer inhibitor

Fig. 1 Example of two entries as they appear in the Health Canada NOC listing

Health Canada's NOC listing has some notable limitations. First, although it is organized alphabetically, listed drugs are not numbered. Therefore, calculating the total number of NOCs issued in a particular year must be done manually. Second, the listing does not specify certain relevant information such as (a) whether an NOC for a given prescription product was issued under New Drug Submission (NDS), Supplementary New Drug Submission (SNDS), Abbreviated New Drug Submission (ANDS), or Supplementary Abbreviated New Drug Submission (SANDS) application stream(s), (b)

whether an NOC was granted under the Priority Review policy, and (c) whether a given prescription product contains a New Active Substance (NAS). Previously known as a “New Chemical Entity” (NCE), an NAS may be directed to the following: a chemical or biological substance not previously approved for sale in Canada as a drug; an isomer, derivative, or salt of a chemical substance previously approved for sale as a drug in Canada but differing in properties with regard to safety and efficacy; or a biological substance previously approved for sale in Canada as a drug, but differing in molecular structure, nature of the source material or manufacturing process.³⁰ Initially, we deemed drugs classified as NAS as “First in Class”. However, Health Canada clarified that NAS drugs are not always first in their class, although on some occasions they can be.³¹ The definition of an NAS therefore determines both First in Class and Me Too compound-indication classifications (cf. Table 2).

Health Canada has supplemented the listings with a searchable database (database) that includes all NOCs issued in Canada since 1994. The database can be searched by a product’s brand name, drug identification number (DIN), NOC/c status, medicinal ingredient, manufacturer, submission class (NAS, Priority, Priority-NAS, or Other), therapeutic class, and type (veterinary, non-prescription, prescription, biologic, or radiopharmaceutical).

To obtain additional information for our listings for each given year, we searched the database by product type (prescription pharmaceutical) and NOC date. Because entering a full year in the date field yielded too many NOCs to hold on one page, each year was broken up into three portions. For example, 2007 was subdivided into January 1 - April 30, May 1 - August 31, and September 1 - December 31. This method generated three NOC lists for a given year, identifying drug brand name, manufacturer, NOC date, medicinal ingredient(s) and DIN. The lists are arranged by date (from most to least recent NOC) and numbered. Numbering allows for easy calculation of the total NOCs in the list. Figure 2 illustrates the beginning portion of the database-generated list for January 1, 2007 to April 30, 2007.

1. HYOSCINE BUTYLBROMIDE INJECTION SANDOZ STANDARD

Manufacturer: SANDOZ CANADA INCORPORATED
 NOC Date: 2007-04-27
 Medicinal Ingredients: HYOSCINE BUTYLBROMIDE
 DIN: 02229868

2. ATRIDOX

Manufacturer: TOLMAR INC
 NOC Date: 2007-04-27
 Medicinal Ingredients: DOXYCYCLINE HYCLATE
 DIN: 02242473

3. PMS-TERBINAFINE

Manufacturer: PHARMASCIENCE INC.
 NOC Date: 2007-04-26
 Medicinal Ingredients: TERBINAFINE HCL
 DIN: 02294273

4. RATIO-TAMSULOSIN

Manufacturer: RATIOPHARM INC.
 NOC Date: 2007-04-26
 Medicinal Ingredients: TAMSULOSIN HYDROCHLORIDE
 DIN: 02294265

³⁰ Health Canada, “Drugs and Health Products—New Active Substance” (4 June 1991), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/nas_nsa_pol-eng.php> [Health Canada, “NAS”]; Health Canada, “Drugs and Health Products—NOC Database Terminology” (1 October 2004), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/noc-acc/term_noc_acc-eng.php>.

³¹ Personal communications with David K. Lee (Director, Progressive Licensing Project, TPD, Health Canada), Dr. Maureca Maher (Senior Scientific Advisor, Progressive Licensing Project, TPD, Health Canada), and Ms. Lesley Brumell (Supervisor, Submissions Processing, Submission and Information Policy Division (SIPD), Health Canada) (April–July 2008), [Health Canada Personal Communication]. One of us (Bouchard) also participated in Health Canada’s PLF stakeholder workshops in November 2006, May 2007, and June 2007.

Fig. 2 Example of Health Canada NOC database-generated list for January 1, 2007 to April 30, 2007. Entries shown are the first four in the database-generated list.

Within the database-generated list, the drug name (shown in bold and underlined capital letters) can be isolated to obtain “Notice of Compliance Information” for a given drug. The NOC Information page provides a product’s NOC date, manufacturer name, type, NOC/c status, submission type (NDS, SNDS, ANDS, or SANDS), reason for supplement if the submission is an SNDS or SANDS (i.e. change in dosage, form, or route of administration), submission class (NAS, Priority, Priority-NAS, or Other), therapeutic class, Canadian reference product if the product is a generic, company name, and country of manufacture. Furthermore, the NOC Information provides the product’s DIN, medicinal ingredient(s), form, route of administration, and dosage. Figure 3 illustrates the Notice of Compliance Information sheet for the first drug shown in Fig. 2, Hyoscine Butylbromide Injection Sandoz Standard.

Notice of Compliance Information		
NOC Date:	2007-04-27	
Manufacturer:	SANDOZ CANADA INCORPORATED	
Product Type:	PRESCRIPTION PHARMACEUTICAL	
NOC with conditions:	No	
Submission type:	ANDS	
Submission class:	OTHER	
Therapeutic class:	ANTISPASMODIC	
Canadian Reference		
Product:	BUSCOPAN	
Company:	BOEHRINGER INGELHEIM	
Country:	CANADA	
Brand 1 of 1:		
HYOSCINE BUTYLBROMIDE INJECTION SANDOZ STANDARD		
Product 1 of 1:		
DIN: 02229868		
Form: SOLUTION		
Routes: INTRAMUSCULAR, SUBCUTANEUS, INTRAVENOUS		
Medicinal Ingredients:		
	Ingredient	Strength
	HYOSCINE BUTYLBROMIDE	20 MG/ML

Fig. 3 Example of a Notice of Compliance Information Sheet as it appears on the Health Canada NOC database. The sheet was obtained by selecting the first drug in the database-generated list shown in Fig. 2.

For each pharmaceutical in the NOC listing, we included additional information found exclusively in the NOC Information through the database-generated list. NOC Information for a given drug in the listing is also available by simply typing in a particular product’s brand name and NOC date, which bypasses the database-generated list. This method, although equally effective and accurate, is painstaking as it takes a considerable amount of time to type in the drug name and NOC date and wait for the database to bring up the desired result. Therefore, a database-generated list for the year, albeit broken up into three portions, was the preferred method of proceeding with the analysis.

B. Methods

Each drug within each year’s (2001 to 2008) listing was classified as an NDS, SNDS, ANDS, or SANDS based on the NOC Information sheet. The total numbers of NDS, SNDS, ANDS, and SANDS were calculated for each year and then double checked by a blind party for accuracy. Unfortunately, the database is not searchable by submission class (i.e. NDS, SNDS, ANDS, and SANDS). For example, we could not search the database by SANDS and year to get a complete list of all prescription pharmaceuticals that received an NOC by virtue of a SANDS application for that year. This is a significant limitation of the Health Canada database.

Initially, we counted all NOCs issued as NDSs. However, a sponsor may manufacture a drug and receive an NOC by virtue of NDS even if the drug does not differ in any respect (i.e. indication, medicinal ingredient, route of administration, or dosage) from a previous drug manufactured by that company. Health Canada mandates that where there is a change in the manufacturer and/or product name or manufacturing site, a drug manufacturer must apply for a new NOC by virtue of an NDS for any drug issued after such a change took place, even if the drug is not new in any other way.³² These NDSs are collectively termed by Health Canada as “administrative NDSs.”³³ Given these NDSs exist solely because of a product or manufacturer change and not because a new drug was issued an NOC, the presence of these NOCs contaminated the data. Therefore, all administrative NDSs were excised prior to analysis. Administrative ANDS NOCs were excised for the same reason. In order to determine which NOCs were administrative, comments provided in the listing were reviewed. The comments clearly stated whether an NOC was granted by virtue of a simple manufacturer or product name change. Once these NOCs were identified, they were subtracted from the initial total number of NDS and ANDS NOCs to yield an accurate representation of how many substantive NDS and ANDS NOCs were issued in a given year.

The percentage of total NDSs in a given year was calculated in two ways. The first involved the inclusion of generic drugs; therefore, the percentage of NDS was calculated as a fraction of the combined total for all NDS, SNDS, ANDS, and SANDS for that respective year. This is summarized by Equation 1:

$$\% \text{ NDS} = \text{NDS} / (\text{NDS} + \text{SNDS} + \text{ANDS} + \text{SANDS}) \quad \text{Eq. 1}$$

The second method involved the exclusion of generic drugs; therefore, the percentage of NDS was calculated as a fraction of the combined total for all NDS and SNDS for that respective year. This is given by Equation 2:

$$\% \text{ NDS} = \text{NDS} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 2}$$

The percentage of SNDSs in a given year was calculated in the same two ways as NDSs. In the first method the percent SNDS was calculated as a fraction of the combined total for all NDS, SNDS, ANDS, and SANDS for that respective year. This is summarized by Equation 3:

$$\% \text{ SNDS} = \text{SNDS} / (\text{NDS} + \text{SNDS} + \text{ANDS} + \text{SANDS}) \quad \text{Eq. 3}$$

In the second method, the percentage of SNDS was calculated as a fraction of the combined total for all NDS and SNDS for that respective year. This is summarized as follows:

$$\% \text{ SNDS} = \text{SNDS} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 4}$$

The total number of NOCs classified as NAS was calculated for each year, 2001 to 2008 inclusive. The Health Canada database is searchable by Submission Class, which includes the following categories: NAS, Priority, Priority-NAS, and Other status. By narrowing the search to prescription pharmaceuticals, a specified year, and NAS, we obtained a numerated list of all NOCs with NAS status that were issued in each given year. Subsequently, we narrowed the search to prescription pharmaceuticals, a specified year and Priority-NAS and obtained a numerated list of all NOCs with Priority-NAS status issued in that year. To calculate the total number of NOCs classified as NAS, we added the totals of both NAS and Priority-NAS NOCs. This is summarized by Equation 5:

³² Health Canada Personal Communication, *supra* note 31.

³³ *Ibid.*

$$\text{Total NAS} = \text{NAS} + \text{Priority-NAS} \quad \text{Eq. 5}$$

Prescription pharmaceuticals classified as NAS are only submitted as NDS. However, for the sake of consistency, the percentage of NAS NOCs was also calculated as a fraction of the combined total of NDS and SNDS (ANDS and SANDS were excluded). This is summarized by Equation 6:

$$\% \text{ NAS} = \text{NAS} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 6}$$

The percentage of ANDS in a given year was calculated as a fraction of the combined total for all NDS, SNDS, ANDS, and SANDS for that respective year:

$$\% \text{ ANDS} = \text{ANDS} / (\text{NDS} + \text{SNDS} + \text{ANDS} + \text{SANDS}) \quad \text{Eq. 7}$$

The percentage of SANDS in a given year was calculated as a fraction of the combined total for all NDS, SNDS, ANDS, and SANDS for that respective year:

$$\% \text{ SANDS} = \text{SANDS} / (\text{NDS} + \text{SNDS} + \text{ANDS} + \text{SANDS}) \quad \text{Eq. 8}$$

The next part of the analysis involved determination of NOCs classified as First in Class or Me Too. This proved to be one of the most difficult aspects of the study, as available definitions of First in Class and Me Too by regulators are very limited. We used information obtained directly from Health Canada to define First in Class and Me Too drugs. We then designed a methodology for determining which NOCs fall under these categories. This methodology is based on the principles outlined below.

According to Health Canada, “First in Class” drugs are drugs that consist of either (a) a new family of active ingredient(s) or (b) old active ingredient(s) used for the treatment of a new indication (Table 2). Therefore, a drug is deemed to be First in Class if there is no other drug on the market that belongs to the same compound family and is used for the same indication.³⁴ In other words, a First in Class drug is a drug for which there is no comparator.³⁵

Conversely, “Me Too” drugs are drugs that offer important therapeutic options with little or no change to the benefit-risk profile.³⁶ They are drugs that are comparable to others in terms of their compound and indication.³⁷ Derivatives or salts of an existing compound are classified as Me Too drugs.³⁸ As per the Health Canada definition, NAS NOCs include those directed to salts and derivatives.³⁹ Therefore, drugs that are labeled as an “NAS” can be either First in Class or Me Too drugs. Initially, we assumed Me Too drugs could only be submitted as NDSs. The reasoning for this was that Me Too drugs are neither generic drugs (ANDS or SANDS) nor Line Extensions (SNDS). However, as shown in Table 2, neither First in Class nor Me Too classifications stop at NOCs submitted as NDSs, depending on the chemical nature and use of the compound. SNDS NOCs can be classified as First in Class or Me Too; thus both can be issued as NDS and Line Extension (SNDS) NOCs.⁴⁰

Based on the drug classification scheme outlined in Table 2, we determined which NDS and SNDS NOCs were First in Class and Me Too drugs. We analyzed all NOCs submitted as NDS for approval first. In analyzing this group, we started off with those NDSs deemed by Health Canada to have NAS status, as all First in Class drugs would be included in this broad group. Obtaining a list of all NAS

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ *Ibid.*

³⁷ *Ibid.*

³⁸ *Ibid.*

³⁹ Health Canada, “NAS”, *supra* note 30.

⁴⁰ Health Canada Personal Communication, *supra* note 31.

NOCs for a given year is relatively straightforward, given the ability to search the NOC database by NAS status.

TABLE 2. HEALTH CANADA COMPOUND-INDICATION CLASSIFICATION

YEAR	COMPOUND/INDICATION	CLASSIFICATION
2000	Compound X (first 'X' Compound) with Indication A	First in Class
2001	Compound X with Indication B	First in Class
2001	Compound <i>aX</i> (Compound in the family of X) with Indication A	Me Too
2001	Compound <i>aX</i> with Indication B	Me Too
2001	Compound <i>aX</i> with Indication C	First in Class

We assessed each NAS for the period 2001–2008 by cross-referencing the NAS drug's active ingredient, NOC date, and indication with the Health Canada online NOC database and the World Health Organization (WHO) Collaborating Center for Drug Statistics Methodology website.⁴¹ If the active ingredient in the NAS was the very first of its family of compounds, the drug was classified as First in Class. If the active ingredient in the NAS was a member of a family of compounds in which a drug already exists but the drug was used for a new indication, the drug was also classified as a First in Class. All NAS not deemed to be First in Class were labeled Me Too NOCs. The number of First in Class NDS NOCs was then calculated. The total number of Me Too NDS NOCs for each year was calculated using Equation 9:

$$\text{Total NDS Me Too} = \text{NDS} - \text{First in Class NDS} \quad \text{Eq. 9}$$

We then analyzed all NOCs submitted as SNDS. Because SNDS drugs are “Line Extensions” of previously existing drugs, the analysis turned strictly on new indications. Essentially, if an SNDS for a particular compound was given a new indication not seen before, as determined by cross-referencing the drug's active ingredient, NOC date, and indication with the NOC database, it was deemed as a First in Class drug.

The designation of First in Class by virtue of a new indication was far from simple. The starting point for this process was the NAS. If Health Canada classified an NOC as being directed to an NAS, it can be assumed that the active ingredient has not been sold in Canada for that specific indication prior to issuance of the NOC. The next step was to determine whether a new indication exists for the medicinal ingredient associated with the NAS following issuance. One way to do this is via Health Canada's searchable database. We entered the medicinal ingredient described by the NAS into the appropriate database field. This yielded a list of all drugs that have the same medicinal ingredient as the NAS. Because the list is arranged by date, the NAS presents as the earliest entry in the list. The next step was to go through each drug listed above the NAS and determine whether it is an SNDS with a new indication, which is indicative of a First in Class drug. Given that the database only goes as far back as 1994, this method may not produce the most accurate quantification. Part of the difficulty in correctly determining First in Class NOCs is that the NOC database includes, when describing reasons for SNDS (as opposed to NDS), NOCs directed to new indications as well as new routes of administration, dosage forms, and contra-indications.⁴² Thus, within the new indication SNDS category, an NOC can be given for a new medical condition as well as for an extended treatment population e.g., pediatric. However,

⁴¹ Online: World Health Organization Collaborating Centre for Drug Statistics Methodology <<http://www.whocc.no/atcddd/>> [WHO Website].

⁴² *Food and Drug Regulations*, *supra* note 4 at s. C.08.003(2).

only NOCs directed to new medical conditions are viewed by Health Canada as First in Class.⁴³ Therefore, assuming that all NOCs in the extended population SNDS subclass are First in Class would artificially increase the number of true First in Class NOCs. All SNDS NOCs not deemed First in Class were labeled Me Too by default.⁴⁴

The number of First in Class SNDS drugs was calculated as described above. The total number of SNDS Me Too drugs for each year is calculated using equation 10:

$$\text{Total SNDS Me Too} = \text{SNDS} - \text{First in Class SNDS} \quad \text{Eq. 10}$$

The next step was to calculate the total number of NOC/c during the period 2001-2008. By narrowing search terms on the Health Canada database to prescription pharmaceuticals, a specific year, and NOC/c, we obtained a list of all NOC/c that were issued in a given year. Because prescription pharmaceuticals provided with market authorization under the NOC/c policy are only submitted as NDS or SNDS, the percentage of NOC/c was calculated as the fraction of total of NDS and SNDS (e.g., ANDS and SANDS were excluded). This is summarized by Equation 11:

$$\% \text{ NOC/c} = \text{NOC/c} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 11}$$

The total number of NOCs issued under Priority Review was calculated for 2001-2008 inclusive. By narrowing the database search to prescription pharmaceuticals, a specific year and Priority Review, we obtained a numerated list of all NOCs issued under Priority Review for that given year. We then searched the database by prescription pharmaceuticals, a specific year and Priority-NAS status and obtained a numerated list of all NOCs with NAS status and that were issued under the Priority Review Policy in that given year. To calculate the total number of NOCs granted via the Priority Review stream we added the totals of both Priority and Priority-NAS NOCs as given by Equation 12:

$$\text{Total Priority} = \text{Priority} + \text{Priority-NAS} \quad \text{Eq. 12}$$

Prescription pharmaceuticals granted an NOC under the Priority Review Policy are only submitted for approval as NDS or SNDS. Thus, the percentage of Priority NOCs was calculated as a fraction of the combined total of NDS and SNDS (ANDS and SANDS were excluded). This is summarized by Equation 13:

$$\% \text{ Priority} = \text{Priority} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 13}$$

The total number of non-priority NOCs was calculated for each year, 2001-2008 inclusive. We subtracted the total number of Priority Review NOCs from the combined total of NDS and SNDS for each year:

$$\text{Non-Priority} = (\text{NDS} + \text{SNDS}) - \text{Priority} \quad \text{Eq. 14}$$

The percentage of non-priority NOCs was taken as a fraction of combined total NDS and SNDS for each year:

$$\% \text{ Non-Priority} = \text{Non-Priority} / (\text{NDS} + \text{SNDS}) \quad \text{Eq. 15}$$

⁴³ Health Canada Personal Communication, *supra* note 31.

⁴⁴ *Ibid.*

Finally, we analyzed whether NOC/*c* granted during the test period had their conditions met. This was done using the NOC database by following appropriate links through the “NOC/*c* conditions” box, entering “Prescription Pharmaceutical” in the Product Type field and entering January 1, 2001 to December 31, 2008 in the date field. This procedure yielded all NOC/*c* granted during the test period, from which we subtracted administrative NDS NOCs, as described above. The resulting list provides the drug name, drug manufacturer, NOC date, medicinal ingredient, NOC/*c* status, and information stating if and when the conditions were met.

Data were tabulated and analyzed using Microsoft Excel® (Microsoft, Corp., Redmond, WA), GraphPad Prism® (Graphpad Software Inc. La Jolla, CA), and SigmaPlot® (Systat Software, Inc. San Jose, CA). GraphPad or SigmaPlot were used to graph data, calculate linear regressions and exponential fits, and obtain R^2 , time constants, slopes, and P values. Solid lines in Figs. 4–10 represent linear regression fits to the data with the exceptions of Figs. 8C, 9A, and 9B, which were fit to exponential functions as described in the Results.

C. Results

The number of NDS NOCs for 2001–2008 inclusive (test period) was 52, 26, 46, 62, 36, 54, 37, and 25 per year, respectively. As illustrated in Fig. 4A, the number of NDS NOCs issued over the test period declined slightly in the presence of stochastic fluctuations. When calculated as a percentage of total brand name and generic submissions (NDS, SNDS, ANDS, and SANDS), a similar trend was seen over the test period (Fig. 4B), from approximately 20% of total NOCs in 2001 to 8% in 2008. When expressed as a fraction of total brand name submissions only (NDS and SNDS), the general trend was also toward a slight decline in NDS NOCs during the test period (Fig. 4C), around an average of about 25% of total brand name submissions.

The total number of SNDS NOCs issued in the period 2001–2008 was 118, 80, 149, 138, 102, 137, 167, and 161 respectively. As illustrated by the data in Fig. 5, supplementary brand name submissions generally increased over the course of the test period. The total number of SNDS NOCs increased by approximately 60% during the period 2001–2008, though there is significant scatter in the data when administrative NOCs are removed (Fig. 5A). SNDS NOCs expressed as a percentage of total brand name NOCs issued (NDS and SNDS) also increased over the test period (Fig. 5C). The increase in the number and percentage SNDS NOCs can be compared with the relative lack of change in SNDS approvals when expressed as a fraction of all NOCs (Fig. 5B).

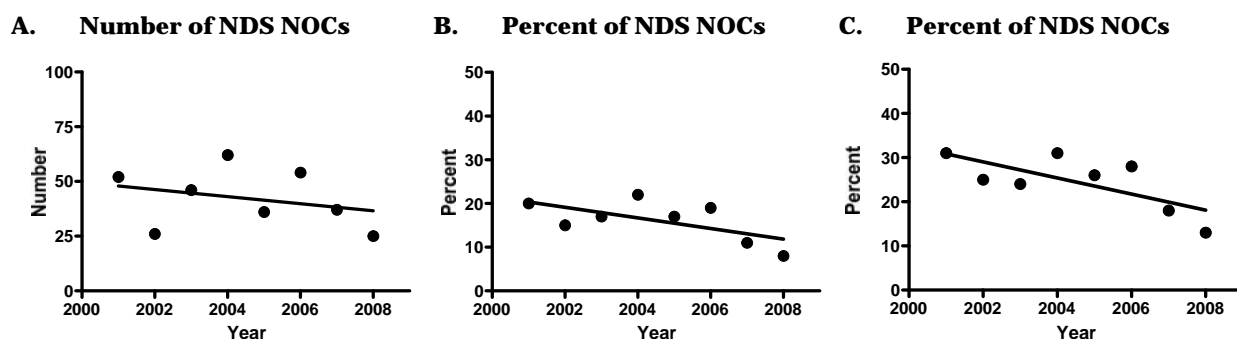


Fig. 4 (A) Number of NDS NOCs and (B) percent of NDS NOCs as a percent of all NOCs (NDS, SNDS, ANDS and SANDS) and (C) as a percent of NDS and SNDS only. Data in this and all other figures and tables are for calendar years 2001–2008 inclusive. Fits to the data are described in detail in the Methods and text. Abbreviations for this and all other figures are provided at the beginning of the text.

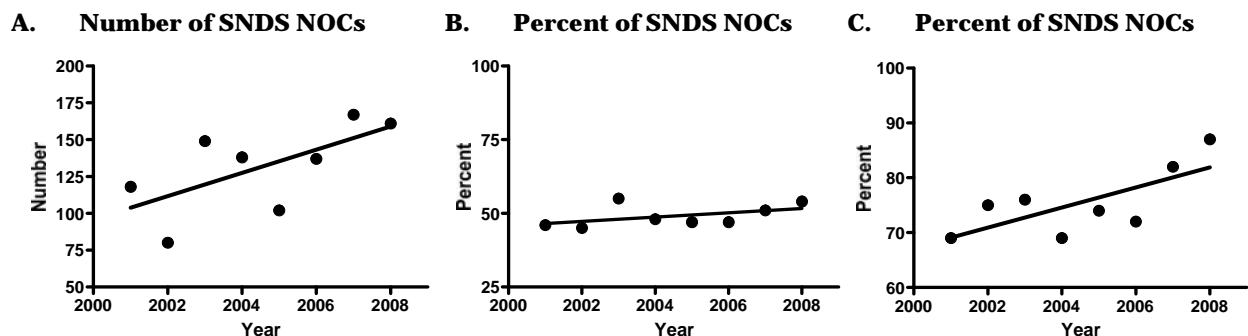


Fig. 5 (A) Number of SNDS NOCs and **(B)** SNDS NOCs as a percent of all NOCs (NDS, SNDS, ANDS and SANDS) and **(C)** SNDS NOCs as a percent of NDS and SNDS only.

Consistent with data for NDS NOCs, NOCs directed to NASs for the period 2001-2008 showed a slight decrease. The number of approvals for NASs per year was 21, 16, 16, 15, 12, 16, 20, and 14 during the test period. Figure 6A shows a declining trend, with significant scatter around an average of about 16 per year. The scatter is reduced when NAS NOCs are expressed as a percent of total NOCs. Figure 6B demonstrates that the percentage of approvals for NAS NOCs was a small fraction of total NDS and SNDS approvals (10%) and that this fraction remained relatively constant during the test period. Along with the decline in NDS NOCs (Fig. 4) and reciprocal increase in SNDS NOCs (Fig. 5), the data in Fig. 6 reveal that brand name pharmaceutical firms are focusing less on new drug submissions and more on follow-on supplementary submissions, even when the broad scope of Health Canada's NAS definition is taken into account.

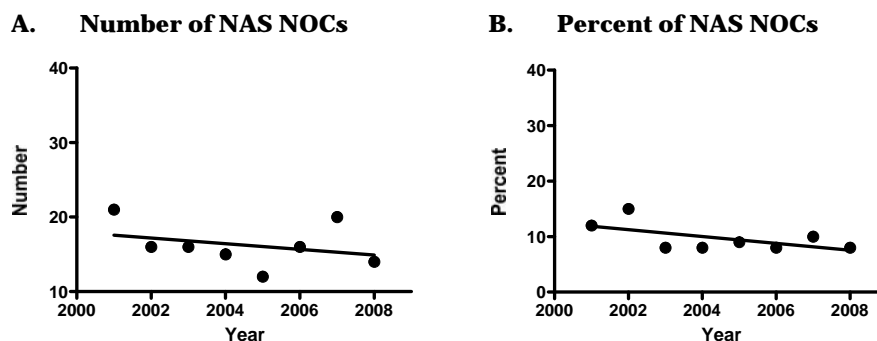


Fig. 6 (A) Number and **(B)** percent (all NDS and SNDS NOCs) of NAS NOCs.

Figure 7 illustrates trends in market approvals issued to generic firms. The total number of NOCs in the ANDS category was 73, 57, 60, 67, 64, 75, 98, and 90 over the test period. As shown in Fig. 7A, the trend was toward an increase in ANDS approvals, from a low of 57 in 2002 to a peak of 98 in 2007. This represents an increase in ANDS NOCs of about 72% over 5 years. ANDS approvals represented a fairly constant fraction of total NOCs issued over the test period, accounting for about a quarter of all NOCs issued by GOC (Fig. 7B). The total number of generic supplemental NOCs also increased over the test period (11, 16, 16, 19, 13, 25, 24, and 24). As illustrated in Fig. 7C, the number of SANDS NOCs more than doubled over this time frame, from a low of about 10 approvals per year in 2001 to a high of about 25 per year in 2007. This trend did not change when the data are expressed as a fraction of total NOCs (NDS, SNDS, ANDS, and SANDS) issued yearly over the test period (Fig. 7D). Thus, the number of supplemental submissions by both brand name (Fig. 5) and generic firms (Fig. 7) is increasing significantly with time.

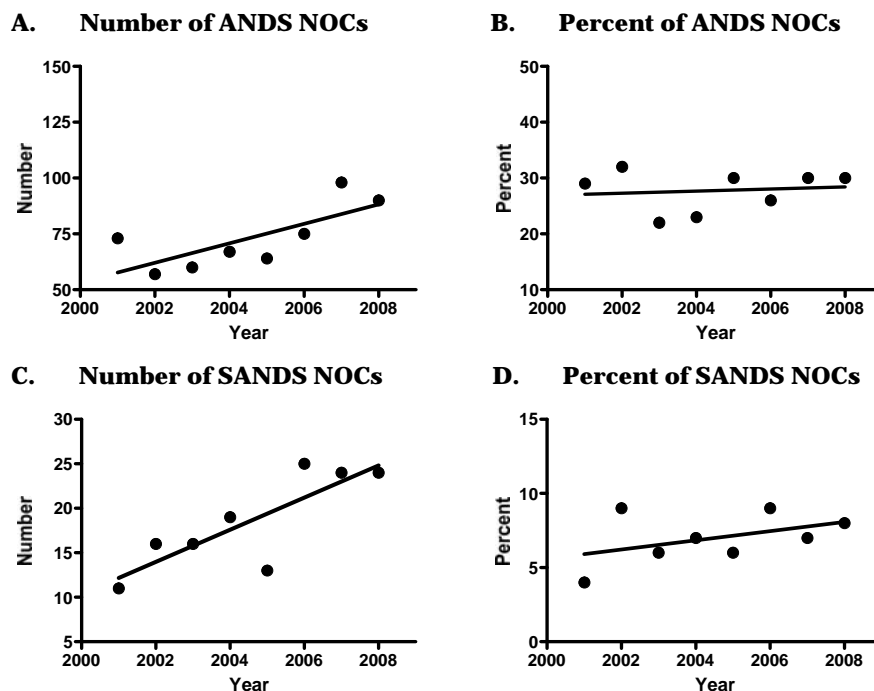


Fig. 7 Number of and percent of all NOCs (NDS, SNDS, ANDS and SANDS) of ANDS (**A and B**) and SANDS (**C and D**).

Results obtained using the method outlined in Section I.B for determining the number of First in Class and Me Too NOCs are given in Fig. 8. The number of First in Class NOCs within the NDS category was 12, 7, 5, 7, 9, 8, 9, and 8 during the test period. Figure 8A shows that the number of these approvals was relatively constant over the period 2001-2008, within a range of 5-12 per year. As illustrated in Fig. 8B, the number of Me Too NDS NOCs decreased slightly over the test period, with a significant amount of scatter in the data around an average of about 34 approvals per year. The number of calculated Me Too NDS NOCs during the period 2001-2008 was 40, 19, 41, 55, 27, 46, 28, and 17.

A substantially different situation was observed with the calculated First in Class and Me Too SNDS data. As illustrated in Fig. 8C, the number of First in Class SNDS NOCs increased substantially over the test period, from a low of 1 in 2001 to a high of 22 in 2008 (1, 1, 6, 7, 4, 13, 19, and 22). We used two methods to calculate the time-dependence, slope, and potential non-linearities in the data set. For simplicity's sake, we present these in reverse order of statistical conservatism. For the first method, the data were fit to a single exponential function of the form $y = a \cdot \exp(t/b)$, where a is amplitude and b is the time constant. Both a and b were treated as free variables, and the fit was only to the time period 2001-2008. R^2 (squared correlation coefficient), representative of the 'goodness of fit' of the function to the data (0-1), was 0.92. This suggests significant acceleration of the increase in follow-on First in Class approvals over time. The second method entailed the use of a linear model. We found that 86% of the variation in Fig. 8C could be described linearly ($P=0.000938$) as opposed to non-linearly. Given the results of the exponential fit however, we also tested for a quadratic non-linearity using an ordinary least squares regression. While this increased the coefficient of determination to 92%, the squared term was not statistically significant at $P \leq 0.05$ ($P=0.102153$). However, given that there are only eight observations, it is possible we are faced with the cliché that "an absence of evidence is not the same as evidence of absence." While it was not possible to provide evidence for a non-linear term using both statistical methods, there clearly is enough of a trend to warrant further investigation as more data become available.

The number of Me Too SNDS NOCs issued during the test period also increased significantly (Fig. 8D), though not as dramatically as First in Class SNDS NOCs. There was an approximate doubling of

Me Too SNDS NOCs over the period analyzed, from a low of 79 in 2002 to a high of 148 in 2007. Along with the data in Figs. 4-6, these results demonstrate a significant trend for domestic brand name pharmaceutical firms to concentrate their efforts on supplementary Line Extension-type submissions rather than on new NDS, NDS NAS, or even NDS Me Too-type submissions.

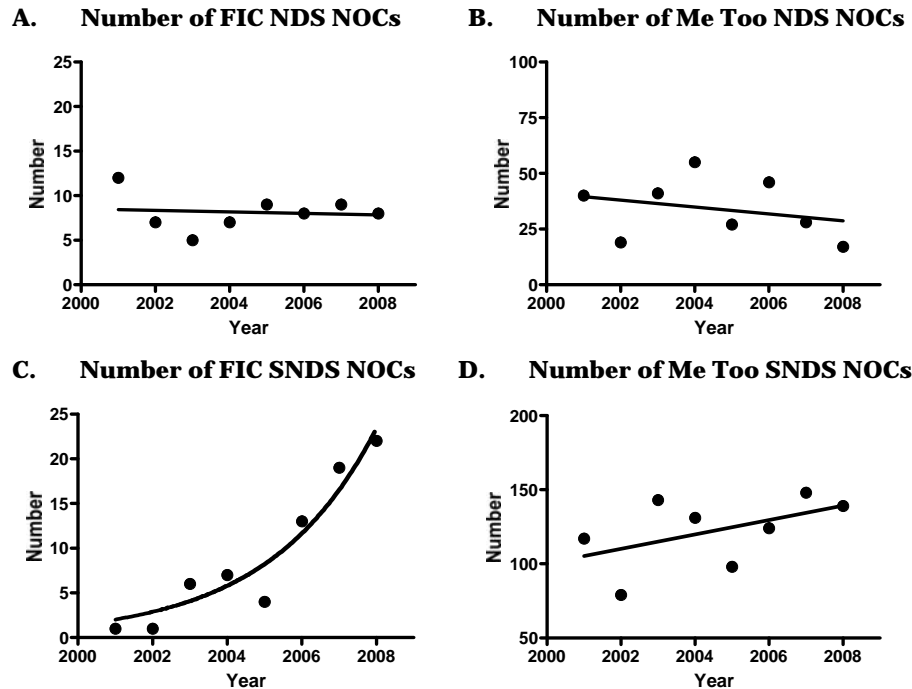


Fig. 8 Number of (A) First in Class (FIC) NDS NOCs, (B) Me Too NDS NOCs, (C) First in Class SNDS NOCs and (D) Me Too SNDS NOCs.

Figure 9 shows the time-dependence of drug approval via the two expedited approval streams (NOC/*c* and Priority Review) over the test period. The total number of NOCs issued under the NOC/*c* policy was 2, 3, 4, 3, 6, 13, 10, and 10 per year during the period 2001-2008. The data illustrate that the increase in NOC/*c* approvals occurred in a strongly time-dependent manner, independent of whether the data were expressed in absolute terms (Fig. 9A) or as a fraction of total brand name submissions (Fig. 9B). Using the first method described for analyzing data in Fig. 8C, the data could be fit to a single exponential function with R^2 values of 0.7 and 0.6 for Figs. 9A and 9B, respectively. The linear model on the other hand did not provide a strong suggestion for a non-linear term. The coefficient of determination for the simple ordinary least squares fit was 74% and 65% for Fig. 9A and 9B, respectively. However, the squared terms were not statistically significant ($P = 0.976373587$ and 0.712446789 , respectively). Even so, the data clearly demonstrate a substantial increase in grant of NOC/*c* approvals over the test period, with an increase from a low of 3 in 2001 to a high of 13 in 2006 (650%, stabilizing at 500% in 2007 and 2008). The fraction of total NOCs represented by NOC/*c* approvals increased from a nominal value of about 1% in 2001 to a peak of 7% of all NOCs issued by Health Canada to brand name firms in 2006 (stabilizing at 5% in 2007 and 2008). As such, there is good evidence favouring a positive time-dependent increase in NOC/*c* approvals over the test period using both statistical methods. There is some evidence from the exponential fits supporting acceleration of this trend ($R^2 = 0.7$ Fig. 9A; 0.6 Fig. 9B), but the trends are not as strong as that reported for Fig. 8C ($R^2 = 0.92$) and differ from the results of the ordinary least squares analysis.

The data in Figs. 9A and 9B contrast significantly with the Priority Review data set, where both the absolute number (Fig. 9C) and fraction of total (Fig. 9D) NOCs that were issued under the Priority Review stream decreased over the period 2001-2008 (13, 9, 5, 5, 8, 7, 9, and 5 per year). In comparison, non-Priority Review NOCs increased slightly over the test period, expressed either in absolute terms

(Fig. 9E) or as a fraction of total NOCs issued (Fig. 9F). Indeed, comparison of data in Figs. 9A–9D demonstrate that while the number and percentage of Priority Review NOCs exceeded those for NOC/*c* approvals in 2001 by two-fold, both trends were completely reversed by 2008. Given the relative lack of change in the fraction of total NOCs that were subject to Priority Review (Fig. 9F), the data in Fig. 9 demonstrate that brand name firms have been highly successful in facilitating early access via the NOC/*c* limb of the expedited stream.

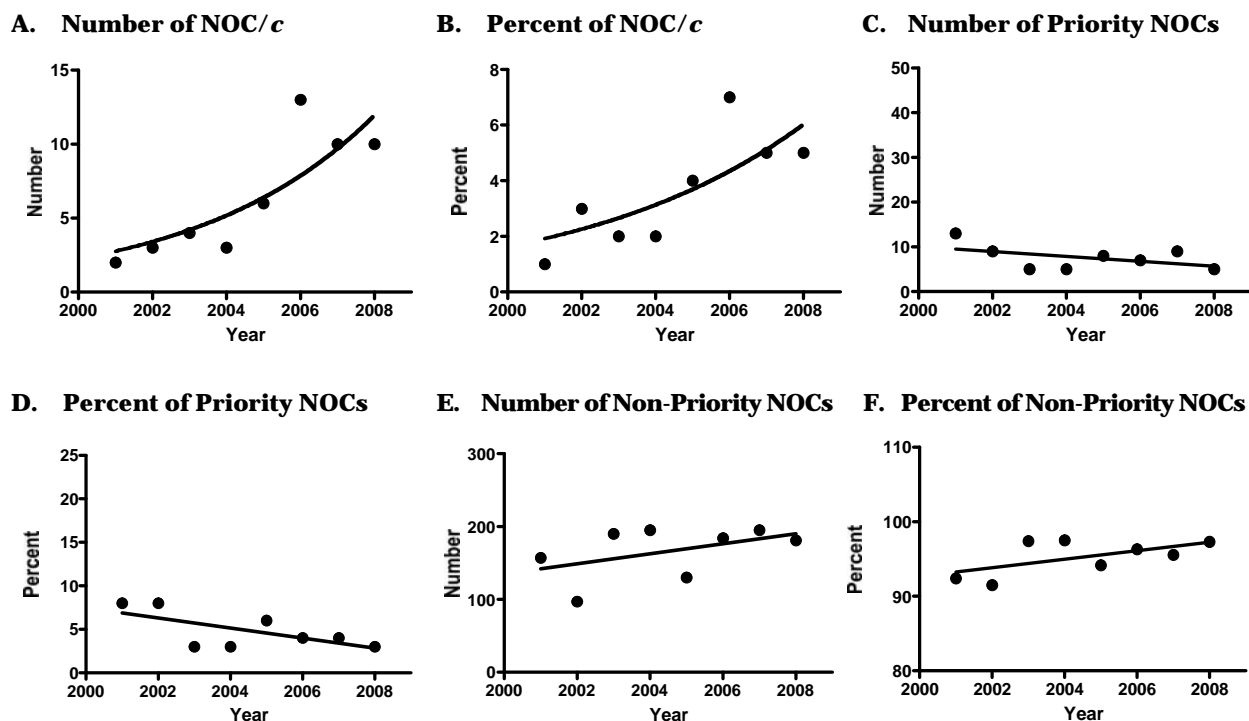


Fig. 9 Number and percent (percent of all NDS and SNDS NOCs) of NOC/*c* (**A and B**), Priority NOCs (**C and D**), and Non-priority NOCs (**E and F**).

Data relating to whether or not the “conditions” associated with NOC/*c* approval were actually met during the test period are given in Fig. 10 and Table 3. Figure 10A depicts the number of NOC/*c* approvals issued per year that *eventually* had their conditions met: the filled portion of each bar represents the number of NOC/*c* approvals issued in a given year that had their conditions met, while the unfilled portion represents the number of NOC/*c* approvals granted in a given year that have not yet had their conditions met to date (i.e. filled and unfilled portions represent the fraction of total NOC/*c* with conditions met and unmet, respectively). For example, in 2001 two NOC/*c* approvals were granted: one had its conditions met in 2004 and one has not yet had its conditions met. Therefore the bar is half filled. In 2002, three NOC/*c* approvals were granted, and all three have not yet had their conditions met. The data in Fig. 10A suggest a significant positive trend toward NOC/*c* approvals not having their conditions met during the test period, at least in the short period of time since issuance.

TABLE 3. DATE OF NOC/C GRANT AND DATE CONDITIONS ASSOCIATED WITH NOC/C WERE MET DURING THE PERIOD 2001-2008

Year	NOC/c (Date of Grant)	Conditions Met NO	Conditions Met YES
2001	2001-03-01	--	2004-07-5 (n=1)
	2001-09-20	NOT met to date (n=1)	--
2002	2002-05-28; 2002-08-07; 2002-11-25	NOT met to date (n=3)	--
2003	2003-03-18	--	2005-07-20 (n=1)
	2003-07-07; 2003-10-08; 2003-12-17	NOT met to date (n=3)	--
2004	2004-06-30	--	2008-12-02 (n=1)
	2004-06-02; 2004-12-08	NOT met to date (n=2)	--
2005	2005-01-27; 2005-11-01; 2005-12-07	--	2007-09-11; 2008-12-02; 2008-10-23 (n=3)
	2005-04-01; 2005-04-15; 2005-12-29	NOT met to date (n=3)	--
2006	2006-04-24; 2006-05-12	--	2007-09-11; 2008-06-06 (n=2)
	2006-05-03; 2006-06-16; 2006-06-26; 2006-07-18; 2006-07-28; 2006-07-28; 2006-08-17; 2006-10-06; 2006-10-18; 2006-11-07; 2006-12-14	NOT met to date (n= 11)	--
2007	2007-03-01; 2007-03-26; 2007-05-24; 2007-08-01; 2007-09-12; 2007-09-22; 2007-11-09; 2007-11-27; 2007-11-30; 2007-12-20	NOT met to date (n=10)	--
2008	2008-01-17; 2008-03-03; 2008-05-02; 2008-06-18; 2008-07-23; 2008-09-09; 2008-09-30; 2008-10-15; 2008-12-09; 2008-12-19	NOT met to date (n=10)	--
TOTAL	N= 51	N= 43	N= 8
PERCENT	100%	84.3%	15.7%

Figure 10B shows the same data expressed as the year in which conditions for NOC/c approvals were met *independent of the year* NOCs were granted. Whereas Fig. 10A is focused on the year NOC/c approvals were issued, Fig. 10B is focused on the year conditions were met. Note that the Y axis is set slightly (-0.25) below zero. This was done in order to ensure years where no conditions were met were still represented by an observable bar. For example, in 2001, 2002, 2003, and 2006 no NOC/c licences that were issued within the test period had their conditions met. This can be contrasted with data from 2004, 2005, 2007, and 2008, where 1, 1, 2, and 4, NOC/c approvals ultimately had their conditions met. Unlike data in Fig. 10A, which appear to indicate a trend toward increasing non-compliance, the data in Fig. 10B demonstrate a smaller yet parallel trend toward an increased likelihood that conditions attached to an NOC/c were met over the test period.

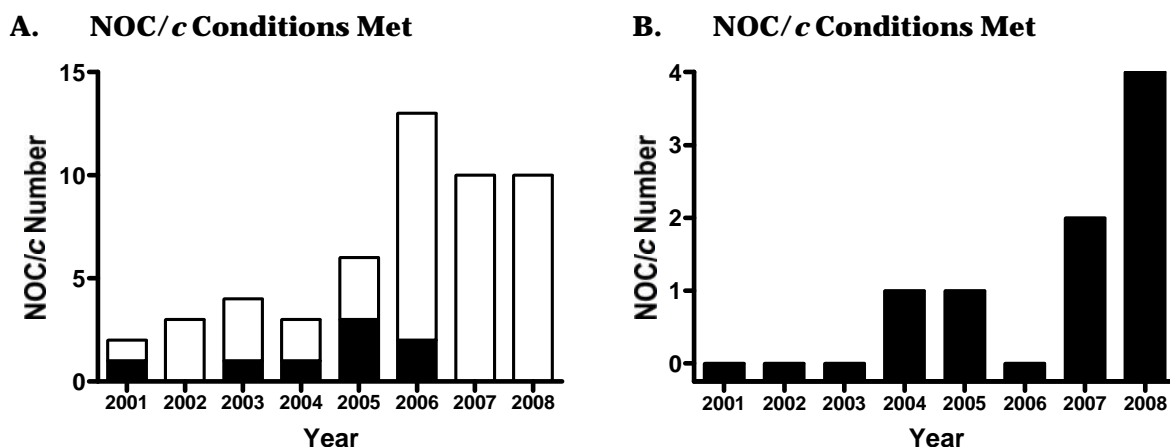


Fig. 10 Number of NOC/c granted by GOC during the 2001-2008 test period that had their conditions met. **(A)** Filled bar portions represent the number of NOC/c issued in that calendar year that eventually had their conditions met. Unfilled bars represent NOC/c issued in that year which have not yet had their conditions met to date. **(B)** Year in which conditions attached to NOC/c were met independent of the year NOCs were granted.

Finally, we analyzed the number of NOCs approved during the period 2001-2008 that were withdrawn for safety reasons.⁴⁵ The data in Table 4 illustrates that a very small percentage of NOCs issued during the test period have been withdrawn in Canada to date.

These data can be parsed in two ways: first, as withdrawn NOCs ($n=10$) expressed as a fraction of total NOCs ($n=2,122$) granted over the test period; and second, as withdrawn products ($n=4$) expressed as a fraction of total products ($n=608$) associated with the larger number of NOCs. For the first procedure, 2,122 NOCs were issued over the test period, 10 of which were withdrawn within the same time frame. This amounts to 0.47% issued NOCs that were withdrawn. However, this value is somewhat misleading because consumers do not purchase NOCs. Rather they purchase and consume, and drug agencies typically regulate, drug products. Of 608 products receiving NOCs during the course of the test period, only four were withdrawn (Gatifloxacin, June 29, 2006; Lumiricoxib, October 3, 2007; Tegaserod, March 30, 2007; Valdecoxib April 7, 2005). This amounts to a small percentage (0.66%) of marketed products issued in the test period that were subsequently withdrawn for safety reasons within the same time frame.

Withdrawals in Canada were slightly higher than withdrawals for the same drug pool in at least two comparator jurisdictions (0.2%, U.S.; 0%, France). However, of the total number of products or NOCs withdrawn in Canada for safety reasons during the test period ($n=4$), none were withdrawn in the two expedited streams (NOC/c, Priority Review). Data were drawn from published studies in Canada,⁴⁶ the U.S.,⁴⁷ and France.⁴⁸

⁴⁵ A drug withdrawal or recall has the effect of removing a health product, such as a prescription or non-prescription pharmaceutical, from the marketplace. On its website, Health Canada addresses the issue of safety and drug withdrawals and states that "Health Canada posts safety alerts, public health advisories, warnings, recalls, press releases, and other notices from industry on marketed health products, including Natural Health Products and medical devices". Health Canada, "Drugs and Health Products—Advisories, Warnings and Recalls", online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php>> (The website elaborates by saying "this service to health professionals, consumers, and other interested parties informs and educates Canadians about new health risks associated with the use of certain marketed health products. Recalls are initiated by importers and manufacturers after recognizing that there may be a safety concern related to a specific health product. Health Canada works with the health product industry to ensure hazardous products are removed from the marketplace in an effective and efficient manner").

⁴⁶ Joel Lexchin, "Drug Withdrawals from the Canadian Market for Safety Reasons, 1963-2004" (2005) 172 *Canadian Medical Association Journal* 765 [Lexchin, "Withdrawals"]. Updated via Personal Communication with Joel Lexchin, September 23, 2008 and March 4, 2009; Health Canada, "Drugs and Health Products—Past Advisories, Warnings and Recalls", online: Health Canada <<http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/index-eng.php>>.

TABLE 4. DRUG WITHDRAWALS FOR EXPEDITED AND STANDARD REVIEW STREAMS FOR NOCS APPROVED 2001-2008 IN CANADA AND COMPARATOR JURISDICTIONS.

SUBMISSION CLASS	NOC ISSUED	WITHDRAWALS (Country)		
	CANADA	CANADA	U.S.	FRANCE
	2001-2008	2001-2008 ⁴⁶	2001-2007 ⁴⁷	2001-2008 ⁴⁸
A. Expedited				
NOC/c	51	0	0	0
Priority Review	61	0	0	0
B. Standard				
NDS	338	4	1	0
SNDS	1,052	0	0	0
ANDS	584	0	0	0
SANDS	148	0	0	0
TOTAL	2,122	4	1	0

II DISCUSSION

Data from the qualitative and quantitative analyses undertaken here suggest that concerns expressed over PLF pushing Canada in a new direction concerning the workings and output of its drug regulatory regime may be somewhat overstated. The data demonstrate that the approval mechanism enshrined in the existing *Food and Drugs Act* and *Food and Drug Regulations* already anticipates the lifecycle approach, at least as it is described in the *Blueprint*,⁴⁹ PLF Concept Paper,⁵⁰ and Bill C-51.⁵¹ Analysis of eight years of GOC approval statistics shows that new drug submissions have been on the decline for at least this long, while supplementary submissions from both brand name and generic firms during this time have conversely increased. Moreover, Priority Reviews, which have the same or similar evidentiary requirements as standard review submissions, declined slightly over the period analyzed. By contrast, NOC/c submissions, which have reduced front-end evidentiary requirements compared to standard submissions, increased substantially. Thus, despite little or no change in the unmet medical needs of the Canadian population, a relatively small but significant percentage of drugs have entered our national market increasingly earlier in their product development lifecycle. The data further imply that the Canadian pharmaceutical industry as a whole may be “doing more with less”. This conclusion applies to both the rate and direction of innovative activity undertaken by brand name and generic firms. New or standard drug submissions are flat while supplementary and generic submissions have increased substantially. Even approvals for Me Too drugs remained relatively constant or slightly elevated when compared to Line Extensions and new uses. The data reveal a trend away

⁴⁷ Amalia M. Issa *et al.*, “Drug Withdrawals in the United States: A Systematic Review of the Evidence and Analysis of Trends” (2007) 2 *Current Drug Safety* 177. Updated March 4, 2009 using information from U.S., Food and Drug Administration, “Index to Drug-Specific Information”, online: FDA <<http://www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm>>.

⁴⁸ Pascale Olivier & Jean-Louis Montastruc, “The Nature of Scientific Evidence Leading to Drug Withdrawals for Pharmacovigilance Reasons in France” (2006) 15 *Pharmacoepidemiology and Drug Safety* 808 (Updated via Personal Communication with Pascale Olivier, September 28, 2008 and March 4, 2009).

⁴⁹ Health Canada, “Blueprint for Renewal: Transforming Canada’s Approach to Regulating Health Products and Food” (October 2006), online: Health Canada <http://www.hc-sc.gc.ca/ahc-asc/alt_formats/hpfb-dgpsa/pdf/hpfb-dgpsa/blueprint-plan-eng.pdf> [Health Canada, “Blueprint”].

⁵⁰ Health Canada, “The Progressive Licensing Framework Concept Paper for Discussion”, online: Health Canada <http://hc-sc.gc.ca/dhp-mps/homologation-licensing/develop/progluc_homprog_concept-eng.php> [Health Canada, “Concept Paper”].

⁵¹ *Bill C-51*, *supra* note 5.

from development of novel “breakthrough” pharmaceuticals over the course of the test period. Results of this nature may provide an example of policy resistance,⁵² whereby government policy inhibits or prevents the very thing it seeks to facilitate through the unintended consequences of its action(s).⁵³

A. Interpretation of Data

Our analysis of NOCs issued in Canada in the period 2001–2008 yields a number of major observations relevant to PLF. First, the data demonstrate that the current drug regulatory regime already anticipates the lifecycle approach. Second, it provides insight into the types of drug submissions that are likely candidates to receive expedited drug approval under the terms of flexible departure. Third, the data speak to the issue of innovation patterns in the area of pharmaceutical development. Together, the data have important implications for the manner in which PLF is likely to be rolled out, the types of drugs that the public are likely to see on the market in the near future, and those drugs with which they are likely to be provided in the long term, absent significant changes in IPR rights associated with drug approval and marketing.

Data generated in this study show that the existing regulatory system in Canada is already moving in a direction consistent with what is proposed under the PLF system: that is, toward earlier access to drugs that occupy the “extraordinary need” niche with emphasis on post-market surveillance. This is most clearly exemplified by the NOC/c data set, expressed either as the number of NOC/c or as a fraction of total NOCs (Figs. 9A and 9B). As described in the Results, while the absolute number of NOC/c approvals is relatively small (peaking at 13 in 2006), the number when expressed as a function of total brand name NOCs granted by GOC is not insignificant (7%). Moreover, it is evident that the fractional number of NOC/c approvals is increasing significantly over time (from 1% in 2001 to 7% in 2006) and that this increase is occurring in a strongly time-dependent manner (Figs. 9A and 9B). The trend toward increasing NOC/c approvals is occurring despite a slight downward trend in new drug submissions expressed either in absolute terms (Fig. 4A) or as a function of total brand name submissions (Fig. 4C). Even more dramatically, the escalation in NOC/c approvals has been accompanied by a reverse trend in Priority Review NOCs (compare Figs. 9A and 9C). Since the NOC/c policy issues NOCs faster and under the condition that additional post-market authorization safety and/or efficacy studies are undertaken, there is an overall increase of drugs that are being authorized in a similar manner to that contemplated by Health Canada in the *Blueprint* and PLF Concept Paper policies and in Bill C-51.

The data also suggest that the trend toward flexible departure is being accompanied by a small but significant trend for sponsors to meet conditions associated with NOC/c approval (Fig. 10B). This conclusion is tempered however by the large number of outstanding NOC/c approvals where the conditions have not yet been met (Fig. 10A; Table 4). A second caveat is the fact that there is not a great deal of data in this regard given the gap between issuance and conditions met in later years which does not apply to analysis of approvals per se. The observation that an increasing number of drugs are being made available to the public under the circumstance that they meet certain conditions in order to maintain market authorization demonstrates that Health Canada is already approving drugs with PLF in mind. Positively, none of these drugs have been recalled for safety reasons to date (Table 4).

Of interest, the data show that the number and fraction of total NOCs issued under the Priority Review policy have steadily declined over the test period (Fig. 9C). The number has hovered fairly constantly around 7 or 8 per year (Fig. 9C) compared with increases in the number and fraction of non-

⁵² John D. Sterman, “All Models Are Wrong: Reflections on Becoming a Systems Scientist” (2002) 18 *Systems Dynamics Review* 501 [Sterman, “Reflections”].

⁵³ In *AstraZeneca Canada Inc. v Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 at para. 39, Justice Binnie stated that it is “entirely understandable” that brand name pharmaceutical firms avail themselves of loopholes in the *NOC Regulations* that permit ever-greening of older products by “adding bells and whistles” to them after the original patent has expired. See also Ron A. Bouchard, “Should Scientific Research in the Lead-Up to Invention Vitiolate Obviousness Under the Patented Medicines (Notice of Compliance) Regulations: To Test or Not to Test?” (2007) 6 C.J.L.T. 1 [Bouchard, “Test”]; Ron A. Bouchard, “Living Separate and Apart is Never Easy: Inventive Capacity of the PHOSITA as the Tie That Binds Obviousness and Inventiveness” (2007) 4 *University of Ottawa Law & Technology Journal* 1 [Bouchard, “Living”]; See also Ron A. Bouchard, “Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?” (2007) 13 *B.U.J. of Sci. & Tech. L.* 120 [Bouchard, “Balancing”].

priority NOCs (Figs. 9E and 9F). At first glance, this might seem inconsistent with the notion that GOC is anticipating PLF. For example, given that progressive licensing is partially geared toward enhanced access, it only seems logical that NOCs issued under Priority Review should also be increasing. On more careful examination however, it is evident that a decreasing number of Priority Reviews is anticipatory of PLF. The policy for fast-tracking eligible NDS and SNDS is intended to provide enhanced availability of products for the treatment, prevention, or diagnosis of serious, life-threatening, or severely debilitating diseases or conditions where there is an unmet medical need or for which a substantial improvement in the benefit/risk profile of the therapy is demonstrated.⁵⁴ Unlike the NOC/*c* policy, Priority Review is aimed at getting drugs approved faster *without* a change in the amount of scientific evidence required for approval prior to market entry. According to leadership at Health Canada, this ensures that drug manufacturers jump ahead of others in the approval queue.⁵⁵ Moreover, Priority Review policy, unlike the NOC/*c* policy, does not demand that sponsors conduct post-marketing studies as a means to continue or maintain the NOC. Priority Review is essentially a fast-tracking mechanism without any further evidentiary obligations imposed on industry. This might be seen to accord less with PLF policy than the NOC/*c* mechanism. While both streams promote faster drug approval, only the latter is centered on the lifecycle approach, which demands that in return for faster drug approval, a drug's safety and efficacy must be subject to legal scrutiny beyond initial market authorization. Thus, it is reasonable to speculate that in anticipation of the PLF regime, Health Canada might shift somewhat away from the Priority Review stream as the primary means of enhancing access toward the NOC/*c* stream.

Anticipation of PLF and consequently faster drug approval is also evident by other trends in the data set. For instance, the percentage of NDS NOCs decreased over the test period (Fig. 4B) whereas the number (Fig. 5A) and fraction (Fig. 5B) of supplemental submissions increased. SNDSs are also known as "Line Extensions" of previously existing products, usually involving changes to a pre-existing drug such as a change in the route of administration (e.g., oral to intravenous), dosage form (e.g., tablet to capsule), salt form (e.g., besylate to mesylate), or indication (e.g., antidepressant to anxiolytic). For the most part, getting a Line Extension or SNDS onto the market is a faster process compared with drugs approved via the new drug submission stream. This is true even where approval times for SNDS and NDS are roughly equal, as production and marketing of Line Extension products takes less time than producing and marketing truly new drugs, owing to manufacturing experience and related competencies. Thus, an increasing number of yearly SNDS NOCs is indicative of a general focus on faster access, if not faster approval. This conclusion is supported by the observation that the number of New Active Substances (NAS) is decreasing over time (expressed either in absolute terms (Fig. 6A) or as a fraction of total brand name NOCs (Fig. 6B) issued), particularly given the broad NAS definition employed by GOC.

The present data also have important implications for the rate and direction of innovation by domestic pharmaceutical firms. For example, approvals relating to both types of NDSs (Fig. 4) declined over the test period. By comparison, the number of supplemental submissions increased when expressed either in absolute terms (Fig. 5A) or as a fraction of total brand name submissions (Fig. 5C). Together, the data indicate that pharmaceutical companies are increasingly doing more with less, implying that firms are expending fewer and fewer resources on developing breakthrough drugs and more on extending the utility of already existing products. This trend is also demonstrated by the decreasing number of NAS NOCs with time (Fig. 6), because drugs in this group include those that differ minimally from pre-existing drugs such as salts, enantiomers, and other derivatives of already marketed compounds. Furthermore, the number of SNDS deemed to be First in Class by virtue of new indications escalated in a strongly time-dependent, and potentially non-linear ($R^2 = 0.92$, Fig. 8C) manner. Brand name pharmaceutical firms are therefore strongly concentrating their efforts on getting as much value as possible from their existing drug development activities rather than focusing on development of first-in-kind products. The data are in line with results from Health Canada indicating that there has been a 225% increase in the number of clinical trial applications since 2001, compared with only a 19%

⁵⁴ Health Canada, "Priority Review Guidance Document", *supra* note 23.

⁵⁵ Health Canada Personal Communication, *supra* note 31.

increase in firm R&D spending over a similar time period.⁵⁶ A parallel conclusion arises from the analysis of generic NOC data. For example, we found that the number of ANDS and SANDS yielding NOCs during the test period increased substantially. This was true independent of whether the data were expressed in absolute terms (Figs. 7A and 7C) or as a percentage of total NOCs (Figs. 7B and 7D). The increase in the number of ANDS (75%, Fig. 7A) and SANDS (100%, Fig. 7C) NOCs was greater than the corresponding increase in NDS (no change, Fig. 4A) and SNDS (15%, Fig. 5A) NOCs. Absolute values for ANDS and SANDS are expected to reflect the increasing release of generic drugs into the market as the number of drugs that come off patent protection under the *NOC Regulations* increases. This trend is reflected in the data expressed as a fraction of total NOCs (Figs. 7B and 7D) as well.

One of the most intriguing findings of the study is that the number of new Me Too (Fig. 8B) and First in Class (Fig. 8A) NDS NOCs decreased slightly over the test period. By contrast, the number of follow-on Me Too SNDS (Fig. 8D) and First in Class SNDS (Fig. 8C) NOCs increased significantly. Me Too SNDS NOCs in particular doubled over the test period. Moreover, First in Class SNDS NOCs increased in a strongly time-dependent manner, from 1 to 22. The slope of this increase well exceeds even that for generic supplemental submissions (Fig. 7C). These data provide support for the conclusion that the Canadian domestic pharmaceutical industry is “doing more with less.” Brand name firms in particular appear to be expanding the market exclusivity duration of existing products, though firms obviously need to get on the market with at least one new compound in a given chemical class prior to expansion via SNDS. Together with data showing a decline in all types of new or standard submissions by brand name firms (Figs. 4C, 6A, 8A, and 8B) and an increase in other types of supplementary submissions assessed (Figs. 5C, 8C, and 8D), the results suggest that (a) the Canadian pharmaceutical industry, as a whole, is expending fewer of its resources on developing novel “first-of-kind” technologies and more on leveraging existing technologies and (b) that technology appropriation is alive and well in Canada.⁵⁷

B. Study Limitations

1. Empirical Considerations

The study is limited by the restrictions typical of empirical studies. First, data analyzed were only those for the test period. The year 2001 was chosen as our starting point, as this was the date when substantial amendments to Canadian drug regulation were made that affected both the mechanisms and speed of approval.⁵⁸ Second, there is significant scatter of the data from one year to the next which impeded a more strongly powered analysis. For example, we not only obtained yearly means as reported in Figs. 1-10, but also calculated quarterly bins for each year in order to improve the statistical power in linear and non-linear analyses. However, we could not use this data owing to a small trend towards quarterly differences in the data set e.g., there was a trend towards more approvals granted in the third and fourth quarters of each year. However, this trend did not reach statistical significance, necessitating the use of yearly averages. As a consequence, both sample sizes and statistical power were reduced. Finally, while we obtained and analyzed approval data independently rather than using GOC Annual Reports, we were nevertheless limited to the results reported by Health Canada.⁵⁹ Equally important, our analysis was dependent on Health Canada’s method of determining the definition of an

⁵⁶ Health Canada: Health Products and Food Branch, “Clinical Trials Regulatory Review—Stakeholder Workshop” (March 26, 2007), online: Health Canada <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/ctrf_o_eccr_a_2007-03-26-eng.pdf> [Health Canada, “Stakeholder Workshop”].

⁵⁷ As used here, the term “appropriation” refers to a party’s ability to capture profits generated from their own inventions or related inventions.

⁵⁸ Health Canada, “Stakeholder Workshop”, *supra* note 56 (according to Health Canada at 6, the objectives of the 2001 regulations were to “Shorten application review times without endangering health and safety; Improve safety mechanisms for research subjects; Regulator to be more involved in clinical trial monitoring and follow-up; Remove obstacles to additional R&D; Improve access to innovative therapies and advice from Canadian physicians with research experience”).

⁵⁹ For an example of differences in the empirical analysis of a “partially” reported database vs. governmental analysis of a “full” data set, see Daniel Carpenter, Evan James Zucker & Jerry Avorn, “Drug-Review Deadlines and Safety Problems” (2008) 358 *New Eng. J. Med.* 1354 at 1360, the subsequent Letter to the Editor from FDA Officials and Correction by the authors: Clark Nardinelli, Michael Lanthier & Robert Temple, “Letter to the Editor” (2008) 359 *New Eng. J. Med.* 95; Daniel Carpenter, “Reply to Letter to the Editor” (2008) 359 *New Eng. J. Med.* 96 [Carpenter, “Reply”].

NAS, which in turn substantially influenced the methods used to calculate the number of First in Class and Me Too drugs. This is discussed in more detail below.

2. *Me Too and First in Class Criteria*

We acknowledge that the Compound-Indication method summarized in Table 2 yields a fraction of Me Too and First in Class drugs that may differ from methods used by other agencies. For example, the WHO Collaborating Center for Drugs Statistics Methodology⁶⁰ produces a different result as to what NOCs would have been classified as First in Class or Me Too, yielding more Me Too than First in Class NOCs. The reason for this discrepancy is that under the WHO methodology, compounds that are in the same chemical family as the original First in Class drug are all deemed to be Me Too drugs irrespective of whether they are directed to new indications. Table 5 illustrates this concept.

TABLE 5. WHO COMPOUND-INDICATION CLASSIFICATION

YEAR	COMPOUND/INDICATION	CLASSIFICATION
2000	Compound X (first 'X' Compound) with Indication A	First in Class
2001	Compound X with Indication B	Me Too
2001	Compound α X (Compound in the family of X) with Indication A	Me Too
2001	Compound α X with Indication B	Me Too
2001	Compound x X with Indication C	Me Too

However, the methods used to obtain the data in Table 5 differ from those used by Health Canada to classify NOCs, particularly in the SNDS category. The Health Canada methodology focuses not on chemical class but rather on indications. Nevertheless, assuming for the moment that the WHO classification is the right one for the purposes of this discussion, using it to analyze our data would have the effect of converting a certain number of supplemental First in Class SNDS NOCs to new Me Too NDS NOCs. While this might appear on the surface to shift emphasis from “supplemental” to “new” submission approvals, both Me Too NDS and First in Class SNDS NOCs are directed to products that are extensions of existing technologies, largely via new use indications, as opposed to first-of-kind technologies. Therefore, using the WHO framework would not alter our major observations and conclusions, including (1) that the pharmaceutical industry as a whole is doing more with less and (2) that an increasing number of drugs are being approved with significant post-marketing obligations over the test period, while NOCs in other expedited streams (e.g., Priority Review) have remained relatively constant or decreased slightly over the same time frame.

3. *Innovative Value of Me Too and Line Extensions*

We did not undertake a study of, nor are we offering a model for, innovation in the domestic Canadian pharmaceutical marketplace. Therefore, we provide definitions for neither “innovation” nor what constitutes an “innovative” therapeutic product. Rather, the point of the present study was to independently analyze several years of drug *approval* data, and to analyze the data from the perspective of the policies underpinning the emerging PLF regime. These include policies pertaining to safety and efficacy, expedited review (NOC/*c* and Priority Review), IPR rights, user fees, precautionary principle, etc.⁶¹ Our concern, within the four corners of the present study, was whether NOCs were directed to (a) “new” active substances, “new” drug submissions, “first” in class drugs, “priority” review drugs, and drugs approved via the NOC/*c* stream versus, (b) “me too” drugs, “line extension” drugs, “abbreviated” generic submissions, and other “supplemental” submissions. We are mindful of the controversial nature of the debate surrounding the economic and therapeutic value of Me Too

⁶⁰ WHO Website, *supra* note 41.

⁶¹ Bouchard & Sawicka, *supra* note 2.

and Line Extension drug products in Canada,⁶² France,⁶³ the U.S.,⁶⁴ the E.U.,⁶⁵ and the U.K.,⁶⁶ as well as recent reports on the need to facilitate innovation⁶⁷ and generic competition⁶⁸ in the context of shifting drug approval and associated IPR rights regimes. We are also mindful of the tendency of certain technological and regulatory systems to experience “lock-in”⁶⁹ as a result of increasing returns,⁷⁰ and that the data described in this study may be a potential example of one or both of these processes. The relevance of our data to the issue of innovation in the pharmaceutical sector is the subject of a follow-up study currently underway on the empirical relationship between patterns of drug approval, patenting, and litigation. Finally, given that Canada and the U.S. are the only two jurisdictions with formal linkage regulations tying drug approval and drug patenting,⁷¹ we have narrowed the interpretation of our empirical data and the associated literature review⁷² to the North American context, as it is likely to be governed by emerging lifecycle regulation models.

C. Assessing the Lifecycle Approach: The Long View

In the companion article,⁷³ a number of concerns are reviewed that, when combined, have provided the impetus for substantial law reform in the area of drug regulation. These include considerations relating to the speed and mechanism of approval, the relation of the former to fee-for-service user fees, the relation of the latter to a shift from the precautionary principle to risk management principles, and an increase in the public-private partnership characteristic of the approval process, including govern-

⁶² Joel Lexchin, “Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go from Here?” (2005) 35 *International Journal of Health Services* 237 at 243 [Lexchin, “IP Rights”]. See also Patented Medicine Prices Review Board Government of Canada, *Annual Report 2000*, online: Patented Medicine Prices Review Board <<http://www.pmprb-cepmb.gc.ca/english/View.asp?x=113&mp=91>> [*Patented Medicine Prices Review Board Annual Report*].

⁶³ “Drugs in 2001: A Number of Ruses Unveiled” (2002) 11 *Prescrire International* 58 [“Drugs in 2001”].

⁶⁴ James Love, “Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines” (Washington, Geneva & London: Consumer Project on Technology 2003), online: Consumer Project on Technology <<http://www.cptech.org/ip/health/rnd/evidenceregardingrnd.pdf>>; Song Hee Hong *et al.*, “Product-Line Extensions and Pricing Strategies of Brand Name Drugs Facing Patent Expiration” (2005) 11 *Journal of Managed Care and Pharmacy* 746. See also Joseph A. DiMasi and Cherie Paquette, “The Economics of Follow-on Drug Research and Development” (2004) 22: *Suppl. 2 Pharmacoeconomics* 1.

⁶⁵ Juan-José Ganuza, Gerard Llobet & Beatriz Dominguez, “R&D in the Pharmaceutical Industry: A World of Small Innovations” (2009) 55 *Management Science* 539.

⁶⁶ John Abraham & Courtney Davis, “A Comparative Analysis of Drug Safety Withdrawals in the UK and the US (1971-1992): Implications for Current Regulatory Thinking and Policy” (2005) 61 *Social Science & Medicine* 881; see also John Abraham & Courtney Davis, “Deficits, Expectations, and Paradigms in British and American Drug Safety Assessments: Prising open the Black Box of Regulatory Science” (2007) 32 *Science, Technology & Human Values* 399; John Abraham, “Sociology of Pharmaceuticals Development and Regulation: A Realist Empirical Research Programme” (2008) 30 *Sociology of Health and Illness* 869.

⁶⁷ U.S., Government Accountability Office, *New Drug Development: Science, Business, Regulatory and Intellectual Property Issues Cited as Hampering Drug Development Efforts* (Washington: United States Government Accountability Office, 2006), online: US GAO <<http://www.gao.gov/new.items/do749.pdf>>; EC, DG Competition Staff, *Pharmaceutical Sector Inquiry: Preliminary Report* (28 November 2008); International Expert Group on Biotechnology, Innovation and Intellectual Property, “Toward a New Era of Intellectual Property: From Confrontation to Negotiation: A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property” (Montreal: 2008), online: The Innovation Partnership <http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf>.

⁶⁸ Competition Bureau, *Benefiting from Generic Drug Competition in Canada: The Way Forward* (Ottawa: Public Works and Government Services Canada, 2008). See also Roy J. Romanow Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: Public Works and Government Services Canada, 2002) [*Romanow*].

⁶⁹ Timothy J. Foxton, “Technological Lock-in and the Role of Innovation” in G. Atkinson, S. Dietz & E. Neumayer, eds., *Handbook of Sustainable Development*, (Cheltenham, UK: Edward Elgar, 2006).

⁷⁰ W. Brian Arthur, “Increasing Returns and the Two Worlds of Business” (1996) July-Aug. *Harvard Business Review* 100.

⁷¹ Gunars K. Gaikis, “Pharmaceutical Patents in Canada: An Update on Compulsory Licensing” (1992) 42 *Patent World* 19; Edward Hore, “A Comparison of US and Canadian Laws as They Affect Generic Pharmaceutical Drug Entry” (2000) 55 *Food & Drug L.J.* 373 [Hore]; Andrew A. Caffrey & Jonathan M. Rotter, “Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act” (2004) 9 *Va. J.L. & Tech.* 1 at 4-7. See also Rebecca S. Eisenberg, “Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development” (2003) 72 *Fordham L. Rev.* 477; Bouchard, “Living”, *supra* note 53.

⁷² Bouchard & Sawicka, *supra* note 2.

⁷³ Bouchard & Sawicka, *supra* note 2.

ment vetting of increasing IPR rights associated with pharmaceutical products. The possibility exists that these issues have combined to result in more drug withdrawals, black box warnings, and dosage form discontinuations for safety reasons, and a significant expansion and acceleration of mortality and morbidity associated with high-profile drug withdrawals. The lifecycle approach has been criticized as only worsening many of these problems. This is particularly true of the focus on access at the cost of post-market safety and prolonged market monopolies on Line Extension and Me Too drugs. The results in this paper do little to ameliorate many of these concerns, as the data indicate GOC is already anticipating PLF in its current regulatory efforts and that pharmaceutical firms are increasing their focus on extending the lifecycle of existing products and technologies rather than inventing new breakthrough products.

We have referred to the rTPL innovation ecology here and in earlier work as an example of a dynamic, emergent, complex adaptive system. What makes a system complex as opposed to merely complicated is the strong nature of the interrelationships and interdependencies of the actors and institutions making up a system or network. In the manner of a spider web, tweaking one strand affects all other strands in the web. As noted by Gell-Mann,⁷⁴ complex systems are characterized by broad rules that have increasing applicability and universality as the symmetry and elegance of the rules increase. We believe this applies to innovation ecologies regulated by law,⁷⁵ particularly where large-scale public and private rights must be balanced. In order to assess the legitimacy of PLF as a regulatory tool in service of a highly complex and adaptive pharmaceutical, clinical, economic, and political system, one must therefore look to both sides of the access-safety equation to see what value PLF has for so-called adaptive⁷⁶ or robust⁷⁷ policy-making. Too narrow a focus on access or post-licensing obligations can only lead to a viewpoint that will miss critical information that arises outside of its bandwidth. PLF is expressly intended to replace static, linear, one-sided, front-loaded, and time-locked models of drug development and regulation. Its legitimacy should be assessed that way, hence the need for the “long view”.

On one side of a shifted evidentiary balance, a lower threshold for initial market authorization will almost certainly equate to faster access to new drugs. The obvious danger of this is that potentially dangerous drugs may slip through the regulatory cracks, compromising patient safety.⁷⁸ Scholars, politicians, public interest groups, and media have argued that recasting the decision-making matrix for safety and efficacy in this manner will turn the public into guinea pigs for drugs that have not been adequately tested.⁷⁹ This position has been taken by Wright,⁸⁰ who claims that “regardless of the safeguards that are put in place, reducing the safety evidence required before new drugs are approved will make it very difficult to monitor and catch problems before it’s too late.” Indeed, there is significant evidence to suggest that post-market studies that have been recommended by regulators thus far are not usually conducted by sponsors once approval has been given.⁸¹ If this scenario were to continue, it is not difficult to envision how the lifecycle approach would create an “evidence-free zone” for drug ap-

⁷⁴ See generally Murray Gell-Mann, *The Quark and the Jaguar: Adventures in the Simple and the Complex* (New York: W.H. Freeman and Company, 1994). The practical implications of elegance and symmetry in physics and mathematics are explored elegantly by Gell-Mann in the videocast. “Beauty and Truth in Physics” *TED TV VideoCast* (March 2007), online: TED Blog <http://blog.ted.com/2007/12/murray_gellmann.php>. But see Bruce Edmonds & Scott Moss, “From KISS to KIDS: An ‘Anti-Simplistic’ Modeling Approach” in Davidson et al., eds., *Multi-Agent and Multi-Based Simulation*, vol. 3415 (New York: Springer Berlin/Heidelberg, 2004) 130.

⁷⁵ Bouchard, “Systems” and Bouchard, “Reflections”, *supra* note 15. See also Wulf, *supra* note 15; David H. Guston, “Innovation Policy: Not Just Jumbo Shrimp” (2008) 454 *Nature* 940; Fred Gault & Sasanne Huttner, “A Cat’s Cradle for Policy” (2008) 455 *Nature* 462.

⁷⁶ For a detailed review of adaptive policy in a legal context, see J.B. Ruhl, “Regulation by Adaptive Management: Is It Possible?” (2005) 7 *Minnesota Journal of Law Science & Technology* 21 and references therein. See also Guston, *ibid*.

⁷⁷ For a detailed review of robust policy-making in a political and international relations context, see: Robert Jervis, *System Effects: Complexity in Political and Social Life* (Princeton, NJ: Princeton University Press, 1997); Neil E. Harrison, ed., *Complexity in World Politics: Concepts and Methods of a New Paradigm* (Albany, NY: SUNY Press, 2006).

⁷⁸ *Supra* note 7.

⁷⁹ Weeks, “Critics”, *supra* note 8.

⁸⁰ *Ibid*. See also Carly Weeks, “Experts Sound Alarm on Drug-Approval Plan: Under Sweeping New Changes, Drug Companies Only Have to Prove that Benefit of Product Outweighs the Harm” *The Globe and Mail* (9 April 2008) A7.

⁸¹ *Supra* note 9.

proval.⁸² In the absence of reciprocal balancing by post-market surveillance, criticisms of this nature are well grounded in light of poor decisions by pharmaceutical firms to design, cover-up, or otherwise report clinical trial data selectively.⁸³

Another significant question relating to PLF is the issue of flexible departure, concerns over which go well beyond the issue of faster approval times. These concerns flow from the fact that, under the terms of the proposed PLF regime, evidence of safety and efficacy in the context of flexible departure would be limited to reports of the most commonly-occurring adverse drug reactions,⁸⁴ presumably overlaid by the broader requirement for an “evidence-based” benefit-risk profile “favourable” to the drug.⁸⁵ Particular attention has been directed to the possibility that the standard for flexible departure under Bill C-51 ($\geq 51\%$ evidence of benefit-risk)⁸⁶ will lead to an industry-focused benefit-risk assessment framework.⁸⁷ Indeed, the issue of a shifted evidentiary framework has attracted consistent attention from commentators since GOC held its stakeholder workshops in 2006–2007, crystallizing with the announcement of Bill C-51 on April 8, 2008. Similar concerns have been expressed over provisions for accelerated⁸⁸ and conditional⁸⁹ approval in the U.S. and E.U.⁹⁰ Despite these criticisms, however, it is reasonable to speculate, based on policy documents published by Health Canada, the U.S. Institute of Medicine (IOM), the European Medicines Agency (EMA), and FDA that the precautionary principle will not be replaced at the locus of the decision-making process in emerging lifecycle models. The “semi-quantitative” decision-making matrix elaborated by EMA⁹¹ in particular suggests that both objective and subjective metrics will be used as part of the benefit-risk analysis. This implies that a moderate articulation of the precautionary principle will be subsumed within benefit-risk calculations.⁹²

Having said this, it remains true that an explicit $\geq 51\%$ benefit-risk standard differs significantly from a soft or normative evidentiary standard of 85%, 75%, or even 65%. Indeed, one of the major implications of emphasizing faster access to innovative drugs is that enhanced access necessarily brings with it risks beyond those already present under the constraints of the existing clinical trial platform.⁹³ This is particularly true for drugs subject to early release to the public via flexible departure. Nevertheless, while drug agencies in Canada,⁹⁴ the U.S.,⁹⁵ and the E.U.⁹⁶ have said that the risks of drug development must be shouldered by those that demand new and untested drugs, public opinion polls have clearly demonstrated that post-market safety should *not* be sacrificed for quick access to drugs. For example, in 2002, about the time that several high-profile safety withdrawals were coming to light and

⁸² Edwin A.M. Gale, “Lessons from the Glitazones: A Story of Drug Development” (2001) 357 *Lancet* 1870.

⁸³ *Supra* note 10. See also Trudo Lemmens, “Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene” (2004) 32 *J.L. Med. & Ethics* 641; Trudo Lemmens, “Piercing the Veil of Corporate Secrecy about Clinical Trials” (2004) 34:5 *Hastings Center Report* 14.

⁸⁴ Health Canada, “Concept Paper”, *supra* note 50 at 19. For a more detailed discussion of the proposed evidentiary threshold under PLF, see Bouchard & Sawicka, *supra* note 2 at Section I.F(a) and Section II.

⁸⁵ Weiss Smith, “Reply to Galson”, *supra* note 11 at 2521.

⁸⁶ *Bill C-51*, *supra* note 5 at cl. 8 ss. 18–19.

⁸⁷ Hébert, *supra* note 7; Wayne Kondro, “Health Canada Proposes New Regulatory Regime for Drugs” (2007) 176 *Canadian Medical Association Journal* 1261.

⁸⁸ FDA, “Fast Track”, *supra* note 12.

⁸⁹ EMA CHMP Guideline, *supra* note 13.

⁹⁰ For review, see Eichler, *supra* note 7 at 823.

⁹¹ European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), *Report of the CHMP Working Group on Benefit-Risk Assessment Models and Methods* (London: European Medicines Agency, 2007), online: EMA <<http://www.emea.europa.eu/pdfs/human/brmethods/1540407en.pdf>> [EMA CHMP 1]; European Medicines Agency: Committee for Medicinal Products for Human Use (CHMP), *Reflection Paper on Benefit-Risk Assessment Methods in the Context of the Evaluation of Marketing Authorization Applications of Medicinal Products for Human Use* (London: European Medicines Agency, 2008), online: EMA <<http://www.emea.europa.eu/pdfs/human/brmethods/1540407enfin.pdf>> [EMA CHMP 2].

⁹² For a discussion of the potential role of the precautionary principle in the PLF regime, see Bouchard & Sawicka, *supra* note 2 at Section I.C.

⁹³ Eichler, *supra* note 7.

⁹⁴ Peterson, “Innovation”, *supra* note 6; Health Canada, “Blueprint”, *supra* note 49.

⁹⁵ IOM Report, *supra* note 9.

⁹⁶ EMA CHMP 1 and EMA CHMP 2, *supra* note 91; European Medicines Agency: Evaluation of Medicines for Human Use, “Innovative Drug Development Approaches: Final Report from the EMA/CHMP-Think-Tank Group on Innovative Drug Development” (London: European Medicines Agency, 2007).

well before GOC's major policy articulations supporting PLF,⁹⁷ an exemplary study showed that two-thirds of the respondents indicated a preference to wait for "thorough safety testing" of new drugs, with two-fifths of the public stating that getting drugs approved "as fast as possible" is the "least important principle of the drug approval process ..."⁹⁸ Regulators moving to embrace emerging lifecycle models would thus do well to heed the growing body of empirical studies on complex public health systems. Results from these investigations imply that in the absence of recognition of the dynamic nature of positive and negative feedback loops within the regulatory process, drug regulation has the potential to tilt precariously: first into subtle forms of policy resistance,⁹⁹ then into more obvious forms of policy failure,¹⁰⁰ and, potentially, into system collapse.¹⁰¹ Given the persistence of serious, high-profile post-marketing safety controversies in the last decade, it could be speculated that the latter of these mechanisms presents the strongest stimulus for regulatory reform.

While the existing drug approval regime has raised many concerns over real or perceived conflicts of interest, it cannot be overlooked that GOC's PLF lifecycle initiative, as well as parallel initiatives by FDA and EMEA, is specifically intended to rectify some of these ills. Public perception of the intent behind these initiatives has not been helped by the previous "black box" nature of drug approval,¹⁰² which is one of the dragons these agencies claim they want to slay.¹⁰³ As already noted, in various discussion and policy guidance documents, GOC, FDA, and EMEA all appear to be explicitly grappling with the inherent uncertainties, risks, and complexities of drug development. It is an obvious truism that this is not an easy path to walk and, as recognized by the major drug agencies in the U.S.¹⁰⁴ and Canada,¹⁰⁵ it will take active cooperation from the full range of public and private actors responsible for drug development, regulation, and consumption to make it work. As such, it is becoming increasingly accepted that the complexity, uncertainty, and risks of an rTPL innovation ecology in the medical sciences go hand in hand. They must be understood that way if we are to take the lessons learned from centuries of "linear" mental models and apply them to our growing understanding of complex "systems" models¹⁰⁶ like PLF which attempt to account for risk and uncertainty. There will be those who resist this evolution, but their numbers will eventually whittle away as empirical data challenge the simplistic assumptions underpinning the majority of linear models.¹⁰⁷

In addition to offering a more realistic understanding of the risks and uncertainties involved in an rTPL ecology, there are other factors that render the lifecycle approach more advantageous than the existing regime. First, data on the correlation between user fee implementation and safety withdrawals

⁹⁷ Peterson, "Innovation", *supra* note 6; Health Canada, "Blueprint", *supra* note 49.

⁹⁸ Commission on the Future of Health Care in Canada, *Public Input on the Future of Health Care: Results from the Issue/Survey Papers* (Ottawa: Pollara, 2002), online: Pollara <http://www.pollara.ca/Library/Reports/3461_pollara_english.pdf> (prepared by Pollara for the Commission). See also *Romanow*, *supra* note 68.

⁹⁹ Bouchard, "Balancing", *supra* note 53; Lemmens & Bouchard, *supra* note 25. See also Sterman, "Reflections", *supra* note 52.

¹⁰⁰ See generally Barry Bozeman, "Public Value Failure: When Efficient Markets May Not Do" (2002) 62 *Public Administration Review* 145; Barry Bozeman & Daniel Sarewitz, "Public Values and Public Failure in US Science Policy" (2005) 32 *Science and Public Policy* 119.

¹⁰¹ See generally Robert M. May, Simon A. Levin & George Sugihara, "Ecology for Bankers" (2008) 451 *Nature* 893. See also Per Bak & Maya Paczuski, "Complexity, Contingency, and Criticality" (1995) 92 *Proceedings of the National Academy of Sciences* 6689.

¹⁰² Ann Silversides, "Transparency and the Drug Approval Process at Health Canada" (2005), online: *Woman and Health Protection* <<http://www.whp-apsf.ca/pdf/transparency.pdf>> (citing (at 3) Abby Hoffman, head of Health Canada's Therapeutics Access Strategy, who made this comment in an address to the June 10, 2004 Health Canada public consultation).

¹⁰³ Health Canada, "Blueprint", *supra* note 49; Health Canada, "Concept Paper", *supra* note 50; *Bill C-51*, *supra* note 5; Neil Yeates, David K. Lee & Maurica Maher, "Health Canada's Progressive Licensing Framework" (2007) 176 *Canadian Medical Association Journal* 1846.

¹⁰⁴ *IOM Report*, *supra* note 9.

¹⁰⁵ Peterson, "Innovation", *supra* note 6.

¹⁰⁶ John H. Miller & Scott E. Page, *Complex Adaptive Systems: An Introduction to Computational Models of Social Life* (Princeton, NJ: Princeton University Press, 2007).

¹⁰⁷ Sterman, "Reflections", *supra* note 52; Benoit Godin, "The Linear Model of Innovation: The Historical Construction of an Analytical Framework" (2006) 31 *Science, Technology & Human Values* 639 (it should be said however that Godin himself (at p. 35) referred to systems models of innovation as a "plate of spaghetti and meatballs").

are equivocal, even though data relating to the speed of review are not.¹⁰⁸ While some studies show a positive correlation, several detailed and statistically powered studies demonstrate a convincing lack of change in the pattern of withdrawals before and after user fees were implemented. Despite these differences, there appears to be significant acceleration in the incidence of serious adverse effects associated with withdrawals when they do happen, potentially due to the speed and breadth of market penetration and physician prescribing practices. Therefore, it would be desirable to have more studies on this issue in order to design a truly effective and efficacious lifecycle-based regulatory scheme. Moreover, as suggested by Carpenter *et al.*¹⁰⁹ and Olson,¹¹⁰ even where it has been empirically demonstrated, an increase in post-user fee withdrawal rates may be due to the effects of reviewers working toward mandated deadlines rather than shorter review times per se. As noted by the authors, this situation could be rectified, at least in part, by devoting more resources toward staffing, including funds appropriated from parent public health agencies rather than via industry user fees.¹¹¹ Others have suggested curtailing direct-to-consumer advertising as a reasonable means to reduce accelerated market penetration and thus acceleration of the rate of adverse effects incidence.¹¹² As increasingly recognized by stakeholders in public debates and government-sponsored stakeholder workshops, it will be critical to educate the public as to the realities of information asymmetry and the principles of informed consent when requests are made for experimental therapies.

There is also the role of the physician-patient nexus to consider. Indeed, complexity theory posits that each actor is just as important as the next in producing positive, negative, and unintended outcomes in a complex system.¹¹³ Even after the severity of recent drug withdrawal and conflict of interest controversies, society continues to be recalcitrant to lay blame on physicians, perhaps due to their “healing” function and fear of its withdrawal. Along these lines, individual members of the public can no longer claim to be passive receptacles of drugs they assume are safe and efficacious. Each actor in the rTPL ecology must accept accountability for their role in the failure of the linear model of drug innovation. The necessity of distributing accountability to include not just obvious targets such as firms and government, but also physicians and the public, was recognized by the IOM in its influential report on drug regulation.¹¹⁴ Narrowing clinical trial populations to hit desired safety or efficacy signals for market authorization differs from the scope of drug-prescribing practices by physicians. Both types of practices have different sets of motivations and incentives.¹¹⁵ Physicians, if they are to play a positive rather than a negative role in moving PLF forward, must be more cognizant and prudent in their prescribing habits regardless of demands on their time. One prospective outcome of the principle of unintended consequences is that even one physician prescribing a drug off-label,¹¹⁶ no matter what his motives (selfish or altruistic), can contribute to a non-linear avalanche of similar prescribing practices.¹¹⁷ Positive feedback loops such as those initiated by pharmaceutical advertising or patient advocacy groups may serve to speed this process exponentially. Support for this assumption comes from the apparent acceleration of mortality and morbidity associated with recent high-profile drug withdrawals as

¹⁰⁸ Bouchard & Sawicka, *supra* note 2 at Section I.B and Section I.E.

¹⁰⁹ Carpenter, Zucker & Avorn, *supra* note 59.

¹¹⁰ Mary K. Olson, “The Risk We Bear: The Effects of Review Speed and Industry User Fees on New Drug Safety” (2008) 27 *Journal of Health Economics* 175.

¹¹¹ Daniel Carpenter *et al.*, “Approval Times for New Drugs: Does the Source of Funding for FDA Staff Matter?” (2003) W3 *Health Affairs* 618 at 623.

¹¹² For review, see Lemmens & Bouchard, *supra* note 25.

¹¹³ Miller & Page, *supra* note 106; Sterman, “Reflections”, *supra* note 52; John D. Sterman, *Business Dynamics: Systems Thinking and Modeling for a Complex World* (Homewood, IL: Irwin/McGraw-Hill, 2000); James Gleick, *Chaos: Making a New Science* (New York: Penguin, 1988); M. Mitchell Waldrop, *Complexity: The Emerging Science at the Edge of Order and Chaos* (New York: Simon & Schuster, 1992); John L. Casti, *Complexification: Explaining a Paradoxical World Through the Science of Surprise* (New York: Harper Collins, 1994); Albert-Laszlo Barabasi, *Linked* (New York: Penguin Group, 2002).

¹¹⁴ *IOM Report*, *supra* note 9 (specifically, the IOM called on the FDA, industry, prescribing physicians, the health care delivery system, academic researchers, patients, and the general public to contribute to enhanced accountability of the drug regulatory system, underscoring (at S-4) that the “FDA’s credibility is intertwined with that of the industry, and a more credible drug safety system is in everyone’s best interest”).

¹¹⁵ Lexchin, “Withdrawals”, *supra* note 46 at 765.

¹¹⁶ Lemmens & Bouchard, *supra* note 25 at 335-337.

¹¹⁷ For description of how small events can give rise to large system-wide effects, see Bak & Paczuski, *supra* note 101.

well as the speed of drug agency withdrawals in response to this trend.¹¹⁸ The FDA's rebuke¹¹⁹ to "think it through" when managing benefits and risks applies equally well to patients and physicians. The relevance of this approach is underscored by the multiple layers of unknowns in the so-called "real world" use of drugs,¹²⁰ which, once understood, should countenance caution rather than innovation in prescribing and consuming practices.

It will of course be left to government as elected representatives to balance the range of competing public and private interests in the commercialization and regulation of publicly-funded medical research. Purposive legal-regulatory balancing is new neither to legal nor political communities, as is evident in the rich interplay between IPR rights and competition law as well as rights balancing in human rights, administrative, and constitutional law.¹²¹ This body of jurisprudence suggests that the goals of society and those of individuals can be appropriately prioritized and balanced and that it is the role of law to do so. Interestingly, there is some evidence to suggest that the withdrawal rate due to post-marketing safety considerations is declining along with reductions in approvals involving New Active Substances/New Chemical Entities, even though the breadth of this submission classification in terms of chemical structure and indication is very wide. If borne out by further empirical research, these data suggest that as pharmaceutical firms increase their benefit-risk ratio and reduce the costs of developing therapeutic products, the benefit-risk profile and social costs of public drug consumption will change correspondingly.

D. Government as Representative Public Agent

The most important actor in the rTPL innovation ecology is government as the elected agent of the public. Balancing layer upon layer of public and private interests in GOC's proposed lifecycle model therefore requires strong, if not aggressive, government leadership in punishing breaches of post-market licence terms and conditions. Drug agencies, however, are not neutral actors. Rather, they are political actors that demonstrate their preferences through relevant networks of laws and regulations.¹²² Of concern in this regard is the fact that the PLF framework enshrined in Bill C-51 contains a highly flexible multi-stage, multi-threshold process for suspension and revocation of clinical trial and market authorizations.¹²³ Such flexibility, combined with wide discretionary powers,¹²⁴ provides the legal grounds for GOC to take either a strong or lax approach to industry post-market compliance, notwithstanding new provisions directed to enforcement.¹²⁵ As discussed previously,¹²⁶ the question is an open one as to which position GOC will take.

It is not surprising that pharmaceutical firms, being self-interested actors, have complied poorly or not at all with their post-market obligations.¹²⁷ Despite claims that much of this has to do with a lack of

¹¹⁸ Carpenter, Zucker & Avorn, *supra* note 59 at 1355.

¹¹⁹ U.S., Center for Drug Evaluation and Research (FDA), "Think It Through: A Guide to Managing the Benefits and Risks of Medicines", online: FDA <<http://www.fda.gov/Drugs/ResourcesForYou/ucm079492.htm>>. See also Sharon Smith Holston, "The Value of Patient's Perspective in FDA's Decision Process" (Presentation at 10th IMS International Symposium, Brussels, 3 November 1997), online: FDA <<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/PatientInvolvement/ucm123864.htm>>.

¹²⁰ Health Canada, "Blueprint", *supra* note 49; Health Canada, "Concept Paper", *supra* note 50; EMEA, *CHMP 1* and EMEA, *CHMP 2*, *supra* note 91; *IOM Report*, *supra* note 9. For review of uncertainties in the context of balancing access and safety, see Eichler, *supra* note 7.

¹²¹ Ron A. Bouchard, "KSR v. Teleflex Part 1: Impact of U.S Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape" (2007) 15 *Health L.J.* 221 [Bouchard, "Landscape"].

¹²² Christopher J. Bosso, *Pesticides and Politics: The Life Cycle of a Public Issue* (Pittsburgh, PA: University of Pittsburgh Press, 1987).

¹²³ *Bill C-51*, *supra* note 5 at cl. 8 ss. 18-19.

¹²⁴ *Ibid.* at cl. 8 ss. 15.1, 18.1-18.9, 19.1-19.9, 20.1-20.9, 21, 21.1-21.2, cl. 10 ss. 23.1-23.9, 24.1, and cl. 11 s. 30.

¹²⁵ *Ibid.* at cl. 10 ss. 23 and 24.

¹²⁶ Lemmens & Bouchard, *supra* note 25 at 365.

¹²⁷ Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science* (Cambridge, MA: Union of Concerned Scientists, 2006), online: Union of Concerned Scientists <http://www.ucsusa.org/assets/documents/scientific_integrity/fda-survey-brochure.pdf> [Union]; David B. Ross, "The FDA and the Case of Ketek" (2007) 356 *New Eng. J. Med.* 1601. See also Susan Okie, "What Ails the FDA?" (2005) 352 *New Eng. J. Med.* 1063; Gardiner Harris, "FDA Scientists Accuse Agency Officials of Misconduct" *New York Times* (18 November 2008), A15 (describing a letter sent by FDA scientists on October 14, 2008 to Congress alleging FDA is engaged in "serious misconduct" by

jurisdiction by relevant drug agencies,¹²⁸ there is no question that these same agencies and pharmaceutical firms have pushed hard to locate common ground in their respective innovation and drug approval mandates. It is imperative, however, that governments maintain an arm's length relationship with industry if they are to embrace the regulatory norms of increased transparency and post-market safety¹²⁹ and to avoid charges of bias and unfairness in the discharge of their public health mandates. This will be hampered to the extent that (a) there is tension in the function of these agencies to stimulate the economy and protect the public and (b) when public health agencies do focus on the latter they are pushed by other governmental agencies and departments to focus on the former. Indeed, as noted by us¹³⁰ and others,¹³¹ it is not just the Therapeutic Products Directorate (TPD) or the Health Products and Food Branch (HPFB) or even Health Canada that is fully responsible for drug regulation and approval. Since repeal of compulsory licensing in favour of the current linkage regulation regime in 1993,¹³² the public health mandate of GOC relating to drug regulation has become increasingly bifurcated. For example, while Health Canada administers the *Food and Drugs Act* and *Regulations*, Industry Canada is responsible for administering both the *Patent Act*¹³³ and *NOC Regulations*,¹³⁴ which link drug approval to drug patenting.¹³⁵ Further, the Privy Council is responsible for setting the tone for domestic regulation/deregulation and the increasing scope of regulatory harmony with food and drug agencies in other jurisdictions. A parallel situation exists in the U.S. with the *Hatch-Waxman*¹³⁶ linkage regime tying patent protection under the U.S. *Patent Act*¹³⁷ to drug approval under the *Food, Drug, and Cosmetic Act*¹³⁸ via patent listings in the Orange Book.¹³⁹

One need not even focus on interagency conflict, as this tension is very much alive and well within drug agencies themselves. As noted by Psaty¹⁴⁰ and Weiss Smith,¹⁴¹ the basic criterion for drug approval is that its benefits outweighs its risks, yet FDA apparently views its “dilemma” (even after the IOM Report was issued) as weighing the trade-off between access and safety.¹⁴² A similar situation exists in the E.U.¹⁴³ and Canada.¹⁴⁴ How this trade-off is parsed is now recognized to permeate all aspects of the regulatory decision-making process,¹⁴⁵ with particular consequences for the assessment of both

approving unsafe or ineffective medications); Carpenter, Zucker & Avorn, *supra* note 59.

¹²⁸ Health Canada, “Blueprint”, *supra* note 49; Health Canada, “Concept Paper”, *supra* note 50; Yeates, Lee & Maher, *supra* note 103; *IOM Report*, *supra* note 9; U.S., Food and Drug Administration: Department of Health and Human Services, “The Future of Drug Safety—Promoting and Protecting the Health of the Public: FDA’s Response to the Institute of Medicine’s 2006 Report” (January 2007), online: FDA <<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108833.htm>>. See also Psaty & Charo, *supra* note 9.

¹²⁹ For a general discussion of the need for transparency in pre-market and post-market stages in the U.S., Canada, and the E.U., see *IOM Report*, *supra* note 9; Weiss Smith, “Sidelineing”, *supra* note 11; Psaty & Burke and Psaty & Charo, *supra* note 9; Health Canada, “Blueprint”, *supra* note 49; Health Canada, “Concept Paper”, *supra* note 50; Yeates, Lee & Maher, *supra* note 103; EMEA, “CHMP Guideline”, *supra* note 13; *EMEA CHMP 2*, *supra* note 91.

¹³⁰ Bouchard, “Balancing”, *supra* note 53; Ron A. Bouchard & Trudo Lemmens, “Privatizing Biomedical Research—A Third Way” (2008) 26 *Nature Biotechnology* 31 [Bouchard & Lemmens, “Third Way”].

¹³¹ Weiss Smith, “Sidelineing”, *supra* note 11 at 961; Janice Graham, “Smart Regulation: Will the Government’s Strategy Work?” (2005) 173 *Canadian Medical Association Journal* 1469; Psaty & Burke, *supra* note 9.

¹³² Bouchard, “Test”, and Bouchard, “Living”, *supra* note 53; Bouchard, “Landscape”, *supra* note 121. See also Hore, *supra* note 71.

¹³³ R.S.C. 1985, c. P-4.

¹³⁴ *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 [*NOC Regulations*].

¹³⁵ Bouchard, “Test”, *supra* note 53.

¹³⁶ *Drug Price Competition and Patent Restoration Act 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2000), commonly known as the *Hatch-Waxman Act*).

¹³⁷ 35 U.S.C. §§ 1-376 (2000).

¹³⁸ 21 U.S.C. §§ 301-399a (2004). See also *Food and Drugs*, 21 C.F.R. §§ 1-1499 (2003).

¹³⁹ 21 U.S.C. §§ 355(j)(7)(A) (2004). For detailed description, see Caffrey & Rotter, *supra* note 71.

¹⁴⁰ Psaty & Charo, *supra* note 9 at 1919.

¹⁴¹ Weiss Smith, “Sidelineing”, *supra* note 11 at 961.

¹⁴² But see Galson, *supra* note 11.

¹⁴³ Eichler, *supra* note 7.

¹⁴⁴ Graham, *supra* note 131; Bouchard, “Balancing”, *supra* note 53.

¹⁴⁵ Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What To Do About It* (New York: Random House, 2004); Jerome P. Kassirer, *On the Take: How Medicine’s Complicity with Big Business Can Endanger Your Health* (New York: Oxford University Press, 2005); John Abramson, *Overdo\$ed America: The Broken Promise of American Medicine* (New York: Harper Collins, 2004); Jay S. Cohen, *Overdose: The Case Against the Drug Companies* (New York: Penguin, 2001); Philip J. Hilts, *Protecting America’s Health: The FDA, Business, and One Hundred Years of Regulation*

the benefits and risks of new drugs¹⁴⁶ under circumstances where vital information is provided only by pharmaceutical sponsors. This tension has produced a clear push-pull dynamic concerning the traditional gate-keeping role of elected government in public health and its now established responsibility to enhance national productivity and prosperity via innovative medical research.¹⁴⁷ Governments fulfill this obligation, in part, through policies favouring strong IPR rights for marketed products, despite ample evidence that stacking IPR rights is not the path to greater therapeutic product development.¹⁴⁸

Here and elsewhere we have provided theoretical,¹⁴⁹ and empirical qualitative¹⁵⁰ and quantitative¹⁵¹ evidence to suggest that too much of a focus on closed IPR rights may stifle innovation in an open rTPL ecology. Emphasis on private IPR rights in a public health context leads naturally to questions relating to the efficiency and effectiveness of innovation from a truly societal perspective,¹⁵² owing not least to the possibility that consumers are paying monopoly prices for drugs that may offer little or no improvement over existing therapeutic products.¹⁵³ Related to this concern is the possibility that core public values underpinning public health care, IPR rights seen to drive national innovation, and public lobbying efforts in support of enhanced access to novel drugs may be quietly, but importantly, evolving over time away from communitarian interests. The result is that traditional conflict of interest models may now be in the direct firing line of sophisticated corporate strategists and lobbying groups. A shift in societal values of this nature may be related to the apparently growing emphasis in developed nations on legal rights protecting personal autonomy and individual choice over those rights emphasizing government fiduciary obligations and other collective rights; a trend that may have co-evolved with the importance of the individual over the collective in everyday life more generally.¹⁵⁴

A shift in public values of this nature may be reflected in the apparently autopoietic standardization of government-industry partnerships over time.¹⁵⁵ Geographic differences in the norms of these partnerships have been discussed by Wiktorowicz.¹⁵⁶ Under her gaze, Canada is seen as a “middle way” jurisdiction, between the U.S. and France, where substantial partnerships and co-dependencies exist side by side with some arm’s length adversarialism between GOC and industry. Canadian policy development relating to drug development and drug regulation has been described as a form of clientele plu-

(New York: Alfred A. Knopf, 2003); Ray Moynihan & Alan Cassels, *Selling Sickness: How the World’s Biggest Pharmaceutical Companies Are Turning Us All Into Patients* (Vancouver: GreyStone Books, 2005).

¹⁴⁶ Weiss Smith, “Sidelineing”, *supra* note 11.

¹⁴⁷ Gordon Schiff, *Contested Ground: Public Purpose and Private Interest in the Regulation of Prescription Drugs* by Peter Davis (1998) 19 *Journal of Public Health Policy* 240; Derek Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (New Jersey: Princeton University Press, 2003); Sheldon Krinsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* (Lanham MD: Rowman & Littlefield, 2003); Janet Atkinson-Grosjean, *Public Science, Private Interests: Culture and Commerce in Canada’s Networks of Centres of Excellence* (Toronto: University of Toronto Press, 2006).

¹⁴⁸ Anita Varma & David Abraham, “DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market” (1996) 9 *Harvard J.L. & Tech.* 53; Glynn S. Lunney Jr., “E-Obviousness” (2001) 7 *Mich. Telecomm. & Tech. L. Rev.* 363; Bouchard, “Test” and Bouchard, “Living”, *supra* note 53.

¹⁴⁹ Bouchard, “Systems”, and Bouchard, “Reflections”, *supra* note 15.

¹⁵⁰ Bouchard, “Balancing”, *supra* note 53; Bouchard, “Test”, and Bouchard, “Living”, *supra* note 53.

¹⁵¹ Bouchard & Sawicka, *supra* note 2.

¹⁵² For a discussion of the public policy implications of the terms “efficiency” and “effectiveness”, see Janice Gross Stein, *The Cult of Efficiency*, rev. 2d ed. (Toronto: House of Anansi Press, 2001).

¹⁵³ Lexchin, “IP Rights”, *supra* note 62; “Drugs in 2001”, *supra* note 63; *Patented Medicine Prices Review Board Annual Report*, *supra* note 62; Tim Hubbard & James Love, “A New Trade Framework for Global Healthcare R&D” (2004) 2:2 *PLoS Biology* 147; Hong *et al.*, *supra* note 64.

¹⁵⁴ Stein, *supra* note 152; Joseph Heath, *The Efficient Society: Why Canada Is as close to Utopia as It Gets* (Toronto: Penguin, 2001); Amartya Sen, “Equality of What?” (Tanner Lecture on Human Values delivered at Stanford University, May 22, 1979), online: The Tanner Lectures on Human Values <<http://www.tannerlectures.utah.edu/lectures/documents/sen80.pdf>>.

¹⁵⁵ Autopoiesis refers to the process of self creation and/or self organization (Gr. *auto*—*avtò* for self- and *poiesis*—*ποιησις* for creation or production). The term underscores a fundamental interrelationship between the structure and function of a system, typical examples being living systems and biological cells. For a general discussion of the importance of interrelationships of actors in social and technological networks, see Bruno Latour, *Science in Action: How to Follow Scientists and Engineers through Society* (Cambridge, MA: Harvard University Press, 1987); Bruno Latour, *We Have Never Been Modern* (Cambridge, MA: Harvard University Press, 2007).

¹⁵⁶ Mary E. Wiktorowicz, “Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain and France” (2003) 28 *J. Health Pol.* 615.

ralism,¹⁵⁷ where a narrow economic interest (e.g., multinational pharmaceutical) strongly informs governmental policy-making in order to “preserve and protect the structural basis of that interest.” There can be no doubt that, based on a review of the *Blueprint*,¹⁵⁸ Concept Paper,¹⁵⁹ and Bill C-51,¹⁶⁰ and related disclosures by GOC,¹⁶¹ clientele pluralism has strongly informed both the policy and legislation underpinning the nation’s lifecycle approach to drug regulation. Enhanced regulatory partnering predictably raises the spectre of regulatory (or mission) creep.¹⁶² Indeed, this scenario has been consistently acknowledged by drug agencies themselves¹⁶³ and is viewed by many to tilt the balance of power toward corporations and away from the public interest.¹⁶⁴ Global harmonization efforts favouring standardization of drug approval may thus trigger a further downward spiral in standard-setting.¹⁶⁵ This trend may, ironically, be enhanced rather than mitigated by a novel and untested regulatory mechanism.¹⁶⁶

Gaps between regulatory science and the science of regulation represent a vital issue for emerging lifecycle models of drug regulation. This is particularly true of the Canadian PLF regime, given the scope of concerns expressed over flexible departure and the substantial degree of discretionary power retained by GOC in relation to suspension and revocation of clinical trials and marketing authorizations. Consequently, and for the purposes of maintaining a robust distributive balance of public and private interests in therapeutic drug development and regulation, drug agency leadership will somehow need to retain the political and normative power to “step away” from their industrial partners in order to enforce fundamental legal powers relating to post-market safety. These powers include revoking expedited or otherwise probationary market authorizations where it is in the public’s best interests rather than the best interests of relevant government-industry partnerships.

SUMMARY & CONCLUSIONS

The data in this report suggest that concerns to the effect that PLF represents a new direction with regard to Canada’s drug regulatory regime may be somewhat overstated. Indeed, our empirical analysis shows that the nation’s existing approval mechanism may already be anticipating the lifecycle approach and that this anticipation is occurring in an accelerated fashion. For this reason, we propose that flexible departure does not represent a new direction in Canadian drug regulation. Patients are already gaining more rapid access to experimental drugs that have a critical need for significant evidence of safety (and potentially efficacy) after the drug has entered the marketplace. Indeed, between 2006 and 2008, 5-7% of all NOCs issued by Health Canada to brand name pharmaceutical firms met this requirement. Remarkably, the trend for Priority Review and NOC/c approvals has completely reversed in the last seven years, with NOC/c approvals now almost double that of Priority Review. To date, none of the drugs approved via these streams have been withdrawn for

¹⁵⁷ *Ibid.*, citing (at 43) M.M. Atkinson & W.D. Coleman, “Corporatism and Liberal Policy” in A. Carson, ed., *Organized Interests and the State* (London: Sage, 1985).

¹⁵⁸ Health Canada, “Blueprint”, *supra* note 49.

¹⁵⁹ Health Canada, “Concept Paper”, *supra* note 50.

¹⁶⁰ *Bill C-51*, *supra* note 5.

¹⁶¹ Health Canada, “Stakeholder Workshop”, *supra* note 56; Peterson, “Innovation”, *supra* note 6.

¹⁶² Michael M. E. Johns, Mark Barnes & Patrick S. Florencio, “Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest” (2003) 289 *Journal of the American Medical Association* 741; Michele Boldrin & David K. Levine, “The Economics of Ideas and Intellectual Property” (2005) 102 *Proceedings of the National Academy of Sciences of the United States of America* 1252; Daniel P. Carpenter, “The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy” (2004) 23:1 *Health Affairs* 52; Stuart Macdonald, “When Means Become Ends: Considering the Impact of Patent Strategy on Innovation” (2004) 16 *Information Economics and Policy* 135; Wayne A. Ray & C. Michael Stein, “Reform of Drug Regulation—Beyond an Independent Drug-Safety Board” (2006) 354 *New Eng. J. Med.* 194.

¹⁶³ Union, Okie, and Ross, *supra* note 127; Carpenter, Zucker & Avorn, *supra* note 109; Harris, *supra* note 127; John Abraham, “The Pharmaceutical Industry as a Political Player” (2002) 360 *The Lancet* 1498.

¹⁶⁴ See generally both Bozeman, and Bozeman & Sarewitz, *supra* note 100.

¹⁶⁵ P. Lurie & L.D. Sasich, “Safety of FDA-Approved Drugs” (1999) 282 *Journal of the American Medical Association* 2297; John Abraham & Tim Reed, “Trading Risks for Markets: The International Harmonization of Pharmaceuticals Regulation” (2001) 3 *Health Risk & Society* 113; Wiktorowicz, *supra* note 156.

¹⁶⁶ M.H. Hoeflich & Karen Norheden Hoeflich, “Accelerating Science: A Problem for the Legal System” (1992) 60 *University of Missouri-Kansas City Law Review* 717.

post-market safety reasons. Given that the available evidence suggests that very few of the post-marketing obligations recommended by regulators are actually met by pharmaceutical firms in other jurisdictions, it would appear that one side of the access-safety balance may be receiving more attention than the other from regulators. It is hoped that this gap, and the attendant ability of drug agencies to enforce post-market terms and conditions, will be remedied by the provisions of Bill C-51 (or future related legislation). In this regard, it is imperative that GOC demonstrates strong and sustained leadership in suspending or revoking clinical trial and market authorizations where firms do not meet their obligations. This would be particularly relevant under conditions where drugs gain early market access via flexible departure. If not, it is plausible that a leftward shift in the access-safety balance will lead to more rather than less post-market safety issues. Strong leadership will also be vital where the incidence of serious adverse effects escalates in a non-linear or otherwise strongly time-dependent manner.

The data further suggest that the Canadian system of pharmaceutical innovation may be “doing more with less.” This conclusion applies equally to the rate and direction of innovative activity undertaken by brand name and generic firms. New or standard drug submissions have been flat while supplementary and generic submissions have increased substantially. Even NOCs for NAS and Me Too drugs declined when compared to NOCs directed to Line Extensions and new indications. Data presented in Figs. 1-10 imply that the Canadian pharmaceutical industry, as a whole, is focusing on prolonging market share and leveraging the utility of existing technologies rather than on the development of first-in-kind “breakthrough” products. As such, the data support the conclusion that technology appropriation is alive and well in Canada. An “incremental” approach to drug development of this nature is supported by innovation theory, which suggests that firms will only innovate in an area to the extent they capture all or most of the surplus from incentives they generate.¹⁶⁷ Even so, too much of a focus on incremental innovation propped up by entrenched IPR rights has the potential to downplay or minimize important discourse(s) relating to the social returns from innovation.¹⁶⁸

Firms are obtaining increasingly more supplementary NOCs, more IPR rights per marketed product, and more control over pre-approval and post-approval processes with fewer pre-market evidentiary requirements, and thus lower costs of drug development; however it is not only the pharmaceutical industry that may be doing more with less. The public is clearly gaining more rapid access to experimental drugs aimed at addressing presumed unmet medical needs. In balancing this benefit, however, the public is also being asked to shoulder more risk with less evidence of pre-market safety and efficacy in the context of flexible departure. Moreover, individuals are being exposed to fewer truly breakthrough drugs while paying more for those whose market value is being propped up by strong IPR rights, although this is offset somewhat by the concomitant increase in the availability of generic products. Whether the public will have more post-market protection on the other side of the balance is an open question, as it cannot be predicted what style of leadership GOC will bring to bear on the issue.

Finally, regulators are experiencing perhaps the greatest challenges to both limbs of the access-safety balance. Indeed, owing to uncertainties regarding post-market compliance and enforcement, it is not clear at this point whether governments will gain more clarity from less focus on the pre-market approval process and more on the post-marketing stage. Certainly, the speed of the approval process has increased owing to user fee implementation, enhanced regulatory harmony with other jurisdictions, and increased cooperation with firms. Unclear however, is whether or not drug regulators will ultimately have a better overall drug safety record as they attempt to recalibrate tolerance of risk and uncertainty at pre-market and post-market approval stages. It is hoped that when implementing the lifecycle approach, public health agencies fully embrace the complexity and systems nature of the rTPL innovation ecology in which drug regulation is embedded.

¹⁶⁷ Ganuza, *supra* note 65, citing (at 2) W.D. Nordhaus, *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change* (Cambridge MA: MIT Press, 1969).

¹⁶⁸ E. Richard Gold, “The Reach of Patent Law and Institutional Competence” (2004) 1 *University of Ottawa Law & Technology Journal* 263; Bouchard & Lemmens, “Third Way”, *supra* note 130.

Taking an adaptive, learning-based approach to drug regulation has a number of advantages over historical linear models of drug development and regulation. First, it allows regulators to accept that there is no such thing as an “optimal” front-loaded policy. Second, it will help broaden agency capacity bandwidth, in turn allowing regulators to adopt a paternalistic, partnership, and adversarial stance in its bargaining scenarios as necessary and sufficient. This should allow a regulatory culture to grow organically in response to complex environmental signals and therefore to help avoid the pitfalls of the existing front-loaded regime. Finally, taking an approach that is both adaptive and distributive in nature may afford government an excellent opportunity to react swiftly in response to dynamically changing post-marketing safety signals in a manner that is in the best interests of the public rather than those of government-industry partnerships.

L'OBLIGATION D'ACCOMMODEMENT AU CANADA ET L'OBLIGATION FRANÇAISE DE RECLASSEMENT : CONVERGENCES, DIVERGENCES ET IMPACTS SUR LE MAINTIEN EN EMPLOI DU SALARIÉ EN ÉTAT D'INCAPACITÉ

Anne-Marie Laflamme et Sophie Fantoni-Quinton*

L'obligation d'accommodement de l'employeur face à une incapacité est un concept canadien issu de la jurisprudence ; en regard, le salarié français en situation d'incapacité est titulaire d'un véritable droit au reclassement inscrit dans la loi, mais un que les juges ont également dû baliser. Dans les deux cas, ces avancées témoignent d'une volonté d'intégrer pleinement les personnes handicapées sur le marché du travail. Si les jurisprudences de ces deux pays ont une même finalité, soit le maintien du lien d'emploi du salarié en état d'incapacité, elles sont intéressantes à mettre en perspective mutuellement dans la mesure où les positions françaises sont moins précises, ce qui n'est pas sans conséquence en termes d'effectivité du maintien en emploi. De plus, la mise en œuvre de ces obligations diffère sensiblement d'un pays à l'autre en raison des particularités propres aux régimes sociaux de chacun ainsi qu'aux différentes responsabilités qui incombent aux acteurs du milieu de travail. L'objectif de cet article est d'examiner les convergences et les divergences de ces deux systèmes de droit positif dans une perspective d'enrichissement mutuel.

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INTRODUCTION

Au Canada comme en France, la jurisprudence relative aux obligations de l'employeur en matière de reclassement de ses salariés souffrant d'une incapacité est particulièrement dense. Elle reflète les préoccupations fortes en matière de maintien dans l'emploi. Au Canada, on parle d'obligation d'accommodement ; en France, d'obligation de reclassement.

Les raisons de ce phénomène sont multiples, essentiellement liées aux aspirations sociales en matière de bien-être, notamment au travail, mais aussi aux exigences du respect du droit à l'égalité et de l'interdiction de discrimination. Ces nouvelles exigences sociales transparaissent d'ailleurs également dans les chartes, dont se dotent de plus en plus d'entreprises voulant afficher une image correspondant aux attentes de la société¹.

L'étendue de ces obligations respectives est difficile à circonscrire, mais il semble clair que malgré certaines divergences, les deux systèmes juridiques convergent, au moins dans leur ambition. Cette tendance est l'œuvre des juges des deux pays, soucieux d'apporter des réponses concrètes aux attentes des salariés victimes d'un handicap, à savoir le maintien en emploi lorsque c'est possible, quitte à sanctionner les employeurs trop peu diligents dans la recherche d'une solution de maintien.

Or, si la jurisprudence canadienne tente de baliser le plus précisément possible l'étendue et les limites de ces obligations, il n'en est pas de même en France, où il n'existe à l'heure actuelle aucun critère précis, et où les exigences envers les employeurs vont toujours en augmentant. De telles imprecisions sont de nature à vider de tout sens l'objectif premier de ces obligations, soit le maintien dans l'emploi, et surtout à générer une situation d'insécurité juridique à force d'exigences impossibles à délimiter. Au contraire, au Canada, les efforts effectués par les juges pour mieux définir les contours de l'obligation d'accommodement sont porteurs de davantage de sécurité juridique et incitent à la recherche d'une véritable solution de maintien en emploi dans le cadre d'une démarche méthodique. Une réflexion croisée sur ces évolutions jurisprudentielles amène donc un éclairage intéressant sur les vocations et les tensions qui sous-tendent ces obligations dans les deux pays et sur les risques que généreraient des exigences trop fortes en ce domaine.

Mettre en perspective les deux systèmes juridiques en matière d'accommodement et de reclassement nécessite au préalable d'analyser les sources de ces obligations, mais également les concepts de maladie, d'aptitude, d'incapacité et d'adaptation. Ainsi, nous nous efforcerons de comprendre, grâce au parallèle entre les deux pays, en quoi l'obligation d'accommodement raisonnable est vectrice d'une réelle volonté des juges de rendre cette obligation réaliste, et ce, malgré certaines difficultés que nous soulignerons au passage. À cet effet, la jurisprudence française, dont on devine des ambitions et des frontières communes avec celles du Canada, suscite une insécurité juridique, mais surtout une inefficacité en matière de maintien dans l'emploi. Nous présenterons d'abord les socles communs et les différences entre les deux types d'obligations (I), pour ensuite en préciser les contours, afin d'en vérifier les effets véritables sur le maintien en emploi (II).

I

LES SOCLES COMMUNS ET LES DIFFÉRENCES ENTRE LES OBLIGATIONS D'ACCOMMODEMENT
ET DE RECLASSEMENT DU TRAVAILLEUR VICTIME D'UNE INCAPACITÉ

La comparaison des obligations dans les deux pays nécessite d'en comprendre les fondements respectifs (I.A et I.B), mais également de préciser certains concepts tels que l'aptitude et l'incapacité, qui conditionnent d'une manière particulière les obligations de l'employeur en France (I.C). Ce parallèle démontre aussi que, dans les deux pays, l'obligation présente des limites liées à sa mise en œuvre tardive, ainsi qu'aux fondements mêmes du contrat de travail qui en encadrent la portée (I.D).

¹ S. Fantoni-Quinton, « Whistleblowing, chartes éthiques, dispositifs d'alertes professionnelles... Quels enjeux possibles en santé-travail ? » (2008) 5 *Éthique et santé* 139.

A. Les fondements de l'obligation d'accommodement au Canada

La *Charte canadienne des droits et libertés*², véritable charte constitutionnelle, interdit, comme la Constitution française, toute discrimination fondée sur un ensemble de motifs incluant, entre autres, les déficiences mentales ou physiques. Pour autant, ni l'un, ni l'autre de ces textes fondamentaux ne prévoit expressément l'obligation d'accommodement ou de reclassement à l'égard d'individus atteints d'incapacité.

La *Loi canadienne sur les droits de la personne*³ interdit, par l'entremise des articles 3 et 7, toute discrimination fondée notamment sur la déficience, particulièrement dans le cadre de la relation d'emploi. L'employeur peut toutefois justifier sa norme d'emploi en démontrant qu'il s'agit d'une exigence professionnelle justifiée ; l'obligation d'accommodement a été introduite en 1998 comme limite à ce moyen de défense⁴. Cette loi gouverne les relations de travail de la fonction publique fédérale, ainsi que celles des entreprises qui relèvent de la compétence fédérale en droit du travail.

Par ailleurs, toutes les provinces canadiennes ont une législation visant la protection des droits de la personne, prohibant la discrimination dans l'emploi, notamment celle fondée sur le handicap, l'incapacité, la déficience ou l'invalidité⁵. Malgré les différentes terminologies utilisées, la Cour suprême du Canada a précisé qu'il fallait accorder à ces termes une même signification, large et libérale⁶. Ces dispositions s'appliquent aux employés de la fonction publique provinciale, ainsi qu'aux salariés des entreprises qui relèvent de la compétence de la province concernée. Toutes ces lois comportent une défense d'exigence professionnelle justifiée et certaines prévoient expressément une obligation d'accommodement⁷. Ainsi, l'absence de dispositions relatives à l'accommodement est peu problématique puisque la jurisprudence canadienne a fait de cette obligation une composante du droit à l'égalité, et ce, dès 1985. En effet, dans l'arrêt *O'Malley c. Simpsons-Sears Ltd.*⁸, la Cour suprême déclara que l'employeur devait prendre des mesures raisonnables afin d'accommoder une employée incapable d'observer ses préceptes religieux en raison de l'horaire de travail qui lui était imposé.

Par la suite, au terme d'une longue évolution jurisprudentielle, la Cour suprême du Canada adopta finalement un test en trois étapes que l'employeur doit franchir, afin de démontrer que sa norme d'emploi, discriminatoire à première vue, constitue une exigence professionnelle justifiée. Dans l'arrêt *Meiorin*⁹, la décision de principe portant sur cette question, elle précisa que l'employeur doit démontrer :

- i) qu'il a adopté la norme dans un but rationnellement lié à l'exécution du travail en cause ;
- ii) qu'il a adopté la norme particulière en croyant sincèrement qu'elle était nécessaire pour réaliser ce but légitime lié au travail ;

² *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. Notons que la *Charte canadienne des droits et libertés* ne s'applique qu'aux actes du Parlement et du gouvernement fédéral pour tous les domaines relevant de sa compétence, ainsi qu'à la législature et au gouvernement de chacune des provinces et territoires, également dans leur champ de compétence. En matière d'emploi, elle s'applique aux employés de la fonction publique ainsi qu'à un certain nombre d'autres salariés plus ou moins associés à l'activité gouvernementale selon les critères établis par la jurisprudence.

³ *Loi canadienne sur les droits de la personne*, L.R.C. 1985, c. H-6, art. 3 et 7.

⁴ *Ibid.*, art. 15.

⁵ Voir par ex., en Ontario : le *Code des droits de la personne*, L.R.O. 1990, c. H-19, art. 5 ; au Manitoba : le *Code des droits de la personne*, L.M. 1987-1988, c. 45, C.P.L.M. c. H175, art. 9, 14 ; en Alberta : *Human Rights, Citizenship, and Multiculturalism Act*, R.S.A. 2000, c. H-14, art. 7.

⁶ *Québec (Commission des droits de la personne et des droits de la jeunesse) c. Montréal (Ville de)*, [2000] 1 R.C.S. 665 [*Commission des droits de la personne*].

⁷ À titre d'exemple, l'obligation d'accommodement est prévue expressément par les art. 17(2) et 24(2) du *Code des droits de la personne* de l'Ontario, *supra* note 5, de même que par l'art. 12 du *Code des droits de la personne* du Manitoba, *supra* note 5. Notons qu'au Québec, la *Charte des droits et libertés de la personne*, L.R.Q. c. C-12, ne prévoit pas expressément d'obligation d'accommodement.

⁸ *O'Malley c. Simpsons-Sears Ltd.*, [1985] 2 R.C.S. 536 [*Simpsons-Sears*].

⁹ *Colombie-Britannique (Public service Employee relations Commission) c. B.C.G.S.E.U.*, [1999] 3 R.C.S. 3 [*Meiorin*].

- iii) que la norme est raisonnablement nécessaire pour réaliser ce but légitime lié au travail. Pour prouver que la norme est raisonnablement nécessaire, il faut démontrer qu'il est impossible de composer avec les employés qui ont les mêmes caractéristiques que le demandeur sans que l'employeur subisse une contrainte excessive [nos soulignés]¹⁰.

Ainsi, la Cour suprême du Canada énonçait dans cet arrêt que l'accommodement doit être intégré à l'intérieur même de la norme d'emploi, cette dernière devant permettre de tenir compte de la situation de chacun lorsqu'il est raisonnablement possible de le faire. En l'espèce, la Cour jugea que la norme aérobique, qui consistait à parcourir une distance de 2,5 km en moins de 11 minutes, imposée par l'employeur à ses pompiers forestiers à titre de condition de leur maintien en emploi, était discriminatoire, car elle ne tenait pas compte des différences physiologiques entre les hommes et les femmes. Elle conclut donc que l'employeur ne pouvait pas invoquer cette norme afin de justifier le congédiement de la salariée qui n'était pas en mesure d'y satisfaire.

En application de ces principes, dès que le salarié démontre avoir été victime d'une mesure discriminatoire, de manière directe ou indirecte, notamment en relation avec son incapacité physique ou mentale, il appartient à l'employeur de faire la preuve que sa norme constitue une exigence professionnelle justifiée. Or, pour satisfaire ce fardeau, l'employeur doit démontrer qu'il a respecté son obligation d'accommodement raisonnable jusqu'à la limite de la contrainte excessive. Rappelons que la Cour suprême du Canada a retenu une interprétation large et généreuse des notions de déficience et de handicap, estimant que ceux-ci pouvaient résulter tout autant d'une limitation physique que d'une affection, d'une construction sociale, d'une perception de limitation ou d'une combinaison de tous ces facteurs¹¹. Ainsi, l'obligation d'accommodement de l'employeur entre en jeu dès que le salarié démontre qu'il a été victime d'une distinction ou d'une exclusion qui compromet son droit à l'égalité et qui est fondée sur son état de santé, et ce, peu importe que l'incapacité du salarié soit réelle ou perçue, permanente ou temporaire¹².

On remarque cependant que dans certaines provinces canadiennes, la mise en œuvre du droit au retour au travail suite à une incapacité peut faire appel à des règles particulières si l'on est en présence d'une lésion d'origine professionnelle. Dans un tel cas, le législateur a parfois introduit dans la législation portant sur la réparation des accidents du travail et des maladies professionnelles, certaines obligations de reclassement variant selon la législation provinciale concernée¹³.

À cet effet, au Québec, la *Loi sur les accidents du travail et les maladies professionnelles*¹⁴ permet aux salariés victimes d'une lésion professionnelle d'invoquer un droit de retour au travail pendant un délai déterminé. Elle impose ainsi à l'employeur l'obligation d'offrir un emploi convenable, respectant les restrictions du salarié aux prises avec des limitations fonctionnelles l'empêchant de réintégrer le poste qu'il occupait au moment de son accident de travail ou de la manifestation de sa maladie professionnelle¹⁵. Or, compte tenu des répercussions de plus en plus larges de l'obligation d'accommodement raisonnable, celle-ci est devenue, à certains égards, plus avantageuse que ce droit au reclassement consacré dans la *LATMP*. Cette situation se révèle problématique en raison du cloisonnement de la compétence des tribunaux administratifs chargés de l'application de ces différentes législations. À titre d'exemple, au Québec, dans le cas de limitations fonctionnelles imputables à une lésion professionnelle, c'est la Commission de la santé et de la sécurité du travail (organisme public chargé de l'application de la *LATMP*) qui possède la compétence exclusive pour déterminer la capaci-

¹⁰ *Ibid.* au para. 54.

¹¹ *Commission des droits de la personne*, supra note 6 à la p. 700. Ce faisant, la Cour suprême rejetait la conception biomédicale du handicap, selon laquelle cette notion impliquait la présence de limitations fonctionnelles, pour adopter une approche multidimensionnelle en s'inspirant notamment de la définition retenue par l'Organisation mondiale de la santé (OMS).

¹² Anne-Marie Laflamme, «L'obligation d'accommodement confère-t-elle aux personnes handicapées un droit à l'emploi?» (2002) 62 R. du B. 125 à la p. 141

¹³ Il faut savoir qu'en vertu des règles régissant le partage des compétences au Canada, les régimes d'indemnisation en matière d'accidents du travail et de maladies professionnelles ont été considérés comme relevant de la compétence exclusive des provinces, le Parlement canadien n'ayant compétence pour légiférer qu'à l'égard de ses propres employés.

¹⁴ *Loi sur les accidents du travail et les maladies professionnelles*, L.R.Q. c. A-3.001 [*LATMP*].

¹⁵ *Ibid.*, art. 234 et suivants.

té du travailleur à exercer son emploi prélesionnel, un emploi équivalent ou un emploi convenable, sans que l'employeur n'ait à démontrer qu'il a satisfait à son obligation d'accommodement. Pourtant, l'obligation d'accommodement devrait s'imposer à l'employeur en toutes situations, compte tenu de son caractère prééminent. Ces questions, à l'heure non résolues, sont susceptibles de priver les salariés victimes d'une lésion professionnelle de la pleine reconnaissance de leur droit à l'égalité¹⁶.

B. Les fondements de l'obligation française de reclassement

Sous l'impulsion européenne¹⁷, la France, dans la *Loi de lutte contre les discriminations*¹⁸ interdit toute discrimination fondée sur un ensemble de motifs, incluant le handicap. En parallèle, le *Code du travail* français, là encore sous l'influence des directives européennes, impose à l'employeur, dans le cadre de l'interdiction de discrimination, l'obligation de justification et de proportionnalité dans les exigences professionnelles qu'il pourrait faire valoir vis-à-vis d'un salarié par rapport aux exigences réelles d'un poste à pourvoir¹⁹. L'article L1134-1 précise l'aménagement de la charge de la preuve en cas de recours auprès des juridictions prud'homales. La victime doit présenter des éléments de fait laissant supposer l'existence d'une discrimination directe ou indirecte exercée par l'entreprise. Au vu de ces éléments, il incombe à la partie défenderesse de prouver que sa décision est justifiée par des éléments objectifs et étrangers à toute discrimination. Le juge forme sa conviction après avoir ordonné, en cas de besoin, toutes les mesures d'instruction qu'il estime utiles.

Toutefois, l'obligation française de reclassement trouve essentiellement sa source, d'une part, dans les textes généraux, et plus particulièrement en application de la théorie générale des obligations du *Code civil*²⁰. Comme le rappelle l'auteure Marion Del Sol²¹, les articles 1134 et 1135 de ce code disposent que les contrats «doivent être [exécutés] de bonne foi», et que ceux-ci «obligent non seulement à ce qui est exprimé, mais encore à toutes les suites que l'équité, l'usage ou la loi donnent à l'obligation d'après sa nature». D'autre part, le *Code du travail* français²² est spécialement venu imposer l'obligation de recherche d'un reclassement lorsque l'inaptitude est d'origine professionnelle. L'employeur ayant fait courir un risque qui s'est réalisé, il se doit d'atténuer les conséquences de ce risque pour son salarié, en s'efforçant de rechercher un poste de travail compatible avec son incapacité résultant de la réalisation de ce risque.

Les tribunaux ont progressivement étendu cette obligation de recherche d'un poste à l'ensemble des inaptitudes, d'origine professionnelle ou non. Mais le législateur n'a entériné ces interventions

¹⁶ Pour une étude de la question, voir Anne-Marie Laflamme, «Le droit de retour au travail et l'obligation d'accommodement : le régime des lésions professionnelles peut-il résister à l'envahisseur ?» (2007) 48 C. de D. 215.

¹⁷ Voir *Convention de sauvegarde des Droits de l'homme et des libertés fondamentales*, 4 novembre 1950, 213 R.T.N.U. 221, S.T.E. 5 (convention qui consacre à son article 14, par l'utilisation des mots «toute autre situation», une interdiction de discrimination très large incluant notamment la discrimination fondée sur le handicap).

¹⁸ *Loi n° 2008-496 du 27 mai 2008 portant diverses dispositions d'adaptation au droit communautaire dans le domaine de la lutte contre les discriminations*, J.O., 28 mai 2008, 8801.

¹⁹ Selon les directives européennes, une discrimination indirecte se produit lorsqu'une disposition, un critère ou une pratique apparemment neutre est susceptible d'entraîner un désavantage particulier pour des personnes relevant d'un des motifs discriminatoires prévus par les directives en rapport à d'autres personnes, à moins que cette disposition, ce critère ou cette pratique ne soit objectivement justifié par un objectif légitime et que les moyens de réaliser cet objectif ne soient appropriés et nécessaires. Voir CE, *Directive 2000/43/CE du Conseil du 29 juin 2000 relative à la mise en œuvre du principe de l'égalité de traitement entre les personnes sans distinction de race ou d'origine ethnique*, [2000] J.O. L 180/22, art. 2(2)b); CE, *Directive 2000/78/CE du Conseil du 27 novembre 2000 portant création d'un cadre général en faveur de l'égalité de traitement en matière d'emploi et de travail*, [2000] J.O. L 303/16 à l'art. 2(2)b).

²⁰ Voir Jean Savatier, «L'obligation de reclassement des salariés devenus physiquement inaptes à leur emploi», dans *Mélanges en l'honneur de Henry Blaise*, Paris, Economica, 1995 à la p. 387. Voir généralement Jean Savatier, «L'obligation de reclassement d'un salarié déclaré par le médecin du travail inapte à tout emploi dans l'entreprise», (2005) 1 Dr. soc. 31.

²¹ Marion Del Sol, «L'obligation prétorienne de reclassement en matière de licenciement économique : esquisse d'un régime juridique», *La Semaine Juridique Entreprise et Affaires* n° 42 (19 octobre 1995) 498.

²² Voir *Loi n° 81-3 du 7 janvier 1981 relative à la protection de l'emploi des salariés victimes d'un accident du travail ou d'une maladie professionnelle*, J.O., 8 janvier 1981, 191 (Loi qui amende le *Code du travail* français et permet aux victimes d'un accident de travail ou d'une maladie professionnelle le maintien dans l'emploi pendant la période d'indisponibilité et limite le droit de l'employeur au licenciement. Ainsi, cette loi pose juridiquement l'idée de recherche de la poursuite du contrat de travail par un reclassement).

jurisprudentielles qu'en 1992²³, en des termes très proches de la loi de 1981, à la nuance près qu'il n'avait pas prévu dans ce dernier texte la possibilité d'aménager le temps de travail²⁴. Cette lacune a été comblée par la loi du 11 février 2005 sur l'égalité des droits et des chances, la participation et la citoyenneté des personnes handicapées²⁵, accentuant ainsi l'harmonisation de l'étendue du champ des recherches en matière de reclassement, quelle que soit l'origine de l'inaptitude. Désormais, les deux régimes juridiques sont presque identiques, à l'exception, des conséquences indemnitaires de leur violation par l'employeur, et de la nécessité des interventions des délégués du personnel dans la recherche de reclassement de l'accidenté du travail. Concrètement, en parallèle parfait avec l'interdiction de discrimination, la charge de la preuve en matière de reclassement repose sur l'employeur, puisque c'est lui le débiteur de cette obligation²⁶. Pour satisfaire à ce fardeau, l'employeur doit démontrer qu'il a respecté son obligation de recherche, sans pour autant que le champ de cette dernière ne soit clairement défini.

Dans les deux pays, le droit à l'égalité et l'interdiction de discrimination offrent donc des socles communs à ces obligations d'accommodement ou de reclassement. Ils ouvrent sur la notion de discrimination positive, qui permet d'accorder un avantage social à une catégorie de salariés considérée défavorisée, tels les salariés présentant une incapacité. Cette conception du droit à l'égalité (écartant l'égalité formelle au profit d'une égalité réelle) met en application les principes promus par l'Organisation mondiale de la santé, selon lesquels le handicap découle le plus souvent d'une construction sociale, de sorte que l'intégration des personnes qui ont une déficience requiert, au premier chef, la modification de l'environnement socio-économique dans lequel elles se trouvent²⁷. On remarque toutefois que le lien avec le droit à l'égalité est plus affirmé dans la jurisprudence canadienne que dans la jurisprudence française²⁸.

C. Les concepts d'aptitude et d'incapacité : des distinguos qui conditionnent, en France, les obligations de l'employeur

Si l'incapacité, la déficience et l'invalidité sont des notions assimilables pour la Cour suprême du Canada (en ce qui concerne leurs implications en matière d'accommodement) et que la notion de handicap est commune aux deux pays grâce à l'approche proposée par l'Organisation mondiale de la santé, la définition de l'incapacité est en revanche différente en France. Ses effets diffèrent selon celui qui constate cette incapacité, notamment en ce qui concerne le point de départ de l'obligation de reclassement de la part de l'employeur. Il faut donc ici approfondir les notions d'incapacité et d'inaptitude qui conditionneront, en France, le champ des obligations de l'employeur en matière de reclassement.

En France, il faut d'abord distinguer si l'incapacité est temporaire ou permanente. L'incapacité temporaire correspond au moment où le salarié perçoit des indemnités journalières par l'organisme de sécurité sociale, et sa période est délimitée par les arrêts de travail de son médecin traitant qui contrôle le médecin-conseil de l'assurance maladie²⁹. Quant à l'incapacité permanente, elle corres-

²³ *Loi n° 92-1446 du 31 décembre 1992*, J.O., 1^{er} janvier 1993, 23.

²⁴ Hubert Seillan, «L'inaptitude médicale à l'emploi occupé après la loi n° 92-1446 du 31 décembre 1992» (1993) *Actualité Législative Dalloz* 126.

²⁵ *Loi n° 2005-102 du 11 février 2005*, J.O., 12 février 2005, 2353.

²⁶ Laurence Péru-Pirotte, «La lutte contre les discriminations : loi n° 2008-496 du 27 mai 2008», *La Semaine Juridique Sociale* n° 23 (3 Juin 2008) 1314. L'auteure y précise que la *Loi n° 2008-496 du 27 mai 2008* transpose le concept de discrimination tel que défini par le droit communautaire. La loi prévoit également un meilleur dispositif de protection des victimes, ainsi qu'un réaménagement de la règle de preuve.

²⁷ Cette façon de différencier les facettes de la déficience qui se trouvent chez la personne elle-même (affection et limitation fonctionnelle) de celles qui résultent d'une construction sociale (le handicap) est approfondie par le professeur J. E. Bickenbach, *Physical Disability and Social Policy*, Toronto, University of Toronto Press, 1993. Voir également la classification internationale des handicaps de l'Organisation mondiale de la santé, disponible en anglais seulement : WHO. «International Classification of Functioning, Disability and Health (ICF)», en ligne : WHO <<http://www.who.int/classifications/icf/en/index.html>>.

²⁸ Voir notamment au Canada les arrêts *Granovsky c. Canada (ministre de l'Emploi et de l'Immigration)*, 2000 CSC 28, [2000] 1 R.C.S. 703 aux para. 34-35 et *Conseil des Canadiens avec déficiences c. VIA Rail Canada Inc.*, 2007 CSC 15, [2007] 1 R.C.S. 650 au para. 181.

²⁹ En l'occurrence, les médecins-conseil des organismes de sécurité sociale sont chargés, entre autres attributions,

pond au moment où la lésion se fixe et prend un caractère définitif, qui va de pair avec l'arrêt du versement des prestations temporaires³⁰, incitant à une reprise du travail par le salarié, mais sans incidence en soi sur une quelconque obligation de l'employeur (mise à part l'obligation de soumettre son salarié à une visite de reprise par le médecin du travail³¹). Le médecin-conseil est donc l'arbitre du champ de l'incapacité au travail³². Le médecin du travail a, quant à lui, la compétence exclusive (et incontournable pour l'employeur) de l'«aptitude au poste de travail», une notion spécifiquement française qui corrèle l'état de santé d'un salarié aux contraintes particulières d'un poste de travail. Ainsi, une adaptation de poste peut être demandée lors d'une incapacité, temporaire ou permanente, reconnue ou non par la Sécurité sociale, dès lors qu'elle est évoquée par le médecin du travail par l'entremise d'un avis d'aptitude avec réserves (*a fortiori* en cas d'inaptitude). D'ailleurs, à l'issue d'un arrêt de travail, le *Code du travail* français prévoit, sous certaines conditions, la nécessité d'une visite de reprise réalisée par le médecin du travail³³. L'avis d'aptitude alors émis peut être nuancé par des propositions d'adaptations de poste (ou aménagements), en fonction des contraintes propres du poste de travail, qui sont susceptibles d'être incompatibles avec l'état de santé du salarié.

Face à ces préconisations, l'employeur est tenu d'adapter le poste de travail de son salarié. Cette obligation d'adaptation au poste connaît un regain d'attention de la part des juges³⁴, compte tenu notamment de la montée en puissance de l'obligation de sécurité qui pèse sur l'employeur³⁵, et qui doit le conduire à offrir au salarié un environnement professionnel physiquement et psychologiquement adéquat. Ainsi, en vertu du contrat de travail le liant à son salarié, l'employeur est tenu envers celui-ci d'une obligation de sécurité de résultat, par exemple en ce qui concerne les maladies professionnelles contractées par ce salarié du fait des produits fabriqués ou utilisés par l'entreprise. Le manquement à cette obligation a le caractère d'une faute inexcusable, lorsque l'employeur avait ou aurait dû avoir conscience du danger auquel était exposé le salarié, et qu'il n'a pas pris les mesures nécessaires pour l'en préserver³⁶. L'employeur doit assurer l'effectivité de cette obligation de sécurité de résultat en matière de protection de la santé et de la sécurité des salariés, notamment en prenant en compte les mesures individuelles préconisées par le médecin du travail³⁷.

L'obligation d'adaptation est ainsi renforcée après un avis d'aptitude avec demande d'aménagement ou d'adaptation du poste de travail par le médecin du travail, car l'employeur se doit de respecter scrupuleusement ces préconisations³⁸ (sauf recours auprès de l'Inspection du travail), sous peine d'être systématiquement condamné, en cas de contentieux, pour rupture du contrat de

d'apprécier et de contrôler le droit aux prestations des assurés sociaux en arrêt de travail dans les cas de maladie personnelle, accident de travail ou maladie professionnelle.

³⁰ Cette phase peut éventuellement, en fonction de l'importance de l'incapacité, aboutir au versement d'une rente.

³¹ Le médecin du travail est un médecin salarié et indépendant de l'employeur qui outre son action sur le milieu de travail, a pour rôle médical de prévenir l'altération de la santé des salariés. Pour ce faire, il voit les salariés en visite médicale et émet un avis (pouvant être contesté) d'aptitude, d'aptitude avec aménagements préconisés ou d'inaptitude au poste de travail.

³² Carole Gayet, «Aptitude, invalidité : rôles respectifs du médecin du travail, du médecin-conseil et du médecin traitant. Pratiques et déontologie» (2005) 104 Documents pour le médecin du travail 441.

³³ Art. R. 4624-21 *Code du travail* français.

³⁴ Voir notamment les nombreux arrêts de la chambre sociale de la Cour de cassation en ce sens : Cass. soc., 9 juillet 2008, Bull. civ. 2008.V.169, n° 151, pourvoi n° 07-41318 [07-41318] ; Cass. soc., 21 mai 2008, pourvoi n° 07-41269 [Non publié au bulletin] ; Cass. soc., 21 mai 2008, pourvoi n° 07-41277 [Non publié au bulletin].

³⁵ Voir Sylvie Bourgeot et Michel Blatman, «De l'obligation de sécurité de l'employeur au droit à la santé des salariés» (2006) 6 Dr. soc. 653.

³⁶ Voir en ce sens l'abondante jurisprudence étayant cette obligation de sécurité de résultat et initiée par les 24 arrêts relatifs à l'exposition à l'amianté émis le 28 février 2002, dont Cass. soc., 28 février 2002, Bull. civ. 2002.V.74, n° 81, pourvoi n° 99-17201.

³⁷ «[L']employeur, tenu d'une obligation de sécurité de résultat en matière de protection de la santé et de la sécurité des travailleurs dans l'entreprise, doit en assurer l'effectivité en prenant en considération les propositions de mesures [individuelles] telles que mutations ou transformations de postes, justifiées par des considérations relatives à l'âge, à la résistance physique ou à l'état de santé des travailleurs que le médecin du travail est habilité à faire[.]». Cass. soc., 20 septembre 2006, pourvoi n° 05-42925 [Non publié au bulletin]. En accord avec Cass. soc., 19 décembre 2007, pourvoi n° 06-46134 [Non publié au bulletin].

³⁸ Voir Cass. soc., 19 décembre 2007, Bull. civ. 2007.V.231, n° 216, pourvoi n° 06-43918 (concernant un salarié dont l'aménagement de poste n'avait pas été effectué par l'employeur et qui avait été ensuite licencié pour diminution de productivité).

travail sans cause réelle et sérieuse. Par exemple, il ne pourra contester auprès du juge la validité de cet avis, ni l'excessivité des aménagements demandés ou encore la difficulté (ou le coût) de leur mise en œuvre. Pourtant, à l'heure actuelle, un avis d'inaptitude au poste antérieur implique une obligation particulière de reclassement dans le délai contraint d'un mois³⁹. Ainsi, l'obligation d'adaptation du poste en cas d'aptitude avec «réserves» ne semble pas devoir aller jusqu'au reclassement, qui n'est imposé que dans la seule hypothèse d'une inaptitude régulièrement constatée après deux visites médicales.

Il faut donc noter que la présence du médecin du travail est incontournable pour obtenir une adaptation ou un reclassement, puisque tout avis émanant d'un autre médecin n'entraînera, en France, aucune obligation pour l'employeur.

Au Canada, la définition de l'incapacité est, quant à elle, extensive, tandis que l'obligation d'accommodement raisonnable s'étend à toute altération de l'état de santé, peu importe qu'elle entraîne des limitations temporaires ou permanentes⁴⁰, dès que l'incapacité est entérinée par un certificat médical, quel que soit l'auteur de ce certificat, sous réserve d'une preuve médicale contradictoire apportée par l'employeur. Par contre, l'exercice du droit à l'accommodement raisonnable par les salariés victimes d'une lésion professionnelle peut présenter certaines limites, tel que nous l'avons exposé précédemment.

D. Des obligations s'imposant tardivement et limitées par les fondements même du contrat de travail

Est-ce à dire que ces obligations n'existent qu'en cas d'inaptitude en France ou de handicap au Canada, et qu'en aucun cas l'accommodement raisonnable ou le reclassement ne peuvent intervenir en amont, soit *avant* que l'état de santé ne s'altère, justement pour éviter (*prévenir*) l'altération de la santé du salarié ? Autrement dit, l'altération de la santé est-elle un préalable nécessaire pour obtenir un emploi adapté aux capacités et limites fonctionnelles du salarié ?

Ici encore, il faut distinguer entre les deux pays. En France, le médecin du travail peut intervenir en amont pour demander une adaptation du poste de travail, même sans incapacité «reconnue» administrativement. Cette possibilité n'est pas prévue explicitement au Canada, où seuls le droit au retrait préventif et le droit de refus, lorsqu'ils sont prévus dans les législations sur la santé et la sécurité au travail, sont susceptibles d'intervenir. Ces droits, lorsqu'ils existent, sont d'application très limitée⁴¹, comme c'est le cas en France⁴². Par contre, l'obligation d'accommodement canadienne entre en jeu dès que le salarié demande à son employeur, preuve médicale à l'appui, une adaptation de ses tâches en raison de son handicap.

En France, même si la loi⁴³, renforcée par la jurisprudence, impose à l'employeur une *adaptation* de poste face à toutes les remarques et préconisations du médecin du travail, l'obligation d'adaptation est moins exigeante en termes d'effort pour l'employeur, qu'un reclassement qui doit aller beaucoup plus loin dans la recherche de solutions. Dans les deux cas pourtant, il existe à l'origine une incapacité du salarié. Dans le premier cas, il s'agit d'une «aptitude conditionnelle» qui s'inscrit dans une démarche de maintien dans l'emploi, et dans le second, cette incapacité aboutit à un «avis d'inaptitude» dont les effets seront différents pour l'employeur. Ces distinctions n'existent

³⁹ Art. L. 1226-2 à 4 *Code du travail* français.

⁴⁰ Anne-Marie Laflamme, *supra* note 12 à la p. 141; Dominic Roux et Anne-Marie Laflamme, «Le droit de congédier un employé physiquement ou psychologiquement inapte : revu et corrigé par le droit à l'égalité et le droit au travail» (2008) 48 C. de D.189 aux pp. 197-99.

⁴¹ Dans les provinces canadiennes, le droit de refus est habituellement limité aux situations où le salarié a des motifs légitimes de croire que l'exécution d'une tâche l'expose à un danger pour sa santé, sa sécurité ou son intégrité physique. Au Québec, la loi reconnaît en outre le droit au retrait préventif pour le salarié exposé à un contaminant et dont l'état de santé présente des signes d'altération, ainsi qu'un droit au retrait préventif pour la salariée enceinte. Voir *Loi sur la santé et la sécurité du travail*, L.R.Q., S-2.1, art. 12, 32, 40 [LSST].

⁴² Le droit de retrait permet à un salarié de se retirer d'une situation de travail dont il a motif de penser qu'elle présente un danger grave et imminent. Si le salarié dispose d'une latitude d'appréciation, en revanche, il est peu utilisé face aux risques autres qu'accidentels. Voir Art. L. 4131-1 *Code du travail* français.

⁴³ Art. L. 4624-1 *Code du travail* français.

pas au Canada. Dans une perspective préventive, l'employeur français devrait être tenu à une obligation de même envergure à l'égard de tous ses salariés qui nécessitent une adaptation de leur poste ou de leurs conditions de travail en raison de leur état de santé, et ce, sans égard au fait qu'ils fassent l'objet d'une « aptitude conditionnelle » ou d'une déclaration d'inaptitude. Cette mesure favoriserait une meilleure adéquation entre le poste de travail du salarié et sa condition physique ou psychologique, de manière à éviter une détérioration de cet état, pour imposer, trop tardivement, un aménagement du poste.

Dans une perspective de prévention, il serait souhaitable que dans les deux pays des mesures plus explicites incitent les employeurs à adapter les postes et des conditions de travail à la physiologie des salariés. En France, certaines conventions collectives octroient expressément un tel avantage à certaines catégories de salariés, par exemple en cas d'intolérance au travail de nuit. C'est le cas notamment dans l'industrie laitière où il est prévu de réaffecter les salariés en poste de jour lorsque le travail de nuit ne leur est plus physiologiquement supportable. Au Canada, même si l'obligation d'accommodement paraît s'imposer dès que l'état de santé le requiert, c'est généralement l'altération de cet état qui engendre la mise en œuvre d'une mesure d'adaptation. Aussi, des textes explicites et plus ciblés offriraient une meilleure protection à l'ensemble des salariés⁴⁴.

Au demeurant, l'étendue de ces obligations soulève, dans les deux pays la question de l'apparente contradiction entre les droits du chef d'entreprise et ceux des salariés présentant une incapacité de travail. Dans les deux systèmes juridiques, l'employeur est libre de conclure un contrat de travail avec l'employé de son choix⁴⁵, sous réserve de ne pas enfreindre les lois d'ordre public ou les droits de la personne. Dans l'exercice de son pouvoir de direction, il peut choisir ses collaborateurs en fonction des besoins qu'il a identifiés en amont, et décider de l'organisation du travail dans un objectif d'efficacité et de productivité, avec les mêmes limites que précédemment. C'est dans cette perspective que le droit canadien reconnaît à l'employeur le droit de justifier une règle apparemment discriminatoire en invoquant la défense d'exigence professionnelle justifiée⁴⁶.

La conciliation des obligations d'accommodement raisonnable et de reclassement avec les objectifs d'efficacité et de productivité de toute entreprise nécessite donc, afin de ne pas corrompre ces notions, de définir leur objectif et leurs limites. Ces tentatives de délimitation caractérisent tant le droit canadien que le droit français, mais paraissent plus complètes dans la jurisprudence canadienne. Cette situation est de nature à mieux asseoir la vocation première de cette obligation d'accommodement, mais aussi à mieux circonscrire, au Canada, l'étendue des obligations des employeurs et des salariés (et de leur syndicat, le cas échéant), et donc à définir plus précisément le rôle et les responsabilités de ces acteurs. Néanmoins, ces balises restent mouvantes et font l'objet de constants remaniements sous la pression respective de chacun.

II

LES CONTOURS DES NOTIONS D'ACCOMMODEMENT ET DE RECLASSEMENT

Au Canada, les limites de l'obligation d'accommodement, mieux définies, sont le fruit d'une longue évolution jurisprudentielle qui contraste avec les décisions peu élaborées issues de la jurisprudence française (II.A). La recherche d'une solution d'accommodement ou de reclassement est également influencée selon le rôle joué par les autres acteurs du milieu du travail, soit les salariés et les instances qui les représentent (II.B).

⁴⁴ Au Québec, l'article 51 de la *LSST* impose à l'employeur l'obligation de prendre les mesures nécessaires afin de protéger la santé, la sécurité et l'intégrité physique du travailleur. Cette obligation de nature préventive pourrait servir d'assise à une obligation d'adaptation des postes et des conditions de travail, avant que l'altération de l'état de santé ne survienne. *LSST*, *supra* note 41, art. 51.

⁴⁵ Fernand Morin, Jean-Yves Brière et Dominic Roux, *Le droit de l'emploi au Québec*, 3^e éd., Montréal, Wilson et Lafleur, 2006, aux pp. 185-197.

⁴⁶ Comme nous l'avons précisé antérieurement, ce moyen de défense est prévu dans toutes les lois provinciales sur les droits de la personne ainsi que dans la *Loi canadienne sur les droits de la personne*, *supra* note 3, art. 15(1)(a).

A. La mise en œuvre de l'obligation d'accommodement canadienne et de l'obligation française de reclassement : des limites mieux définies en droit canadien

Au Canada, l'employeur peut justifier sa norme d'emploi, discriminatoire *a priori*, en démontrant qu'il s'agit d'une exigence professionnelle justifiée, ce qui nécessite la preuve qu'il a satisfait à son obligation d'accommodement raisonnable. En effet, dès lors que les exigences professionnelles sont rationnelles, édictées de bonne foi, raisonnables et nécessaires, elles ne sont pas discriminatoires si l'employeur a tenté, en outre, d'accommoder le salarié handicapé jusqu'à la limite de la contrainte excessive avant de décréter l'impossibilité de maintenir le lien d'emploi.

Le corolaire en France est la notion de libre choix de ses collaborateurs par l'employeur, dans l'exercice de son pouvoir de direction, sous réserve de la seule limite liée à l'interdiction de discrimination. Au demeurant, la comparaison du droit canadien et du droit français laisse apparaître, à la charge du deuxième, le sentiment d'une obligation aux contours plus incertains, délétère quant à l'effectivité du dispositif et donc au maintien du salarié dans son emploi.

S'il existe au Canada des «critères» permettant de circonscrire l'accommodement raisonnable, en revanche ils sont beaucoup plus informels en France s'agissant de l'obligation de reclassement. Il se dessine une jurisprudence plus floue dans la mesure où cette obligation de reclassement est large et incertaine dans ses limites, ce qui nuit à la sécurité juridique de cet édifice jurisprudentiel⁴⁷. Au-delà, on peut s'interroger sur le fait qu'à trop vouloir étendre ces obligations, elles ne puissent jamais être exécutées convenablement au regard des exigences accrues de la part des juges⁴⁸ et que, de ce fait, elles ne fassent même plus l'objet d'un réel effort de la part des employeurs convaincus d'être systématiquement accusés d'insuffisance et condamnés au versement d'une indemnité de licenciement pour rupture du contrat de travail sans cause réelle et sérieuse. Le risque étant qu'en repoussant toujours plus loin l'obligation de reclassement, en sanctionnant quasi systématiquement l'employeur pour ne pas avoir déployé suffisamment d'efforts, l'effet paradoxal soit l'asphyxie pure et simple de ces obligations.

Ainsi, en France, le reclassement proposé au salarié doit en premier lieu tenir compte des conseils du médecin du travail et être aussi proche que possible du statut et du salaire antérieurs du salarié. Ce n'est que si ces conditions ne peuvent être réunies que l'employeur a alors entière latitude pour proposer au salarié toute solution, y compris son reclassement dans un autre établissement de l'entreprise, une mutation géographique emportant ou non modification de son contrat de travail (c'est-à-dire touchant à son statut, son salaire, son lieu et son temps de travail, etc.). Il doit pouvoir tout examiner, faire preuve de créativité et surtout, pouvoir établir la réalité de ses recherches en cas de contentieux ultérieur. On pourrait ainsi parler d'une obligation de moyens renforcée⁴⁹.

Plusieurs arrêts de la Cour de cassation réaffirment l'obligation de reclassement de l'employeur et son intensité, allant même de façon réitérée jusqu'à dire que l'avis du médecin du travail concluant à l'inaptitude du salarié à tout emploi dans l'entreprise ne dispense pas l'employeur de rechercher une possibilité de reclassement au sein de l'entreprise et du groupe auquel elle appartient, le tout suivant un principe voulant que l'inaptitude à tout emploi dans l'entreprise n'emporte nullement l'inaptitude au travail⁵⁰. Dans une affaire récente⁵¹, l'employeur justifie de l'impossibilité de reclas-

⁴⁷ Jean Savatier, «Inaptitude physique. Obligation de reclassement. Refus par le salarié du poste de reclassement proposé. Caractère abusif», (2008) 5 Dr. soc. 614.

⁴⁸ Pierre-Yves Verkindt, «Recherche de reclassement du salarié médicalement inapte à son poste : la Cour de cassation persiste (Cass. soc., 26 nov. 2008)» (2009) 7 La Semaine Juridique — Social 31 (Jurisprudence n° 1065) [Verkindt, «Recherche»].

⁴⁹ P.-Y. Verkindt, «La maladie du salarié et la poursuite de la relation de travail», (1998) 8 *Travail et Protection sociale* 4 ; Sylvie Bourgeot, «Les avis d'aptitude du médecin du travail» *Liaisons Sociales* n° 925 (4 oct. 2005).

⁵⁰ Trois arrêts de la Cour de cassation en date du 7 juillet 2004 opèrent un revirement sur l'obligation de reclassement d'un salarié déclaré inapte par le médecin du travail. L'essentiel de ces arrêts indique que l'avis du médecin du travail déclarant un salarié inapte à tout emploi dans l'entreprise ne dispense pas l'employeur de rechercher une possibilité de reclassement au sein de l'entreprise au besoin par la mise en œuvre de mesures telles que mutations, transformations de poste ou aménagement du temps de travail. Cass. soc., 7 juillet 2004, Bull. civ. 2004.V.183, n° 195, pourvoi n° 02-42891 ; Cass. soc., 7 juillet 2004, Bull. civ. 2004.V.185, n° 197, pourvoi n° 02-43141 ; Cass. soc., 7 juillet 2004, Bull. civ. 2004.V.185, n° 198, pourvoi n° 02-45350.

sement de son salarié, d'une part, par le classement de ce dernier en invalidité de deuxième catégorie par l'organisme de sécurité sociale (qui l'a donc médicalement reconnu comme «invalide absolument incapable d'exercer une activité professionnelle quelconque»⁵²), d'autre part, par les conclusions du médecin du travail qui a médicalement constaté l'inaptitude du salarié à «toute reprise du travail dans l'entreprise»⁵³, autrement dit, une incapacité totale de travail. Pour autant, cet argumentaire logique ne convainc pas la plus haute cour puisqu'elle répond qu'un tel avis «ne dispense pas l'employeur d'établir qu'il s'est trouvé dans l'impossibilité de reclasser le salarié au sein de l'entreprise et le cas échéant au sein du groupe auquel elle appartient, au besoin par des mesures telles que mutations, transformations de poste de travail ou aménagements du temps de travail»⁵⁴.

En somme, les seules limites aujourd'hui identifiées au sein de l'abondante jurisprudence française, sont la trop petite taille de l'entreprise et une très sérieuse argumentation de l'impossibilité de reclassement compte tenu de critères jugés *in concreto* par les juges, mais malheureusement non énumérés. Ainsi, pour la première fois à notre connaissance dans ce type d'affaires, un arrêt de la Cour de cassation⁵⁵ admet que l'intérêt économique de l'entreprise est un argument sérieux de l'employeur. Dans l'une des rares décisions ayant débouté un salarié, la Cour de cassation jugea en effet que l'employeur d'une toute petite entreprise n'était pas tenu de reclasser un carreur qui ne pouvait plus ni se mettre à genou, ni porter des charges lourdes, au regard de la faiblesse des effectifs de l'entreprise ainsi que de l'organisation et de la spécificité du travail à accomplir (sans autre précision). La Cour mentionne qu'en l'espèce, l'aménagement d'un poste qui soit à la fois adapté à l'état de santé du salarié et compatible à long terme avec le bon fonctionnement de l'entreprise est manifestement impossible. Ainsi, dans cette décision, le tribunal impose une limite à l'obligation de reclassement qui rejoint la notion de contrainte excessive développée en droit canadien, comme nous le verrons plus loin. Toutefois, si quelques rares arrêts viennent circonscrire l'obligation de reclassement, aucun critère précis ne peut encore à l'heure actuelle être systématiquement répertorié.

C'est ici que réside la principale différence du droit français avec le droit canadien et surtout, l'intérêt de cette réflexion commune. En effet, des recoupements existent et il est intéressant de les énoncer qualitativement car, tel un faisceau d'arguments, ils sont aussi (même si de façon moins formelle en France) des critères communs d'appréciation par les juges français et canadiens. Ces derniers n'imposent généralement pas, par exemple et en l'état actuel de la jurisprudence, la création de toute pièce d'un nouveau poste de travail⁵⁶. Par ailleurs, et surtout, ils délimitent plus précisément à la fois les obligations de l'employeur, mais aussi leurs limites, grâce à la notion de «contrainte excessive». Chaque balise ainsi fixée contribue à mieux délimiter un objectif à atteindre et non à éloigner un but inaccessible.

Ainsi, au Canada, la notion de contrainte excessive, introduite par la Cour suprême, est venue limiter les obligations de l'employeur. On trouve d'abord un indice des critères constituant la contrainte excessive dans l'arrêt *Simpsons-Sears*, où furent retenus comme éléments pertinents l'entrave induite à l'exploitation de l'entreprise et les coûts excessifs. Dans cette affaire, où la Cour suprême consacrait pour la première fois l'obligation d'accommodement, il fut décidé que l'employeur n'avait pas démontré que la demande d'une vendeuse à temps complet pour être dispensée de tra-

⁵¹ 07-41318, *supra* note 34.

⁵² *Ibid.* à la p. 170.

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ Voir Cass. soc., 31 octobre 2007, pourvoi n° 06-45204 [Non publié au bulletin].

⁵⁶ Voir notamment, au sujet de la jurisprudence québécoise : Anne Pineau, «L'accommodement raisonnable en milieu de travail» (juin 2007), en ligne : Archive.org <<http://web.archive.org/web/20080318064553/http://www.csn.qc.ca/Bulletinsjuridiques/bullejuri-juino7.html>> (l'article n'est pas actuellement disponible sur le site de la Confédération des syndicats nationaux); Jean-Pierre Villaggi et Jean-Yves Brière, «L'obligation d'accommodement de l'employeur : un nouveau paradigme», dans Barreau du Québec, Service de la formation permanente, *Développements récents en droit du travail* (2000), Cowansville (Qc), Yvon Blais, 2000, 219, aux pp. 242-43; Christian Brunelle, *Discrimination et obligation d'accommodement en milieu de travail syndiqué*, Cowansville, Éditions Yvon Blais, 2001, à la p. 305 [Brunelle, *Discrimination*]; Anne-Marie Laflamme, *supra* note 12 à la p. 148. Pour la jurisprudence ontarienne : Michael Lynk, «Disability and the Duty to Accommodate : An Arbitrator's Perspective» dans Kevin Whitaker et al., dir, *Labour Arbitration Yearbook* (2001-2002), vol. 1, Toronto, Lancaster House, 2002, 51 aux pp. 76 à 78.

vailler le vendredi soir et le samedi en raison de motifs religieux lui imposait une contrainte excessive⁵⁷.

Par la suite, dans l'affaire *Central Alberta Dairy Pool*⁵⁸, la Cour suprême du Canada énuméra de façon non exhaustive certains facteurs permettant d'apprécier la notion de contrainte excessive. Elle mentionna le coût financier, l'atteinte à la convention collective, le moral du personnel, l'interchangeabilité des effectifs et des installations, la taille de l'entreprise et les risques à la santé et à la sécurité⁵⁹. La Cour se pencha de nouveau sur la notion de contrainte excessive dans l'arrêt *Renaud*⁶⁰, une autre affaire impliquant une modification de l'horaire de travail pour des motifs religieux. Reprenant les critères qu'elle avait énoncés précédemment, la Cour suprême précisa qu'il fallait plus qu'une atteinte ou un inconvénient minime pour rencontrer la notion de contrainte excessive⁶¹. Aussi, elle rejeta l'argument de l'employeur selon lequel l'accommodement ne pouvait être consenti parce qu'il portait atteinte aux droits d'autres employés, tout en précisant que les dispositions d'une convention collective ne dispensaient pas l'employeur de son obligation d'accommodement raisonnable. La Cour suprême ajouta que le syndicat avait également des obligations en cette matière, non seulement celle de s'assurer que la convention collective n'est pas discriminatoire en soi, mais également celle de participer avec l'employeur à la recherche d'un compromis raisonnable⁶².

En somme, selon la Cour suprême du Canada, la contrainte excessive doit causer bien davantage que de simples difficultés, inconvénients ou désagréments. Dans l'arrêt *Meiorin*, elle rejeta la défense d'exigence professionnelle justifiée au motif que l'employeur n'avait effectué aucune preuve concernant les coûts de l'accommodement, ni démontré l'existence de risques graves pour la sécurité de la salariée, de ses collègues ou du public en général, qui découlerait d'une modulation de la norme d'aptitude physique imposée aux pompiers forestiers afin de tenir compte de la capacité aérobie des femmes. La Cour repoussa également l'argument de l'employeur selon lequel le fait de composer avec la salariée minerait le moral des autres employés, en l'absence de toute preuve d'atteinte réelle aux droits de ces derniers⁶³.

Dans son ouvrage consacré à l'accommodement raisonnable en milieu de travail syndiqué⁶⁴, le professeur Christian Brunelle résume comme suit les principaux critères dégagés par la législation, la jurisprudence et la doctrine canadiennes permettant d'évaluer la présence d'une contrainte excessive :

- 1) Les limites aux ressources financières et matérielles, en tenant compte du coût réel de l'accommodement demandé, des sources extérieures de financement, de la nature de l'entreprise, de son budget total d'opération (maison-mère et filiales réunies), de sa santé financière et de la conjoncture économique ;
- 2) L'atteinte aux droits, et en particulier les risques pour la santé ou la sécurité du salarié, de ses collègues ou du public, l'atteinte à la convention collective, l'effet préjudiciable de l'accommodement sur les autres employés et les conflits de droits, dans la mesure toutefois où telles atteintes ne sont pas anodines, mais réelles et importantes ;
- 3) Les limites associées au bon fonctionnement de l'entreprise, telles que l'interchangeabilité relative des employés, l'adaptabilité des lieux, installations et équipements de travail, l'effet sur la productivité de l'entreprise, le nombre d'employés affectés par la mesure d'accommodement envisagée, l'effet bénéfique de l'accommodement sur les autres employés, la durée et l'étendue de l'accommodement...⁶⁵

⁵⁷ *Simpsons-Sears*, supra note 8, à la p. 555.

⁵⁸ *Central Alberta Dairy Pool c. Alberta (Human Rights Commission)*, [1990] 2 R.C.S. 489 [*Central Alberta Dairy Pool*].

⁵⁹ *Ibid.* aux pp. 520-21.

⁶⁰ *Central Okanagan School District no 23 c. Renaud*, [1992] 2 R.C.S. 970 [*Renaud*].

⁶¹ *Ibid.* aux pp. 984-85. La liste des facteurs énumérés dans *Central Alberta Dairy Pool* a également été reprise par la Cour suprême du Canada dans l'arrêt *Commission scolaire régionale de Chambly c. Bergevin*, [1994] 2 R.C.S. 525 aux pp. 545-46 [*Bergevin*]. *Central Alberta Dairy Pool*, supra note 58.

⁶² *Renaud*, supra note 60 à la p. 993.

⁶³ *Meiorin*, supra note 9, aux pp. 42-43.

⁶⁴ Brunelle, *Discrimination*, supra note 56.

⁶⁵ *Ibid.* aux pp. 248 à 251 (les références ont été omises).

En fonction de ces paramètres, certains facteurs ont ainsi été considérés comme constituant une contrainte excessive, par exemple le risque grave et objectif d'atteinte à la santé ou à la sécurité de l'employé, de ses collègues de travail ou du public⁶⁶. Par contre, d'autres facteurs ont été jugés peu probants et donc carrément exclus de ce qu'est la contrainte excessive. Ainsi en est-il des arguments fondés sur la commodité administrative, les préférences de la clientèle et la crainte de créer un précédent⁶⁷.

Dans le cas où l'employé est inapte à effectuer certaines tâches secondaires de son emploi tout en demeurant capable d'en effectuer les tâches essentielles⁶⁸, l'employeur doit, comme en France, trouver une mesure d'adaptation. De même, si l'incapacité de l'employé d'accomplir les tâches essentielles de son emploi est d'une durée limitée dans le temps, l'employeur pourra généralement trouver une mesure d'accommodement temporaire sans que cela ne constitue une contrainte excessive⁶⁹. La formule pourrait être reprise utilement en droit français et conduirait les médecins du travail à inscrire systématiquement une durée prévisible (et limitée) à leurs réserves d'aptitude, surtout quand celles-ci touchent aux fonctions essentielles de l'emploi.

Ces tentatives de délimitation plus précise des contours de l'obligation de l'employeur en matière d'accommodement ne nous semblent aucunement constituer un frein à l'ambition initiale de ces constructions juridiques ; bien au contraire, elles sont porteuses de davantage de sécurité juridique, et ceci, tant pour l'employeur que pour le salarié. De plus, elles suscitent une démarche plus méthodique dans la recherche d'une solution d'accommodement.

Dans tous les cas, au Canada, le fardeau de la preuve demeure lourd et c'est à celui à qui l'acte discriminatoire est imputable (généralement l'employeur, mais le syndicat peut aussi être conjointement responsable de la discrimination) qu'il appartient de faire la preuve que la mise en œuvre d'une mesure d'accommodement l'exposerait à une contrainte excessive. Ce n'est pas au salarié de prouver que l'accommodement qu'il réclame est raisonnable :

[L]e demandeur n'aura pas à prouver que sa demande d'accommodement est raisonnable. Il reviendra plutôt au défendeur — tantôt l'employeur, tantôt le syndicat, tantôt les deux, selon le cas — d'établir, par une preuve factuelle étoffée et non des hypothèses fondées sur des stéréotypes ou des impressions, que la mesure d'accommodement sollicitée est déraisonnable du fait que sa mise en œuvre l'exposerait à une contrainte excessive. En ce sens, l'obligation d'accommodement raisonnable est un moyen de défense ou encore un moyen de limiter sa responsabilité⁷⁰.

Par ailleurs, la preuve d'une contrainte excessive doit être objective, réelle, et directe lorsqu'il s'agit de coûts, quantifiable. Les preuves matérielles peuvent notamment inclure les éléments suivants : l'état financier du groupe, des données scientifiques pour appuyer un argument voulant que l'adaptation proposée cause réellement un préjudice injustifié, au besoin à l'aide d'une expertise (cela n'est jamais demandé en France), des renseignements détaillés sur l'activité et l'adaptation demandée et sur les conditions de travail et leurs effets sur la personne présentant une incapacité⁷¹.

Récemment, la Cour suprême du Canada a toutefois rappelé que l'obligation d'accommodement n'était ni absolue ni illimitée⁷², et qu'elle n'avait pas pour objet de dénaturer l'essence du contrat de

⁶⁶ *Central Alberta Dairy Pool*, supra note 58 à la p. 521.

⁶⁷ Brunelle, *Discrimination*, supra note 56 aux pp. 243-51.

⁶⁸ Voir notamment *Commission des droits de la personne et des droits de la jeunesse c. Emballage Polystar inc.*, 1996 CanLII 3306, D.T.E. 96T-873 (T.D.P.Q.).

⁶⁹ Brunelle, *Discrimination*, supra note 56 à la p. 290.

⁷⁰ *Ibid.* à la p. 245. Notons toutefois que la Cour suprême du Canada a récemment apporté un tempérament à cette règle lorsque la convention collective contient une clause concédant une mesure d'accommodement, comme par exemple une clause prévoyant la perte d'emploi au terme d'une période d'absence continue prédéterminée. Selon la Cour, la présence d'une telle clause ferait preuve du délai au-delà duquel l'employeur est susceptible de subir une contrainte excessive, de sorte qu'il y aurait renversement de preuve sur les épaules du salarié (et de son syndicat). Voir *Centre universitaire de santé McGill (Hôpital général de Montréal) c. Syndicat des employés de l'Hôpital général de Montréal*, [2007] 1 R.C.S. 161 [*Centre universitaire de santé McGill*].

⁷¹ Voir notamment Ontario, Commission ontarienne des droits de la personne, *Politique et directives concernant le handicap et l'obligation d'accommodement*, 23 novembre 2000 au para. 4 <<http://www.ohrc.on.ca>>.

⁷² *Centre universitaire de santé McGill*, supra note 70 au para. 38.

travail, soit l'obligation de fournir, contre rémunération, une prestation de travail⁷³. Dans l'arrêt *Hydro-Québec*, la Cour suprême déclare que l'employeur a satisfait à son obligation d'accommodement à l'égard d'une salariée souffrant d'absentéisme chronique et dont il avait tenté d'adapter les conditions de travail pendant plusieurs années, puisque celle-ci demeurait, selon toutes probabilités, incapable de fournir une prestation de travail normale⁷⁴. La Cour ajoute que la notion de contrainte excessive doit s'évaluer en considérant l'ensemble des mesures mises en place par l'employeur à compter du début de l'invalidité⁷⁵. Elle rappelle que les mesures d'accommodement ont pour objectif de permettre à l'employé capable de travailler de le faire : ainsi, si l'employeur peut, sans en subir de contrainte excessive, assouplir l'horaire ou la tâche du salarié, voire procéder à des déplacements de personnel de manière à lui permettre de fournir sa prestation de travail, il devra l'accommoder. Toutefois, si l'employeur démontre que malgré les accommodements, l'employé ne sera pas en mesure de fournir sa prestation de travail dans un avenir raisonnablement prévisible, il aura satisfait à son fardeau de preuve et aura établi l'existence d'une contrainte excessive⁷⁶.

Les orientations jurisprudentielles canadiennes énoncées par l'arrêt *Hydro-Québec* diffèrent des positions françaises. En effet, il n'a jamais été explicitement dit par les juges français que l'obligation de reclassement n'était ni absolue, ni illimitée et qu'elle ne devait pas dénaturer le contrat de travail. Par ailleurs, la Cour suprême du Canada tient compte de l'ensemble des efforts faits par l'employeur depuis le début de l'invalidité alors qu'en France, seuls les efforts faits après la deuxième visite d'inaptitude comptent⁷⁷. Enfin, il est clair dans la jurisprudence canadienne que le salarié doit encore être capable de travailler, ce que n'affirme absolument pas la jurisprudence française, qui semble même entretenir une certaine ambiguïté sur ce point puisque même en présence d'un salarié considéré incapable de tout travail (en situation d'invalidité pour le médecin-conseil, donc), l'employeur doit tenter de le reclasser.

En somme, si dans les deux pays, la charge de la preuve repose de la même manière sur les épaules de l'employeur, il semble que le niveau d'exigence en France soit plus élevé sans pour autant être explicitement formalisé par les juges. Ce niveau d'exigence se révèle à travers les décisions rendues *in concreto* par les juges, en tenant compte des faits objectifs qui leur sont présentés⁷⁸. En ce sens, en l'absence d'élément objectif (et vérifiable), le juge estime que l'effort de reclassement n'a pas été suffisant et sanctionne le licenciement subséquent pour absence de cause réelle et sérieuse, ce qui entraîne, non pas la réintégration en emploi, mais le versement de dommages-intérêts. Dans le cadre d'un arrêt du 6 février 2008⁷⁹, la Cour de cassation a rappelé que c'est à l'employeur de prouver qu'il a mis en oeuvre tous les moyens pertinents dont il dispose pour tenter de remplir son obligation de reclassement. Aussi, dans l'éventualité d'un litige, il doit donc ménager les preuves de sa recherche et pouvoir justifier de l'impossibilité de reclassement. N'y aurait-il pas alors matière à ce que les employeurs ne concentrent tous leurs efforts dans la constitution d'un « dossier » irréprochable aux yeux des juges plutôt que sur un effort réel de reclassement ? Et que l'obligation de reclassement ne devienne que pure formalité ? Ce risque pourrait être relativisé grâce à la participation et à la vigilance des autres acteurs de l'entreprise.

⁷³ *Hydro-Québec c. Syndicat des employé-e-s de techniques professionnelles et de bureau d'Hydro-Québec, section locale 2000 (SCFP-FTQ)*, 2008 CSC 43 au para. 15 [*Hydro-Québec*].

⁷⁴ *Ibid.* aux para. 18, 19 et 22.

⁷⁵ *Ibid.* au para. 21. La Cour appliquait ici le raisonnement qu'elle avait tenu l'année précédente dans l'arrêt *Centre universitaire de santé McGill*, *supra* note 70 au para. 33.

⁷⁶ *Hydro-Québec*, *supra* note 73 aux para. 17-18.

⁷⁷ Voir Verkindt, « Recherche », *supra* note 48 où l'auteur estime que les efforts fournis par l'employeur avant la deuxième visite d'inaptitude sont négligés par les juges.

⁷⁸ À titre d'exemple, dans Cass. soc., 20 février 2008, pourvoi n° 06-45335 [Non publié au bulletin], la Cour de cassation a précisé que les entreprises exerçant leur activité sous une même enseigne commerciale, dans le cadre d'un contrat de franchise, ne sont pas nécessairement exclues du périmètre de l'obligation de reclassement du salarié inapte, le critère essentiel étant la recherche de possibilité de permutation du personnel pour les entreprises franchisées. Par ailleurs, dans l'arrêt Cass. soc., 6 février 2008, n° 06-43944 [Non publié au bulletin], la Cour de cassation a sanctionné l'employeur qui s'était borné à rechercher les postes de reclassement situés à proximité du domicile du salarié.

⁷⁹ Cass. soc., 6 février 2008, pourvoi n° 06-44898 [Non publié au bulletin].

B. Les obligations du salarié et le rôle des instances syndicales et des représentations du personnel

En ce qui concerne le salarié, la jurisprudence canadienne estime qu'il doit faire preuve de souplesse dans la recherche d'une solution, qu'il est tenu d'en faciliter la mise en œuvre sans s'attendre à une solution parfaite⁸⁰ et qu'il doit être prêt à certaines concessions comme un changement de poste ou d'horaire sans faire preuve de trop de rigidité et en collaborant⁸¹. Ainsi, «la plaignante ne peut, selon sa seule volonté, choisir le poste qu'elle souhaiterait détenir comme s'il s'agissait d'un 'libre service'»⁸² !

En France, une solution similaire est adoptée, mais rarement énoncée de façon aussi explicite. S'il est à l'origine de l'échec du maintien ou du retour à l'emploi, toute plainte ultérieure du salarié canadien sera rejetée. Il en va de même en France, avec cette différence importante cependant qu'un tel refus de reclassement, même abusif, ne peut constituer, en soi, un motif de licenciement disciplinaire⁸³.

Au Canada, le syndicat n'est pas, quant à lui, un simple spectateur en matière d'accommodement⁸⁴. Évidemment, le monopole de représentation dont il jouit impose son implication dans la recherche d'un accommodement raisonnable. Il peut en effet être tenu responsable des effets discriminatoires d'une règle donnée soit à titre de coauteur, avec l'employeur, de la discrimination (si par exemple la discrimination découle d'une règle inscrite à la convention collective) ou encore s'il fait défaut de collaborer à la recherche d'une solution visant à remédier à la discrimination⁸⁵. Il peut également intervenir pour la défense des intérêts collectifs, par exemple vis-à-vis d'une mesure qui brimerait les droits des autres employés, pour le respect de la convention collective négociée⁸⁶. L'obligation d'accommodement est donc une obligation qui se discute, à la fois avec le salarié, mais également avec le syndicat qui le représente⁸⁷.

En France, les partenaires sociaux n'ont que peu à dire à ce sujet. Leur consultation est explicitement et uniquement prévue⁸⁸ dans la recherche d'un reclassement d'un salarié inapte en raison d'une lésion professionnelle. Encore convient-il de noter que seuls les délégués du personnel sont fondés à intervenir à l'exclusion de tout autre représentant (comité d'entreprise, comité d'hygiène, de sécurité et des conditions de travail, délégué syndical). Si une concertation avec les membres de la représentation du personnel n'est pas interdite, elle ne s'impose nullement et n'est pas encouragée par la jurisprudence, ce qui rend cette concertation marginale. Elle serait pourtant sans doute porteuse de réflexions croisées enrichissantes, et surtout elle pourrait être garante des efforts réellement effectués par l'employeur.

⁸⁰ *Renaud*, supra note 60 aux pp. 994-95.

⁸¹ Pour des exemples concrets où l'on a sanctionné l'obligation de collaborer du salarié, voir les décisions suivantes rendues au Québec : *Syndicat des travailleuses et travailleurs Intragaz – CSN c. Fortin*, 2006 QCCS 969, AZ-50357422, D.T.E. 2006T-301 (C.S.), autorisation de pourvoi à la C.A. rejetée, 2006 QCCA 834 ; *Syndicat canadien de la fonction publique, section locale 940 et Côte St-Luc (Ville de)*, AZ-50397162, D.T.E. 2006T-1056 (T.A.) ; *Société canadienne des postes et Syndicat des travailleuses et travailleurs des postes*, AZ-50411684, D.T.E. 2007T-138 ; *Termaco ltée et Métallurgistes unis d'Amérique, section locale 8896*, 2006 CanLII 32332, AZ-50377041, D.T.E. 2006T-617 (T.A.).

⁸² Ce passage est tiré d'une décision arbitrale rendue au Québec : *Syndicat des fonctionnaires municipaux de Montréal (SCFP) et Montréal (Ville de)*, AZ-50399778, D.T.E. 2007T-30 au para. 7 (T.A.).

⁸³ Voir Cass. soc., 12 janvier 2005, n° 02-44643 [Non publié au bulletin] (en soi, le simple refus d'une proposition de reclassement ne peut suffire à licencier un salarié sans indemnité).

⁸⁴ La Cour suprême du Canada a en effet reconnu que le devoir d'accommodement pouvait également incomber, selon les circonstances, aux organisations syndicales. Voir *Renaud*, supra note 60 à la p. 993.

⁸⁵ Brunelle, *Discrimination*, supra note 56 aux pp. 238-39.

⁸⁶ Sous réserve toutefois que l'on soit en présence d'une atteinte réelle, non pas anodine mais importante, aux droits d'autres salariés : voir *Renaud*, supra note 60 aux pp. 984-85.

⁸⁷ À titre d'exemple, le fait de procéder sans consulter le salarié et son syndicat a été sanctionné dans une décision arbitrale québécoise récente : *Syndicat des travailleuses et travailleurs des Papiers Perkins ltée (FTPF-CSN) et Cascades Groupe tissu (usine de Laval)*, AZ-50368590, D.T.E. 2006T-597 (T.A.). Sur le rôle que les syndicats sont appelés à jouer en matière de droit à l'égalité, voir Christian Brunelle, «Le droit à l'accommodement raisonnable dans les milieux de travail syndiqués : une invasion barbare ?» dans M. Jézéquel, dir., *Les accommodements raisonnables : quoi, comment, jusqu'où ?*, Cowansville, Yvon Blais, 2007 aux p. 51-83.

⁸⁸ Art. L. 1226-10 *Code du travail* français.

CONCLUSION

L'histoire du droit du travail a déjà démontré sa capacité à évoluer et à s'adapter, grâce en particulier à sa jurisprudence pragmatique⁸⁹. Pourtant, le périmètre des obligations d'accommodement et de reclassement face à un salarié présentant une incapacité physique et psychologique reste difficile à circonscrire⁹⁰. Si certains auteurs et tribunaux considèrent que cette obligation confère aux employés handicapés un véritable droit au maintien du lien d'emploi, cette opinion ne fait pas nécessairement l'unanimité. Au demeurant, il s'agit d'une obligation de moyens et non d'une obligation de résultat. À cet égard les paramètres établis dans le droit canadien favorisent une démarche systématique afin de tout mettre en œuvre pour trouver une solution d'accommodement satisfaisante pour tous, pour autant que cette mesure permette au salarié de fournir sa prestation de travail.

Au surplus, le rôle joué par les salariés et par l'acteur syndical, auquel la jurisprudence canadienne a imputé une responsabilité particulière en matière d'accommodement raisonnable, favorise la recherche d'une solution de maintien dans l'emploi. Car c'est bien de cela qu'il s'agit; protéger la dignité du salarié victime d'une incapacité, non pas en lui versant des indemnités de licenciement ou d'invalidité, mais en lui permettant de demeurer réellement actif sur le marché du travail, ce lieu privilégié d'accomplissement personnel et social.

La comparaison des systèmes français et canadiens montre l'intérêt d'une confrontation des solutions dans un contexte où l'évolution démographique, les transformations économiques et leur impact sur l'organisation et les conditions de travail devraient faire de la question du maintien en emploi des travailleurs fragilisés par leur état de santé, une question primordiale.

⁸⁹ Jean Emmanuel Ray, *Droit du travail, droit vivant*, 17^e éd., Reuil-Malmaison, Groupe Liaisons, Collection Droit vivant, 2008, p. 11-14.

⁹⁰ Pierre Yves Verkindt, «Le licenciement pour inaptitude médicale», (2008) 9-10 Dr. soc. 941.

LOST IN TRANSLATION?: THE DISABILITY PERSPECTIVE IN HONDA V. KEAYS AND HYDRO-QUÉBEC V. SYNDICAT

*Judith Mosoff**

Two recent decisions from the Supreme Court of Canada, Honda Canada Inc. v. Keays and Hydro-Québec v. Syndicat des employé-e-s de techniques professionnelles et de bureau d'Hydro-Québec raise concerns about the extent of human rights protections for employees with disabilities. In this comment the author argues that when disabilities do not fit neatly into a standard medical framework such as the conditions of chronic fatigue syndrome or mental illness, there is a tendency to disbelieve the employee, not take the individual seriously, or set out special regimes for confirmation. With a focus on the employment contract rather than discrimination, the author argues that an analysis of human rights obligations was virtually absent in the employment law context. In the labour law context, the Court gave no real guidance about the meaning of undue hardship. The author suggests that these cases do not reflect the broad vision of an inclusive workplace previously set out in Meiorin.

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INTRODUCTION

Nearly ten years ago, in *Meiorin*,¹ the Supreme Court of Canada set the gold standard for understanding human rights obligations in the workplace. In *Meiorin*, the Court described the importance of human rights law to promote inclusion and to address systemic discrimination in employment. The Court held that a fitness standard for forest firefighters, developed in a male dominated work environment, discriminated against women. In addition, it provided employers with a rough operational definition for the duty to accommodate.² To claim that the duty to accommodate had been met, an employer would have to demonstrate that further accommodation was “impossible” without imposing undue hardship on the enterprise.³

Thus, over the last decade, employers have been bound by an extensive duty to accommodate employees who were protected by human rights law. However, the two cases that are the subject of this comment, *Honda Canada Inc. v. Keays*⁴ and *Hydro-Québec*⁵, call into question the expansive vision of human rights where employees with disabilities are concerned.

While the heart of the *Meiorin* decision was the recognition of the importance of legal rules to promote an inclusionary workforce, the present cases raise questions about how far an employer needs to go to accommodate employees with disabilities. Statistics on labour force participation by people with disabilities are revealing. According to a recent Statistics Canada report, for those between the ages of 25 and 54, the prime working age range, 49.7% of people with disabilities were working compared to 83.5% of the non-disabled population.⁶ People with mental disabilities fared particularly badly. Of Canadians with psychological illnesses, 45.2% participated in the workforce while only 32.7% of persons with developmental disabilities participated in the workforce.⁷ In 2001, just 40% of women aged 15 to 64 with disabilities were part of the Canadian work force compared to 69% of women in this age range without disabilities.⁸ Given the significance of employment in our society, for reasons of economic security, social recognition and feelings of self worth, the extent of an employer’s obligation to accommodate is a pressing question for people with disabilities.

Both *Honda* and *Hydro-Québec* involved employees who were fired because of absenteeism that stemmed from their disabilities. Mr. Keays had chronic fatigue syndrome (CFS) while Ms. Laverrière had a variety of physical problems as well as several psychiatric diagnoses including personality disorder. Mr. Keays sued Honda for wrongful dismissal when he was fired because he refused to see another doctor about his condition. Ms. Laverrière filed a grievance under a collective agreement after she lost her job following a long period of disability-related absenteeism. Ultimately, the Supreme Court of Canada found that neither employer had discriminated against their respective employee.

In my view, both decisions stray from the view of human rights in the workplace that envisions a broad application of human rights principles for the purpose of encouraging an inclusionary workforce.

¹ *British Columbia (Public Service Employee Relations Commission) v. British Columbia Government and Service Employees’ Union (B.C.G.S.E.U.)*, [1999] 3 S.C.R. 3, [1999] S.C.J. No. 46 [*Meiorin* cited to S.C.R.].

² The extent of the obligation to accommodate people with disabilities in important public activities was reiterated soon after in the context of eligibility criteria for driving tests. See *British Columbia (Superintendent of Motor Vehicles) v. British Columbia (Council of Human Rights)*, [1999] 3 S.C.R. 868, [1999] S.C.J. No. 78, 181 D.L.R. (4th) 385.

³ *Meiorin*, *supra* note 1 at para. 54.

⁴ *Honda Canada Inc. v. Keays*, 2008 SCC 39, [2008] 2 S.C.R. 362, [2008] S.C.J. No. 40. [*Honda*].

⁵ *Hydro-Québec v. Syndicat des employé-e-s de techniques professionnelles et de bureau d’Hydro-Québec, section locale 2000 (SCFP-FTQ)*, 2008 SCC 43, [2008] 2 S.C.R. 561, S.C.J. No. 44 [*Hydro-Québec*].

⁶ Human Resources and Social Development Canada, *Advancing the Inclusion of People with Disabilities (2006)* (Ottawa: Human Resources and Social Development Canada, 2006) at 92, online: Human Resources and Skills Development Canada <http://www.hrsdc.gc.ca/eng/disability_issues/reports/fdr/2006/advancinginclusion.pdf>.

⁷ Statistics Canada, *Participation and Activity Limitation Survey 2006: Labour Force Experience of People with Disabilities in Canada*, Catalogue No. 89-628-X (Ottawa: Minister of Industry, 2008) at 10, online: Government of Canada: Depository Services Program <http://dsp-psd.pwgsc.gc.ca/collection_2008/statcan/89-628-X/89-628-XIE2008007.pdf> [PALS 2006].

⁸ Statistics Canada, *Women in Canada: A Gender-based Statistical Report*, 5th ed., Catalogue no. 89-503-XIE (Ottawa: Minister of Industry, 2006) at 294, online: Statistics Canada <<http://www.statcan.gc.ca/pub/89-503-x/89-503-x2005001-eng.pdf>>.

In this comment, I will develop two themes in the decisions which have contributed to an apparent retreat from the *Meiorin* analysis. First, the type of disability of both Mr. Keays and Ms. Laverrière was considered to be outside of the norm, not easily confirmed or explained by standard medical analysis. Often, people with some conditions, such as CFS or mental illness, are simply not believed or not taken seriously. They are frequently subjected to endless medical scrutiny to legitimate their disability. With certain conditions, such as personality disorder, which is disabling only in a social environment, medicine can offer neither definitive diagnosis nor effective treatment. The second theme concerns the ways that human rights principles are applied to issues of employment law and labour law in these cases. Although there seems to have been an obvious disability discrimination issue in both cases, the decisions did not rely on human rights law as paramount. The Court was not primarily concerned with the duty to accommodate and undue hardship. Rather, the decisions focused on the principles of contract law and the technical rules about damages. Human rights became quite secondary.

This comment is divided into 4 sections. In Section I, I will give a brief description of the facts and the judicial history of each case. In Section II, I will move on to an analysis of two themes in the decisions: first, the significance of the controversial nature of the disabilities involved and second, the uncertainty about the meaning of the duty to accommodate and undue hardship in the context of employment and labour law. Finally I will draw some concluding observations about the discrepancy of these cases with the *Meiroin* analysis.

I DESCRIPTION OF THE CASES

A. Keays and Honda Canada

In March 2000, Kevin Keays was fired from Honda Canada after working for the company for 14 years. In 1997, he was diagnosed with chronic fatigue syndrome. For the following year he did not work and received insurance benefits from an insurer, London Life. After one year, London Life stopped paying his benefits on the basis of a medical opinion that he was fit to return to work full-time.

Mr. Keays' return to work was not smooth. He was placed in Honda's Disability Program which allowed employees absences if they were confirmed as disability-related. Unlike the protocol for other conditions, Mr. Keays was required to provide a doctor's note to confirm that every absence was related to his non-"mainstream" disability, a term first used by the trial judge.⁹ Despite the many notes, Honda became concerned that the doctors were not evaluating Mr. Keays' absences independently but were simply repeating his own explanations for being off work. To confirm Keays' diagnosis, Honda requested that he see Dr. Brennan, a company doctor. On the advice of his lawyer, Mr. Keays requested more information about the proposed consultation before he would agree to attend. On March 28, Honda replied with an ultimatum: either Mr. Keays would meet with Dr. Brennan, or he would be dismissed. Mr. Keays did not see Dr. Brennan and was dismissed. He sued for wrongful dismissal.

At trial, McIsaac J. found that Mr. Keays was wrongfully dismissed because Honda's direction to see Dr. Brennan was not reasonable in the circumstances and Mr. Keays had a reasonable excuse for resisting. McIsaac J. concluded that Mr. Keays should have been given 15 months notice but extended this to 24 months because of the bad faith associated with the manner of the dismissal and the medical consequences that ensued for Mr. Keays. The trial judge awarded \$500,000 in punitive damages against Honda because of its discriminatory and harassing treatment of Mr. Keays.

The Ontario Court of Appeal dismissed the appeal by Honda. Goudge J.A. wrote for the Court except on the quantum of punitive damages. He was reluctant to interfere with the findings of the trial judge in a case so heavily laden with facts. On the issue of the availability of punitive damages, Goudge J.A. held that discrimination may constitute an independent actionable wrong giving rise to

⁹ *Keays v. Honda Canada Inc.*, [2005] O.J. No. 1145, 40 C.C.E.L. (3d) 258 at para. 7 (Ont. S.C.J.) [*Honda trial* cited to O.J.].

punitive damages. Writing only for himself, Goudge J.A. would have upheld the award of the trial judge of \$500,000. Rosenberg J.A., who wrote for the majority on the quantum of punitive damages, did not agree that there was evidence of a protracted conspiracy to warrant such a high award. The majority, therefore, set punitive damages at \$100,000.

At the Supreme Court of Canada, Bastarache J. (McLachlin C.J., Binnie, Deschamps, Abella, Charron, Rothstein J.J. concurring) wrote for the majority. LeBel and Fish J.J. dissented in part. The Court upheld the decision that Mr. Keays had been wrongfully dismissed and agreed with the 15 month notice period set at trial. The Court was unanimous in setting aside the punitive damages award but differed on damages for the manner of dismissal. Unlike the majority, the dissenting justices would have upheld the damages for the manner of dismissal.

The majority found an extraordinary number of errors in the findings of fact by the trial judge. One of the most significant errors, according to the majority, was the finding that Honda had engaged in a corporate conspiracy. Other errors included a finding that Dr. Brennan had already concluded that Mr. Keays' condition was "bogus",¹⁰ that Dr. Brennan took a "hardball"¹¹ attitude, and that Honda's cancellation of accommodation was a reprisal for Keays retaining legal counsel.¹² Based on the majority's findings, there was no longer any evidence of bad faith in the manner of Keays' dismissal and thus no damage award based on the conduct of the dismissal.

In its analysis of the case's human rights dimension, the majority did not find evidence of discrimination.¹³ Like the courts below, the majority referred to its previous decision in *Bhadauria*¹⁴ that established that a breach of human rights legislation could not constitute a distinct tort.¹⁵ Furthermore, despite its decision in *McKinley v. BC Tel*,¹⁶ the majority seemed to be of the view that discrimination could not be "an independent actionable wrong" on which a punitive damages award could rest.¹⁷

LeBel J., writing in dissent, began by emphasizing that a review of damages for the breach of an employment contract must be informed by the values of human rights codes and the *Canadian Charter of Rights and Freedoms*.¹⁸ While the dissent agreed with the majority that there was no basis for punitive damages, it held that it was appropriate for the trial judge to award damages for manner of dismissal because it was done in bad faith and in a discriminatory manner. Unlike the majority, the dissent found very few errors in the findings of fact at trial.

B. Ms. Laverrière, Syndicat des employé-e-s de techniques professionnelles et de bureau d'Hydro-Québec and Hydro-Québec

During her last seven and a half years working for Hydro-Québec, Ms. Laverrière missed 960 days of work. She had a number of physical and mental disabilities including tendonitis, epicondylitis, hyperthyroidism, hypertension as well as episodes of reactive depression and mixed personality disorder with borderline and dependent character traits. One of Ms. Laverrière's main disability-related difficulties was her relationships with supervisors and co-workers. During the period of her employment, Hydro-Québec tried to respond to Ms. Laverrière's difficulties by giving her light duties, a gradual return to work after a period of depression and, eventually, a new position to which, according to the union, she was not entitled. When she was dismissed, Ms. Laverrière had not been to work for 5 months.

¹⁰ *Honda*, *supra* note 4 at para. 43.

¹¹ *Ibid.* at para. 46.

¹² *Ibid.* at para. 47.

¹³ *Ibid.* at para. 67.

¹⁴ *Seneca College of Applied Arts and Technology v. Bhadauria*, [1981] 2 S.C.R. 181 [*Bhadauria*].

¹⁵ *Honda*, *supra* note 4 at para. 67.

¹⁶ *McKinley v. BC Tel*, 2001 SCC 38, [2001] 2 S.C.R. 161, S.C.J. No. 40 at para. 89 (case involving the dismissal of a chartered accountant with hypertension, a unanimous court mentioned in *obiter* that discrimination may give rise to a punitive damages award).

¹⁷ *Honda*, *supra* note 4 at para. 64. See also *Vorvis v. Insurance Corporation of British Columbia*, [1989] 1 S.C.R. 1085.

¹⁸ *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.

Medical reports suggested that she would continue to be absent as she had in the past. The complainant grieved the dismissal as unjust.

The arbitrator dismissed the grievance on the basis that the employer could terminate the contract if the complainant was unable, “for the reasonably foreseeable future, to work steadily and regularly as provided for in the contract.”¹⁹ The Union’s expert evidence stated that improvement was possible if all stressors could be removed from Ms. Laverrière’s environment. This would mean completely changing her work environment and eliminating the stresses within her family. According to the arbitrator, this would require the employer to provide the complainant, periodically and repeatedly, with a completely new working environment including a new supervisor and coworkers. According to the arbitrator, this level of accommodation would constitute undue hardship.

On judicial review in the Quebec Superior Court, Matteau J. upheld the arbitrator’s decision. Matteau J. did not agree with the Union’s submission that the employer had to show that Ms. Laverrière’s absences had “insurmountable consequences”.²⁰ The Quebec Court of Appeal took a different view. From its perspective, in order to follow the approach set out in *Meiorin*, to claim undue hardship the employer had to prove that it was impossible to accommodate the employee’s characteristics.

At the Supreme Court of Canada, Deschamps J. wrote for a unanimous Court and dealt with the meaning of the term “impossible” as it was set out in *Meiorin*. The question was not whether it was impossible to accommodate the employee but, more specifically, whether it was impossible to accommodate the employee without causing the employer undue hardship. Undue hardship involved the questions of whether the employer’s operation was excessively hampered or whether the employee was unable to work for the foreseeable future, despite the employer’s attempts to accommodate. The basic obligation of the employment contract, being the exchange of labour for wages, however, remains intact. Hydro-Québec had no obligation to alter the employment relationship in a fundamental way. It was, therefore, Ms. Laverrière’s breach of the employment contract that justified her dismissal.

II ANALYSIS OF THE DECISIONS

A. The Nature of the Disability Effects the Legal Outcome

In this section, I will argue that the nature of the particular disabilities of Mr. Keays and Ms. Laverrière was an important factor in the legal outcome. Underpinned by a medical model of disability, the Court’s perception of certain disabilities as “non-mainstream” reflects a disability hierarchy with respect to legitimacy. Disabilities that are poorly understood, or do not fit neatly into a medical model, are considered less legitimate than others. In previous equality and human rights cases, the Court has often recognized the particular difficulties faced by people with controversial disabilities. This was not recognized in the current cases. Rather, attitudes about the particular nature of these disabilities set the stage for the Court to minimize the human rights obligations of employers to accommodate the disabilities of these employees.

1. *Disability as “Non-Mainstream”: A Hierarchy of Legitimacy*

The disabilities of both Mr. Keays and Ms. Laverrière were considered outside the norm or not “mainstream”. This is not because CFS or mental illness is uncommon. To the contrary, the prevalence of these conditions is very high, with considerably higher rates in women.²¹ According to the

¹⁹ *Hydro-Québec*, *supra* note 5 at para. 5.

²⁰ *Ibid.* at para. 7 quoting from *Syndicat des employé-e-s de techniques professionnelles et de bureau d’Hydro-Québec, section locale 2000 (SCFP-FTQ) c. Corbeil*, [2004] J.Q. no 11048 at para. 52 (QL) [translation by the Supreme Court of Canada].

²¹ Jungwee Park & Sarah Knudson, “Medically unexplained physical symptoms” (2007) 18:1 Health Reports 43. (According to a Statistics Canada study, entitled *Medically Unexplained Physical Symptoms*, in 2003 it was estimated that 341 000 Canadians aged 12 or older, approximately 1.3% of the national population, had chronic fatigue syndrome. Approximately 69% of these individuals were women).

Department of Health and Human Services: Centers for Disease Control and Prevention webpage, a source cited in the *Honda trial* judgment,²² more than one million Americans have CFS.²³ This makes the incidence of CFS higher than that of multiple sclerosis, lupus, lung cancer, or ovarian cancer. According to this same source, CFS occurs four times more often in women than in men.²⁴ In 2002, Statistics Canada estimated that 2,600,000 Canadians, or 10.4% of the national population, had a mental illness or substance dependency, the majority of them women.²⁵

The Court's description in *Honda* of certain disabilities as "non-mainstream" is problematic. If this term does not refer to numbers, what does it mean? Probably it suggests that a condition is inconsistent with a medical model of disability and is, therefore, questionable. A medical model views disability as individual pathology or deficiency where medical tests, doctors and other health professionals establish legitimacy. Neither CFS nor mental illness, especially personality disorder, fit well in a medical model of disability. This likely influenced the Court's view of the disabilities of Mr. Keays and Ms. Laverrière as not particularly compelling, legitimate, or comprehensible.

When the Ontario Superior Court of Justice first differentiated "mainstream" illnesses from conditions like CFS in *Honda trial*, it seemed to refer to conditions that are "invisible" impairments to the outside observer.²⁶ However, the idea of conditions outside of the "mainstream" in this context has an evaluative dimension. Unlike "mainstream" disabilities like blindness, deafness, or the effects of a spinal cord injury, people with chronic pain or fatigue are often suspected of malingering by employers, compensation officials, and even physicians.²⁷ This interpretation finds further support in the following statement by the Court of Appeal:

The need for this large employer, and indeed all employers, to take seriously their responsibilities in accommodating employees with disabilities is very important. This is, if anything, more true for employees whose disabilities may be seen by some as outside the mainstream and therefore not genuine.²⁸

These excerpts reveal the current underlying suspicion that conditions like CFS are dubious. Quite possibly the conditions are either not "real" or not very serious.

Within the medical community itself, we see opinions that suggest CFS can be faked. In *Honda*, the majority quoted Dr. Brennan who referred to the authoritative Centre for Disease Control as developing "some strict diagnostic criteria for Chronic Fatigue Syndrome (CFS) to aid in its diagnosis and differentiation from depression, fatigue of chronic illness, *malingering*, multiple rheumatic diseases etc."²⁹ Because of this underlying scepticism, employers are more likely to insist on repeated doctors' visits to confirm a diagnosis or special systems to monitor disability-related absences, as Honda did with Mr. Keays.

Unfortunately, the same scepticism that motivates employers to impose unduly strenuous monitoring systems on people with non-mainstream disabilities is what allowed the majority to perceive Honda's actions as appropriate, non-discriminatory and to find errors in the trial judge's findings of fact. The judgments indicate that Mr. Keays was seen by at least three doctors before Honda insisted that he see Dr. Brennan. Based on his London Life disability benefits, there was little doubt that at least one of those doctors had already made the chronic fatigue syndrome diagnosis. In interpreting the March 28 ultimatum, the trial judge therefore found that Honda had intimidated Mr. Keays by deliberately misstating and misinterpreting whether his file revealed that there had already been a diagnosis of CFS. However, the

²² The *Honda trial* judgment refers to a webpage on the Centers for Disease Control and Prevention website that has since been removed. We are using the information currently available on the website. *Honda trial*, *supra* note 9 at para. 13.

²³ U.S. Centers for Disease Control, "Chronic Fatigue Syndrome—Basic Facts", online: Department of Health and Human Services: Centers for Disease Control and Prevention <<http://www.cdc.gov/cfs/cfsbasicfacts.htm>>.

²⁴ *Ibid.*

²⁵ Statistics Canada, "Canadian Community Health Survey: Mental health and Well-being" *The Daily* (3 September 2003) 2, online: Statistics Canada <<http://www.statcan.gc.ca/daily-quotidien/030903/dq030903-eng.pdf>>.

²⁶ *Honda trial*, *supra* note 9 at para. 53. "Invisible" disability is a common term in disability discourse meaning unseen. This is different from the concept of "mainstream," a word that has other connotations such as "regular" or "acceptable" or even "believable."

²⁷ *Honda trial*, *supra* note 9 at para. 53.

²⁸ *Keays v. Honda Canada Inc. (c.o.b. Honda of Canada MFG)* (2006), 82 O.R. (3d) 161, [2006] O.J. No. 3891 at para. 65 (C.A.) [*Honda Ont. C.A.*].

²⁹ *Honda*, *supra* note 4 at para. 44 [emphasis added].

majority showed no deference to this determination, finding instead that Honda simply conveyed the information gathered from its experts. The trial judge also found that Dr. Brennan had already decided prior to the consultation that the claim by Mr. Keays was “bogus” and that Keays’ referral was a “set up”. Again, the majority overturned this finding of fact, finding instead that Dr. Brennan was taking a cautious approach, a position endorsed by the medical profession. Finally, the majority did not accept the trial judge’s finding that, had the consultation occurred, Dr. Brennan would have taken a “hardball” approach. Rather, it held that Dr. Brennan needed to see Keays in order to make his diagnosis according to the standards set out by the Centre for Disease Control. While the intemperate language of the trial judge may have contributed to the willingness of the Court to disturb the findings of fact, the ambiguous nature of the disability paved the way for such interference. If Mr. Keays had a spinal cord injury, readily confirmed by X-rays, it is unlikely that the trial judge’s negative perception of Honda’s actions would have been considered an error. However, in cases of CFS and other “non-mainstream” conditions, self-reported data is often the primary source of medical “proof”. In these situations, the credibility of the employee becomes central to the case. By looking at the majority’s conclusions, it is clear that most, if not all, of Mr. Keays’ evidence was examined through a lens of doubt created by the medical model’s characterization of “non-mainstream” disabilities.

Unlike Mr. Keays, Ms. Laverrière had a number of physical conditions that could be confirmed by standard medical tests and were consistent with a medical model of disability. However, she also had a psychiatric diagnosis, personality disorder, which was particularly problematic. This aspect of Ms. Laverrière’s disability was even less mainstream and less compatible with the medical model because of its psychiatric nature. While the Court did not focus on the ambiguities of mental illness in Ms. Laverrière’s circumstances, but rather her extended absences from work, concepts of mental illness diverge from the manner of diagnosis and prognosis usually associated with physical disabilities. Personality disorder probably exemplifies the essence of the social construction of disability in which the social environment, rather than an individual’s trait, defines the condition. This disability made it difficult for Ms. Laverrière to get along with others. When the Union experts recommended that accommodation involve periodic change to Ms. Laverrière’s environment, they were predicting an ongoing inability to get along with other people. From a medical perspective, neither drugs nor psychotherapy provide a remedy for a personality disorder. If Ms. Laverrière did return to work, the same problems were likely to occur with a period of absenteeism as part of the cycle.

The medical model that forms the background to these decisions is a blunt, limited view of disability and a step backwards from previous disability decisions by the Court. Conditions such as multiple sclerosis provide examples of conditions that were not previously considered legitimate for lack of a clear medical explanation. It was not until a biological basis was discovered that the medical community fully accepted that persons with this condition were not malingering.³⁰ Increasingly, previously unexplained mental illnesses, such as schizophrenia, have been determined to have a biochemical basis. That being said, the search for a medical explanation of disability is frequently not helpful.

Activists, policymakers and scholars have argued that the appropriate approach to disability depends on context.³¹ Some types of disability arise from a clear biological impairment accompanied by physical signs that can be confirmed by medical tests. Other physical conditions, equally real, cannot be determined by objective medical assessments but depend on the reported experience of the individual. Disability may also be defined on a functional basis which looks at the range of activities that a person can perform, an approach which is often most relevant to the question of work. Another approach strongly favoured in critical disability studies, views disability as the product of social attitudes and structures that create handicap. In *Mercier*, the Court itself recognized that a “handicap” may be “the result of a physical

³⁰ See generally Judith Richman et al., “Feminist Perspectives on the Social Construction of Chronic Fatigue Syndrome” (2000) 21 *Health Care for Women International* 173; P. Moss & K. Teghtsoonian, *Contesting Illness Processes and Practice* (Toronto: University of Toronto Press, 2008); Judy A. Le Page, Grant L. Iverson & Peter Collins, “The impact of judges’ perceptions of credibility in fibromyalgia claims” (2008) 31 *International Journal of Law and Psychiatry* 30.

³¹ See e.g. Jerome Bickenbach, *Physical Disability and Social Policy* (Toronto, University of Toronto Press: 1993) at chapters 1-3; See also Dianne Pothier, “Appendix: Legal Developments in the Supreme Court of Canada Regarding Disability” in Dianne Pothier & Richard Devlin, eds., *Critical Disability Theory: Essays in Philosophy, Politics, Policy and Law* (Vancouver: UBC Press, 2006) at 305.

limitation, an ailment, a social construct, a perceived limitation or a combination of all of these factors. Indeed, it is the combined effect of all these circumstances that determines whether the individual has a 'handicap' for the purposes of the *Charter*.³² The reality is that disabilities are not all alike.

Just because we do not fully understand a disability does not mean that it is not legitimate or serious. Both Mr. Keays and Ms. Laverrière were unable to work as a result of their disabilities. This suggests that a functional rather than a biomedical approach to disability would have been much more appropriate in both cases. However, a hierarchy of disability supported by a medical model of disability was more influential in the analysis.

2. *Specialized Regimes for "Non-Mainstream" Disabilities*

In previous *Charter* equality and human rights cases, the Supreme Court has dealt with numerous situations in which employees with "non-mainstream" disabilities were subjected to specialized schemes in employment-related contexts. In striking down several such schemes, the Court recognized the particular problems, stigma and discrimination that go along with controversial disabilities. This was not the view in *Honda*. As mentioned above, the specialized system used by Honda to monitor Keays' absences was more onerous than the system used for employees with other disabilities that were more consistent with a medical model. Keays had to provide confirmation from a doctor for every single disability-related absence. The majority did not see Honda's demands as inappropriate.

In *Battlefords and District Co-Operative Ltd. v. Gibbs*,³³ the Court found that an eligibility criterion for long term disability benefits, that required people with a mental disability as opposed to a physical disability to be institutionalized, was discriminatory. This decision recognized that persons with mental disabilities have suffered a particular disadvantage, a conclusion echoed by the Court in other decisions.³⁴ In *Nova Scotia (Workers' Compensation Board) v. Martin*,³⁵ the Court found that a separate regime for workers with chronic pain, under Nova Scotia's Workers' Compensation Act and the Functional Restoration Program Regulations, violated section 15 of the *Charter* and was not a reasonable limit under section 1. By legislating separate benefits, argued to be uniquely tailored to chronic pain, "far from dispelling the negative assumptions about chronic pain sufferers, the scheme actually reinforces them by sending the message that this condition is not 'real.' ... This message clearly indicates that, in the Nova Scotia legislature's eyes, chronic pain sufferers are not equally valued as members of Canadian society."³⁶

Both *Gibbs* and *Martin*, however, occurred in contexts different from the present cases. In those cases, the primary focus was access to insurance benefits that flowed from employment rather than employment itself. The Court did not need to contemplate what was necessary for Gibbs or Martin to remain in the workplace with their disabilities. Rather, the question concerned the fairness of the employment insurance scheme that came into effect after the decision had been made that the disabled employees should not work either temporarily or permanently. In the past, a decent level of economic support outside the workplace was the best people with disabilities could hope for. In the present cases, the plaintiffs wanted to continue working.

Even in the context of employment-related benefits, the Court has not consistently recognized the unique difficulties associated with common disabling conditions when these conditions do not fit a neat medical model. In *Granovsky*,³⁷ by way of contrast to *Martin* and *Gibbs*, the court did not find discrimination. Mr. Granovsky claimed disability benefits because of a back condition.³⁸ However,

³² *Québec (Commission des droits de la personne & des droits de la jeunesse) v. Montréal (City)*, 2000 SCC 27, [2000] 1 S.C.R. 665, [2000] S.C.J. No. 24 at para. 79 [Mercier].

³³ *Battlefords and District Co-operative Ltd. v. Gibbs*, [1996] 3 S.C.R. 566, [1996] S.C.J. No. 55.

³⁴ See *Winko v. British Columbia (Forensic Psychiatric Institute)*, [1999] 2 S.C.R. 625, [1999] S.C.J. No. 31; *R. v. Swain*, [1991] 1 S.C.R. 933, [1991] S.C.J. No. 32.

³⁵ *Nova Scotia (Workers' Compensation Board) v. Martin*, 2003 SCC 54, [2003] 2 S.C.R. 504.

³⁶ *Ibid.* at para. 105.

³⁷ *Granovsky v. Canada (Minister of Employment and Immigration)*, 2000 SCC 28, [2000] 1 S.C.R. 703.

³⁸ *Ibid.* at para. 4.

the effects of Mr. Granovsky's chronic, deteriorating and intermittent back condition had prevented him from accumulating the 10 year continuous work pattern that would qualify him for Canada Pension Plan Disability Benefits.³⁹ While the scheme made available certain "drop-out" provisions, under which periods of disability were not counted in the recency of contribution calculation, Mr. Granovsky's deteriorating back problem did not qualify as a severe and permanent disability, making him ineligible for these exemptions.⁴⁰ The Court found that there was no disability discrimination in Mr. Granovsky's case even though it was his disability that produced his sporadic work pattern and, therefore, his disability that disqualified him from receiving benefits. The Court concluded that those who experience temporary disabilities are "better off" than those with pre-existing disabilities. Again, as in *Honda*, we see the emergence of a hierarchy of legitimacy in which some disabilities are considered more legitimate, more worthy or more real than others.⁴¹

B. The Duty to Accommodate and Undue Hardship in the Context of Employment Law and Labour Law

One of the most significant questions arising from these decisions is whether the burden on the employer to prove undue hardship has been relaxed from the high standard set out in *Meiorin*. Unfortunately, the cases do not provide a straightforward answer. Rather, the Court chose to prioritize the principles of contract law, both in the context of employment law in *Honda* and in labour law in *Hydro-Québec*.

In both cases, the Court failed to provide real guidance regarding the point at which the accommodation of disability-related absenteeism becomes undue hardship, a difficult issue both in principle and in practice. The leading cases on undue hardship hold that the burden rests on the employer to prove undue hardship as the limit on the duty to accommodate. An employer is expected to be "conscientious",⁴² "serious",⁴³ and "genuine"⁴⁴ in its efforts to accommodate. Common workplace accommodations for individuals with disabilities include modified or reduced hours or days, special chairs or back supports, job redesigns, and modified or ergonomic workstations.⁴⁵ The exact meaning of undue hardship varies with the circumstances and has always been heavily dependent on the nature of the employer's operation and the plaintiff's employment. Factors that may be considered when assessing the undue hardship limit include "financial cost, disruption of a collective agreement, problems of morale of other employees, [and] interchangeability of work force and facilities."⁴⁶ An alleged hardship must be undue, meaning more than a mere nuisance or inconvenience to the employer. In *Central Okanagan School District No. 23 v. Renaud*, the Court said:

More than mere negligible effort is required to satisfy the duty to accommodate. The use of the term 'undue' infers that some hardship is acceptable; it is only 'undue' hardship that satisfies this test. ... Minor interference or inconvenience is the price to be paid for religious freedom in a multicultural society.⁴⁷

While *Renaud* was a case about religious accommodation, the Court made it clear that broad social goals require that undue hardship mean more than minor inconvenience.⁴⁸ This would certainly pertain to the inclusion of people with disabilities, especially given their underrepresentation in the workforce.

Despite the elevated position the Court has previously granted to human rights obligations, the Court did not underscore their paramountcy in these cases. Because human rights law serves to protect

³⁹ *Ibid.* at para. 5.

⁴⁰ *Ibid.* at para. 8.

⁴¹ See Fiona Sampson's case comment on this point. Fiona Sampson, "Granovsky v. Canada (Minister of Employment and Immigration): adding insult to injury?" (2005) 17 C.J.W.L. 71.

⁴² *C.U.P.W. v. Canada Post Corp.*, 1997 CarswellNat 1864 at para. 49 (Canada Arbitration Board) (WLeC).

⁴³ *Krznaric v. Chevrette* (1997), 154 D.L.R. (4th) 527 at 547, [1997] O.J. No. 4712, at para. 86 (Ont. C.J.).

⁴⁴ *Holmes v Canada (Attorney General)* (1997), (1998) 130 F.T.R. 251, [1997] F.C.J. No. 577 at para. 34.

⁴⁵ *PALS 2006*, *supra* note 7 at 18.

⁴⁶ *Central Alberta Dairy Pool v. Alberta (Human Rights Commission)*, [1990] 2 S.C.R. 489 at 521, [1990] S.C.J. No. 80 at para. 62.

⁴⁷ *Central Okanagan School District No. 23 v. Renaud*, [1992] 2 S.C.R. 970 at 984-85, [1992] S.C.J. No. 75 at para. 19, 20 [*Renaud*].

⁴⁸ *Ibid.*

our most important values, human rights considerations are central to interpreting any piece of legislation, common law rule or contract.⁴⁹ Human rights law has a special nature that is “not quite constitutional but certainly more than the ordinary ...”⁵⁰ However, there is no indication that the majority viewed human rights in this broad social sense, reflected in *Renaud* or *Meiorin*. Rather, it was the essence of the private employment contract that was pivotal.

1. *Disability Discrimination and Unjust Dismissal*

In *Honda*, the approach of the Court was to separate completely the human rights analysis from an examination of whether the employment contract was breached. According to the majority, the Human Rights Code is a complete and self-contained system. “Thus, a person who alleges a breach of the provisions of the Code must seek a remedy within the statutory scheme set out in the Code itself.”⁵¹ The overall effect of the decision is somewhat contradictory. Although the Court upheld the finding that Mr. Keays was unjustly dismissed, the majority strongly defended the conduct of Honda, largely by rejecting an analysis that would include discrimination.

In the context of unjust dismissal, the majority in *Honda* never used the critical concepts of the duty to accommodate or the undue hardship limit. Instead of recognizing that disability discrimination was at issue in ordering Mr. Keays to see the company doctor, the case was framed as a matter of insubordination because Mr. Keays refused to do so. Human rights were addressed in a very limited way, only to determine whether discrimination could be a factor in the calculation of damages. Systematically, the majority eliminated even that possibility. As mentioned above in this comment, the majority found errors in a great number of facts found at trial, many of which had suggested discrimination upon which damages for manner of dismissal or punitive damages could rest.⁵² Without this factual foundation, there was no evidence to support a finding of discrimination. Additionally, however, the majority seemed to support the proposition that since *Bhadauria* established that discrimination was not an independent tort,⁵³ discrimination could not, in law, constitute an independent actionable wrong on which to base punitive damages.⁵⁴ In contrast to the finding of the trial judge that the monitoring system for Mr. Keays’ absences due to his “non-mainstream” disability was itself discriminatory, the majority found this system to be itself an accommodation, beneficial to Mr. Keays in the circumstances.⁵⁵ Monitoring regular absenteeism went to the very nature of the employment contract.⁵⁶ While the dissent agreed that management had the right to monitor absences, it cautioned against assuming all methods were equally non-discriminatory.⁵⁷

The failure to incorporate human rights obligations in a case of employment law involving disability is extremely problematic. Human rights tribunals had developed an extensive body of law on the right to accommodation for disabilities.⁵⁸ As demonstrated by *Honda*, however, this seemed to have little effect on this case. Human rights obligations should be viewed as implied terms of any employment contract. Implied terms have long been a part of the law of contract, and include the right to reasonable notice upon termination, the implied term at issue in *Honda*. In *Parry Sound*,⁵⁹

⁴⁹ Some light may be shed by misconduct cases involving employees with addictions in the labour law context. These decisions distinguish between culpable voluntary behaviour, non-culpable non-voluntary behaviour and hybrid misconduct. Where misconduct is non-culpable or hybrid, as in the cases of Mr. Keays and Ms. Laverrière, a human rights analysis is certainly required. See *Health Employers Assn. of B.C. (Kootenay Boundary Regional Hospital) v. B.C. Nurses’ Union*, 2006 BCCA 57, [2006] 54 B.C.L.R. (4th) 113 ; *Fraser Lake Sawmills Ltd. (Re)*, [2002] B.C.L.R.B.D. no. 390 (British Columbia Labour Relations Board).

⁵⁰ *Ontario (Human Rights Commission) v. Simpsons-Sears Ltd.*, [1985] 2 S.C.R. 536 at 547.

⁵¹ *Honda*, *supra* note 4 at para. 63.

⁵² See *Honda*, *supra* note 4 at para. 62; *Whiten v. Pilot Insurance Co.*, 2002 SCC 18, [2002] 1 S.C.R. 595 at para. 82.

⁵³ *Bhadauria*, *supra* note 15.

⁵⁴ *Honda*, *supra* note 4 at para. 64.

⁵⁵ *Ibid.* at para. 67.

⁵⁶ *Ibid.* at para. 71.

⁵⁷ *Ibid.* at para. 121.

⁵⁸ See generally Michael Lynk, *Disability and the Duty to Accommodate in the Canadian Workplace*, online: Ontario Federation of Labour <http://www.ofl.ca/uploads/library/disability_issues/ACCOMMODATION.pdf>.

⁵⁹ *Parry Sound (District) Welfare Administration Board v. O.P.S.E.U., Local 324*, 2003 SCC 4, [2003] 2 S.C.R. 157 [*Parry Sound*].

the Court gave jurisdiction to arbitrators to decide human rights issues and held that the substantive rights and obligations of the Ontario *Human Rights Code* were incorporated into collective agreements. As Iacobucci J. for the majority stated: “[H]uman rights and other employment-related statutes establish a floor beneath which an employer and a union cannot contract.”⁶⁰ There is no justification for restricting this principle to unionized employees. Obligations in the employment contract simply cannot be considered apart from human rights obligations.

LeBel J., speaking for the dissent in *Honda*, recognized that even damages for the breach of an employment contract must be considered in view of the values of human rights codes and the *Canadian Charter of Rights and Freedoms*. These considerations should not represent a separate or secondary inquiry but should be combined into one integrated inquiry. LeBel J.’s analysis exemplified this integrated approach. For instance, the dissent acknowledged that, while monitoring absences of disabled employees is a valid objective for any employer, it should not be assumed that all methods are acceptable and non-discriminatory. LeBel J. also recognized that sending Mr. Keays to Dr. Brennan, in view of his perspective on “non-mainstream” conditions, was intended to serve the interests of the employer rather than to promote inclusivity in the workplace. He said:

Dr. Brennan’s objective is to recommend the “accommodation” that is best for Honda, not the one that is best for the employee. Although he suggests that he is only giving a “medical” opinion, his opinion is focussed on maximizing an employee’s productivity for Honda in light of the employee’s condition. His goal is clearly not to find ways for Honda to make it easier for the employee to do his or her current job.⁶¹

2. Undue Hardship and the Fundamental Nature of the Employment Contract

By way of contrast, the Court in *Hydro-Québec* claimed that it was dealing squarely with the human rights analysis by refining the phrase “impossible to accommodate”, taken from *Meiorin*. Nevertheless, the decision rested ultimately on the employment contract. *Hydro-Québec* was a grievance decided in the context of labour relations arbitration, where the collective agreement is the central concern of both parties. In this context, the principles of longstanding importance to the parties, such as management rights for the employer and seniority for the union, may take precedence over the creation of an inclusive work environment.⁶² Unlike the mandate of human rights tribunals, where the promotion of diversity, dignity, and inclusion form the *raison d’être* of the decision-making process, arbitrators are concerned with the interpretation of a collective agreement with a background of an ongoing relationship between the parties.

In *Hydro-Québec*, the Court described the goal of accommodation as ensuring that “an employee who is able to work can do so”⁶³ or, more specifically, that those who are “otherwise fit to work are not unfairly excluded where working conditions can be adjusted without undue hardship.” In setting out the undue hardship limit, the Court pointed to the fundamental nature of the employment contract as the exchange of labour for wages. Since Ms. Laverrière failed to meet these basic obligations, even after significant attempts at accommodation, the employer had shown that it was impossible to accommodate her without incurring undue hardship. Adopting the words of Thibault J. in *Québec (Procureur général) v. Syndicat des professionnelles et professionnels du gouvernement du Québec (SPGQ)* the Court stated that “it is less the employee’s handicap that forms the basis of the dismissal than his or her inability to fulfill the fundamental obligations arising from the employment relationship.”⁶⁴

One interpretation of this decision is that the fundamental terms of an employment contract now make up the standard for undue hardship. Another related possibility is that the terms of the employment contract help interpret the undue hardship limit. This is similar to the approach taken in

⁶⁰ *Ibid.* at para. 28.

⁶¹ *Honda*, *supra* note 4 at para. 100.

⁶² Of course, this criticism does not apply to the human rights decisions of all arbitrations. In fact, *Meiorin*, *supra* note 1, was decided by an arbitrator in the first instance.

⁶³ *Hydro-Québec*, *supra* note 5 at para. 14.

⁶⁴ *Ibid.* at para. 18 citing approvingly and translating from *Québec (Procureur général) c. Syndicat des professionnelles et professionnels du gouvernement du Québec (SPGQ)*, 2005 QCCA 311, 2005 R.J.Q 944 at para. 76.

*McGill University Health Centre (Montreal General Hospital) v. Syndicat des employés de l'Hôpital général de Montréal*⁶⁵ where the collective agreement specified the period when dismissal could follow after a lengthy absence. Because the parties to a collective agreement are knowledgeable about the enterprise and the workforce, such a term is useful, but not definitive. The majority held that a provision in a collective agreement should be one factor in determining whether the employer had satisfied the duty to accommodate, but this could not substitute for a case by case analysis.⁶⁶

In *Hydro-Québec* the Court explicitly drew the connection between undue hardship and the fundamental terms of the contract in the context of chronic absenteeism. Deschamps J. said:

In a case involving chronic absenteeism, if the employer shows that, despite measures taken to accommodate the employee, the employee will be unable to resume his or her work in the reasonably foreseeable future, the employer will have discharged its burden of proof and established undue hardship.⁶⁷

Here the Court was quite clear that the duty to accommodate did not go so far as requiring that the fundamental nature of the employment contract be altered. That is, the employer is entitled to some benefit for the wages paid to the employee. Although this general principle may be correct, it leads to a number of thorny questions. Does this elision of undue hardship with the fundamental nature of the employment contract apply only to absenteeism? What is the minimum obligation of the employee to “perform work” as per the employment bargain? Is it enough for an employee to merely show up at his or her place of work? How frequent must his or her attendance be? Can employers claim that a fundamental term of the contract is the production of a certain number of widgets? These questions are particularly pertinent to employees with disabilities and raise the question of whether the fundamental nature of the employment contract is itself subject to accommodation.

The decision in *Hydro-Québec* reflects the idea that an employer should not be required to bear the cost of an employee from which there is no benefit at all to the enterprise. In my view, this principle is correct. However, it is important to recognize that this case still sets a very high standard for the undue hardship limit. The extreme nature of the facts here must be underscored. Ms. Laverrière had not been at work for many months and was not expected to return in the foreseeable future. Over several years the employer had undertaken significant measures to accommodate Ms. Laverrière, going so far as the creation of a new job for her after corporate restructuring. While there was some difference of opinion among experts, it was clear that certain issues, such as the stresses within Ms. Laverrière’s family that contributed to her absenteeism, were completely outside the control of the employer. Thus, the limit described here is met where an employee is absent, does not perform any work at all for a protracted period of time, and expects no change in the foreseeable future despite extensive efforts at accommodation.

While the undue hardship limit here may be appropriate on these facts, it reveals an important policy consideration given the drastic statistics concerning people with disabilities and employment. While private employers should not shoulder the entire cost when the requirements for accommodation are extreme, persons with disabilities who want to work should have the opportunity to do so. Rather, there should be a shared responsibility between both the public and private sectors. For everyone, the significance of employment is multi-faceted, with dimensions of economic security, personal satisfaction and social validation. For this reason, the spirit of anti-discrimination law should require extensive public support for employers to hire and retain employees with disabilities in such circumstances.⁶⁸

⁶⁵ *McGill University Health Centre (Montreal General Hospital) v. Syndicat des employés de l'Hôpital général de Montréal*, 2007 SCC 4, [2007] 1 S.C.R. 161, [2007] S.C.J. No. 4.

⁶⁶ *Ibid.* at para. 20. As the majority explains:

The period negotiated by the parties is therefore a factor to consider when assessing the duty of reasonable accommodation. Such clauses do not definitively determine the specific accommodation measure to which an employee is entitled, since each case must be evaluated on the basis of its particular circumstances.

⁶⁷ *Hydro-Québec*, *supra* note 5 at para. 17.

⁶⁸ It is beyond the scope of this comment to outline the possibilities, but these could include wage subsidies to employers, a taxation system or an externally funded service to the employer community

CONCLUSION

In many ways, *Meiorin* was an easy case. Tawney Meiorin was a female forest firefighter who had worked at her job competently and without incident. The case dealt with formal equality in that it revolved around the exclusionary effect of a fitness standard that was set for all employees regardless of gender. *But for* the rule that excluded the complainant as a result of a physical fitness standard developed for men, Meiorin had demonstrated that she was perfectly proficient at her job. Only an arbitrary standard was the obstacle. The remedy did not require any change in the job description or re-organization of the workplace. The only change necessary was a revision of the standard, a change that caused no disruption and incurred absolutely no cost to the employer.

At best, the decisions in *Honda* and *Hydro-Québec* suggest that the Court has failed to clarify how the *Meiorin* vision applies to disability cases in employment. Outside of the specialized human rights decision-making process, the Court has marginalized the human rights dimensions of a wrongful dismissal action and left unanswered critical questions in the interpretation of a collective agreement. The Court has confounded undue hardship with the fundamental principles in an employment contract without having considered fully the nature of the contract in the disability context. At worst, the cases suggest that an employer needs to pay little attention to accommodating employees with disabilities if it is too difficult. This is especially true if the disability arises from a condition that is non-specific, difficult to treat, or where there is poor foreseeability regarding prognosis. Further, employers can require endless confirmations of disability even when these run roughshod over the individual employee. Medical expertise can be used to legitimate the exclusionary agenda of the employer. This was not the *Meiorin* vision of an inclusive workplace.

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