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

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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.

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[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:

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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

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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.

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[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.

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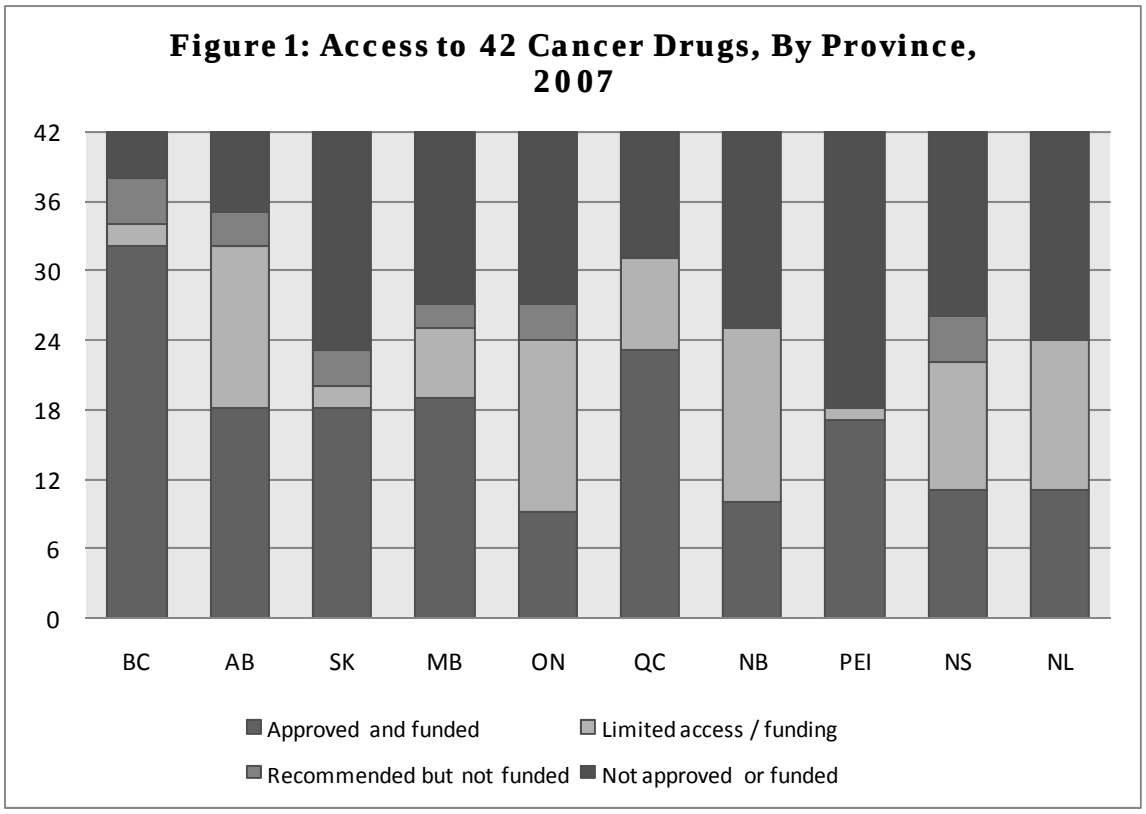
[25] Cancer Advocacy Coalition of Canada, *Report Card on Cancer in Canada 2007* at 46, online: <http://www.canceradvocacy.ca/reportcard/2007/Report%20Card%20on%20Cancer%20in%20Canada,%202007.pdf> [*Report Card*].

[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

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[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

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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-

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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 (felicitously known as "NICE") also makes formulary recommenda-

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[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.

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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>.

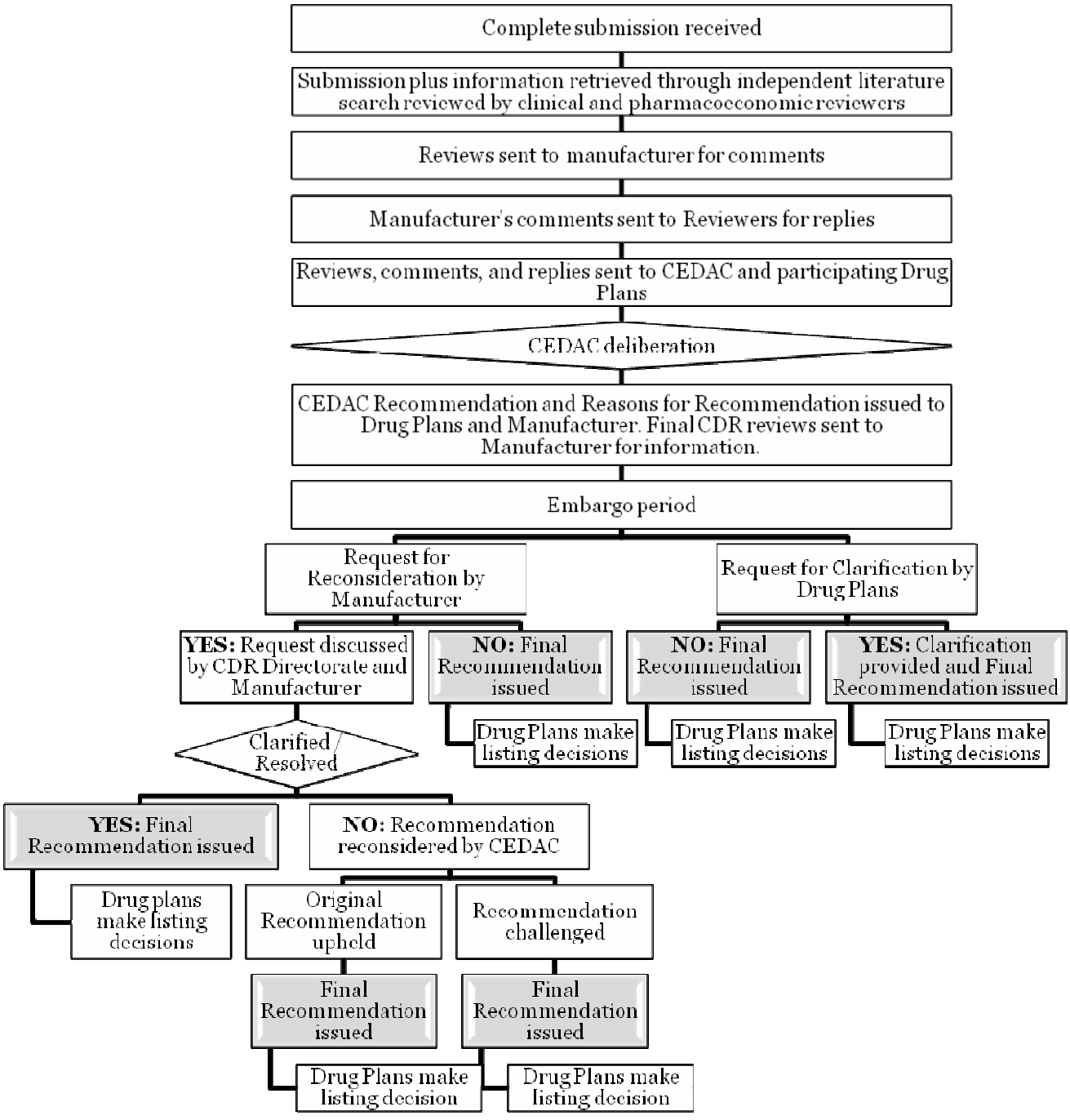
64 Laupacis, "Economic Evaluations", *supra* note 47, at 1161.

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

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[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

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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.

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[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#0606122000097>.

> 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.

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[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).