THE PRIVATE SALE OF CANCER DRUGS IN ONTARIO'S PUBLIC HOSPITALS: TOUGH ISSUES AT THE PUBLIC/PRIVATE INTERFACE IN HEALTH CARE

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As increases in health care spending outpace economic growth, governments increasingly face tough choices. One significant cost driver is the influx of new technologies, particularly expensive drug therapies. In response, provincial governments are increasingly scrutinizing the costs and benefits of new drugs and determining that despite having some therapeutic benefit, they are not sufficiently beneficial to receive public funding. These choices raise complex legal, economic, political, and ethical issues.

This paper explores these issues as they pertain to Ontario's recent decision not to publicly fund three cancer drugs—Velcade, Alimta, and Zevalin. To be clear, although not considered sufficiently cost-effective to warrant public funding in Ontario, these drugs are of some therapeutic benefit; indeed, a physician may strongly recommend one or more of these drugs to extend a patient's life by a few months. This is illustrated by the fact that the provinces of Quebec, Alberta, and British Columbia have all elected to fund these drugs in their public hospitals. That they have chosen public funding, when Ontario has not, illustrates that no sharp distinctions can be drawn about what is "medically necessary" (and thus publicly funded) and what is not.

Ontario's decision has resulted in pressure from patients who want to buy the drugs but have the drugs administered within *public hospitals. For safety reasons, these drugs need to be provided in hospital-like settings. Patients who can afford to pay for the drug still find it difficult to access them because there is only one private cancer clinic in Ontario (downtown Toronto). The Ontario government is considering whether or not to allow private-pay drugs to be administered within public hospitals—so that people who can afford to pay for the drugs can access them more readily. We explore Ontario's dilemma in three parts. First, we address how Ontario's statutory context permits or acts as a bar to the sale of drugs in public hospitals. Second, we discuss the myriad of policy concerns the government faces in deciding whether to permit the sale of cancer drugs in public hospitals: fairness, equality, sustainability, compassion, safety, and the effects of such a policy on the public system. Finally, given the difficulty in obtaining these drugs safely in a private setting, we address whether the government could be compelled to allow patients access to privately purchased drugs in public hospitals via a successful challenge under section 7 of the* Canadian Charter of Rights and Freedoms*.*

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INTRODUCTION

Health care systems in developed countries around the world are concerned with their future sustainability as increases in health care spending outpace economic growth. Canada is no exception. For example, if health care spending continues at its present pace, more than 50% of Ontario's total public budget will soon be spent on health care.[1] There is general agreement that a significant cause of cost increases is the influx of new technologies, particularly expensive drug therapies.[2] In response, publicly funded insurance schemes, including Canada's ten provincial systems, are increasingly scrutinizing the costs and benefits of new drugs and may increasingly decide that a drug, although of therapeutic benefit, is not sufficiently beneficial given its price to warrant public funding. The drug is thus not considered "medically necessary" for the purposes of the public plan, although a physician may recommend it in treating a patient.

Electing to leave an increasing number of drugs and therapies out of public Medicare raises many complex legal, economic, political, and ethical issues. Here we explore some of these issues as they pertain to a recent decision in Ontario not to fund certain cancer drugs,[3] particularly Velcade, Alimta, and Zevalin.[4] Velcade, Alimta, and Zevalin are not publicly funded in Ontario[5] because they are viewed as not sufficiently cost-effective; given their high cost and relatively small benefits (extending patients' lives by months as opposed to years), the money can be used for other pressing demands. For example, Velcade, a last-resort medication for multiple-myeloma blood cancer, costs approximately $55,000 for a full course of treatment.[6] However, to reiterate, these drugs are of *some* therapeutic benefit; indeed, a physician may strongly recommend one or more of these drugs to extend a patient's life by a few months. This is illustrated by the fact that the provinces of Quebec, Alberta, and British Columbia have all elected to fund these drugs in their public hospitals. That they have chosen public funding, when Ontario has not, illustrates that no sharp distinction can be drawn between what is "medically necessary" (and thus publicly funded) and what is not. Consequently, it is not surprising that many cancer patients in Ontario still wish to access the drugs in question, although a determination has been made that the drugs are not

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[1] Ontario government projections indicate that health care's share of provincial program spending could rise from 45% in 2004–2005 to nearly 55% in 2024–2025. Ontario Ministry of Finance, News Release, "Toward 2025: Assessing Ontario's Long-Term Outlook" (4 October 2005), online: Ontario Ministry of Finance <http://www.fin.gov.on.ca/english/media/2005/nr10-ltr.html>. For further discussion on sustainability issues in health care in Canada, see e.g. Commission on the Future of Health Care in Canada, *Building on Values: The Future of Health Care in Canada* (Ottawa: 2002) at 1–44 [*Romanow Report*] and Colleen M. Flood, Carolyn Tuohy & Mark Stabile, "What's In and Out of Medicare? Who Decides?" in Colleen M. Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: University of Toronto Press, 2006) at 15 [Flood, *Just Medicare*]. For international comparisons on variables affecting sustainability, see *OECD Health Data 2006*, CD-ROM (Paris: Organisation for Economic Co-operation and Development, 2006).

[2] See e.g. Andreas Laupacis, Geoffrey Anderson & Bernie O'Brien, "Drug Policy: Making Effective Drugs Available Without Bankrupting the Healthcare System" (2002) 3:1 Healthcare Papers 12 at 16 and Commission on the Future of Health Care in Canada, *Discussion Paper No. 14: Influences on the "Health Care Technology Cost-Driver"* by Steve Morgan & Jeremiah Hurley (Ottawa: 2002), online: Health Canada <http://www.hc-sc.gc.ca/english/pdf/romanow/pdfs/14_Morgan_E.pdf>. For the American context, see also Patricia Seliger Keenan, Peter J. Neumann & Kathryn A. Phillips, "Biotechnology and Medicare's New Technology Policy: Lessons From Three Case Studies" (2006) 25 Health Affairs 1260.

[3] The mechanics of decision-making for funding of a new cancer drug in Ontario are as follows: when a new drug, or a new indication for an existing drug, is brought before the Cancer Care Ontario/Drug Quality and Therapeutics Committee Subcommittee, the Subcommittee obtains external reviews on both pharmaco-economics and clinical considerations and makes a recommendation to the Drug Quality and Therapeutics Committee. This Committee then makes a recommendation to the Ministry of Health and Long-Term Care which, in the case of hospital-based intravenous drugs, decides whether to make these medications available through the New Drug Funding Program.

[4] Velcade is a drug used to treat multiple myeloma, a cancer of the bone marrow: Millennium Pharmaceuticals, Inc., "A Patient's Guide to Velcade" (Cambridge, MA: Millennium Pharmaceuticals, Inc., 2006), online: Millennium Pharmaceuticals, Inc. <http://mlnm.com/patients/cancer/velcade/patient_brochure.pdf>. Alimta is used in the treatment of lung cancer: Eli Lilly and Company, "Home: Determine Your Course", online: Alimta <http://www.alimta.com/index.jsp>. Zevalin is used in the treatment of lymphoma: Biogen Idec Inc., "Welcome to ZEVALIN.com", online: Zevalin <http://www.zevalin.com/>.

[5] This case has been recently highlighted by Catherine Pytel, who received Zevalin free of charge from its manufacturer, Biogen Idec Inc., on a "compassionate" basis. Once the Drug Quality and Therapeutics Committee decided not to fund Zevalin, Ontario hospitals would not provide the drug: see Lisa Priest, "Woman's last hope tied up in red tape" *The Globe and Mail* (16 March 2006) A1. Pytel ultimately travelled to a public hospital in Quebec that was willing to allow the transfusion. Lisa Priest, "An Infusion of New Hope: Hospital Ends Patient's Months-Long Battle to be Treated With Cancer Drug Zevalin" *The Globe and Mail* (31 March 2006) A5.

[6] Carolyn Abraham, "Cancer clinic opens the door for private care" *The Globe and Mail* (22 August 2005) A1.

sufficiently cost-effective to warrant public funding in that province. For example, a 35-year-old mother of three young children or a 65-year-old man who wants to attend his daughter's wedding may consider the chance of even one additional month of life as extremely valuable and might be willing to use his or her savings to pay for the drugs. In addition, patients may have private insurance that covers the cost of these drugs.

I
Ontario's Dilemma

When a provincial government elects not to fund a drug, the drug is left to be funded by the private sector (either through insurance or by way of an out-of-pocket payment). The situation is complicated in the case of new cancer drugs like Velcade, Alimta, and Zevalin, which may need to be infused—necessitating nursing staff and supervision for proper administration in a hospital environment. However, because of limitations and restrictions on the private health care sector, there is as yet only one private clinic in Ontario capable of providing these cancer drugs to private patients: the Provis Infusion Clinic Inc., located in downtown Toronto.[7] Whether due to confusion about the regulations, an inability or unwillingness to travel to Toronto, a desire to avoid fees associated with provision at a private clinic, or a combination of the above, there have been stories of patients obtaining these drugs and having them administered in family doctors' offices; others have asked staff in public hospitals, who may be inadequately trained in how to administer drugs not listed on their formulary.[8] Some cancer patients are asking that they be permitted to buy these new cancer drugs within public hospitals, saving them the additional cost and stress of having to travel to a private clinic.[9]

Presently, public hospitals in Ontario do not facilitate the private sale of drugs to patients. With respect to in-patients, all drugs provided within public hospitals are free of charge. It would be a significant change to allow patients to pay privately for drugs requiring infusion in a public hospital. With respect to out-patients, hospitals do charge them for drugs, but an exception is made for cancer patients. It would thus also be a significant change in practice for hospitals to sell cancer drugs that are not listed on the hospital formulary to out-patients.

Cancer Care Ontario (an arm's-length agency charged with the administration of Ontario's delivery of cancer services across the province) has recommended to the Ontario government that in-patients be allowed to buy these new cancer drugs in public hospitals. This proposal is motivated by both safety concerns and compassion. A patient dying of cancer who has sufficient private insurance or other means to buy the drug will benefit if a public hospital can sell the drug to her; this policy will ensure better continuity of care with other treatments and will help reduce the unsafe practice of asking family doctors or untrained hospital staff to infuse the drugs. Compassionate concerns have been taken into account in that these private-pay patients will not be required to pay the price of travelling to and accessing a private clinic, whether in Toronto or in another province or country.

Compassion in this regard only goes so far, however, and the situation of a person wanting but unable to buy an uninsured cancer drug remains unclear. It is certainly possible that hospitals may find ways to fund the drug for a needy person or that drug companies may provide some of the drug free of charge for hospitals to distribute. Nevertheless, it is also equally possible that a low-income individual will go without the cancer drug in question. Their perception of this loss will likely be affected by the fact that the drug is considered sufficiently important that public hospitals are able to sell it to those who are able to pay.

The Ontario government is caught in a bind between what it is allowed to do, what it should do, and what it may be made to do. To be more specific, the government is asking—or should ask:

1. What do existing statutes and regulations allow presently in terms of selling private drugs in Ontario's public hospitals?;
2. What should the government's policy be with regard to the preceding question, given that it wants to enhance and to ensure both fairness and sustainability of Medicare?; and

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[7] See Provis Inc., "About Provis", online: The Provis Group Inc. <http://www.provis.ca/index.html>.

[8] This point was made by Terrence Sullivan, President of Cancer Care Ontario. A hospital's formulary is the list of drugs that are available within that hospital.

[9] See Lisa Priest, "Let cancer patients pay for unfunded therapy, study says" *The Globe and Mail* (29 July 2006) A7; Lisa Priest, "Ontario minister supports user-pay plan for cancer drugs" *The Globe and Mail* (6 May 2006) A8; Lisa Priest, "Ontario changes tack on cancer drugs" *The Globe and Mail* (5 May 2006) A1.

3. Regardless of the answers to the previous two questions, could it be forced to change its policy through a successful *Charter* challenge on the part of patients frustrated by public hospitals failing to allow the private sale of cancer drugs?

We address each of these three issues in turn. Although the analysis that follows is limited to Ontario's dilemma, our discussion of this recent policy development in Ontario is illustrative of issues that will continue to arise in the ongoing debate over the appropriate role for public and private financing of health and the protection of the public health care system within all Canadian provinces. Indeed, a recent newspaper article suggests that while some provinces, such as Saskatchewan, permit the infusion of privately purchased drugs in public hospitals, others, such as Manitoba, refuse to do so.[10]

II
WHAT THE ONTARIO GOVERNMENT CAN DO: LEGISLATIVE PROVISIONS PROHIBITING THE SALE OF PRIVATE DRUGS IN PUBLIC HOSPITALS

We turn first to exploring what existing statutes and regulations prescribe in terms of the sale of private drugs within public hospitals, looking both at relevant Ontario statutes and regulations and at the *Canada Health Act* (*CHA*).[11]

A. Ontario Legislation

The *Commitment to the Future of Medicare Act, 2004*[12] seeks to prohibit a number of practices viewed as detrimental to Medicare. For example, the *Act* prohibits extra billing for insured services[13] and payment for preferential access to insured services[14] except where otherwise provided for by regulation. The relevant regulation states that a hospital may charge or accept "payment for private or semi-private accommodation, except where an insured person is entitled to the accommodation without charge" and "co-payments as permitted … under the *Health Insurance Act*".[15] One interpretation of this regulation is that the only charges a hospital may make to an insured person are for semi-private accommodation or explicitly permitted co-payments; in our view, this interpretation is not persuasive. Subsection 10(5) of the *Regulation* focuses on the status of the service itself (insured or uninsured), saying that private payment is not allowed "for an *insured service* rendered to an insured person".[16] It does not, however, say that a hospital may never sell an uninsured service to an insured person. If hospitals were not entitled to charge insured patients for anything other than semi-private accommodation and permitted co-payments, they would not be able to charge patients for services such as telephones or televisions in their rooms.[17]

The other relevant statute is the *Health Insurance Act*,[18] which provides for the operation and administration of the Ontario Health Insurance Plan (OHIP). The Lieutenant Governor in Council has the power to enact regulations "governing insured services, including specifying those services that are not insured services", and states that any regulation made under this section may provide "[w]hich services rendered in or by hospitals and health facilities are insured services".[19] There is nothing explicit that

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10 In this regard, Priest notes that Saskatchewan allows patients to purchase Avastin and have it infused in the hospital, with the costs of infusion being absorbed by the public system. In contrast, Manitoba refuses to allow patients to have these drugs infused in the hospital as it "creates inequality amongst patients and generates emotional discomfort for caregivers who are dealing with similar patients, one of whom can pay and one of whom can't." Roberta Koscielny, Director of Communications and Public Affairs, CancerCare Manitoba, cited in Lisa Priest, "Clinics let cancer patients purchase treatment" *The Globe and Mail* (8 December 2006) A1.

11 R.S., 1985, c. C-6 [*CHA*].

12 S.O. 2004, c. 5.

13 *Ibid.*, s. 10.

14 *Ibid.*, s. 17.

15 *General Regulation*, O. Reg. 288/04, s. 4. Section 15(1) of the *General Regulation* made pursuant to the *Health Insurance Act* states that ambulance services are insured if they are provided by one of the listed ambulance operators; the hospital is one of a listed class, and the insured pays a $45 co-payment to the hospital.

16 *Ibid.* [emphasis added].

17 These are services for which hospitals typically charge through a third party. For example, a number of hospitals in Canada have these services provided through the Hospitality Network: Hospitality Network, "Patient TV and Phone Rental Availability and Pricing", online: Hospitality Network <http://www.hospitalitynetwork.ca/pricing/>.

18 R.S.O. 1990, c. H-6.

19 *Ibid.*, s. 45(3.2)(1).

empowers public hospitals to sell uninsured services; however, there is nothing to prevent it. Much turns on the definition of "insured service", which we turn to now, for if all drugs provided in a hospital must be insured, then it is beside the point whether hospitals are entitled to sell uninsured services or products like drugs.

Section 8 of the *Commitment to the Future of Medicare Act, 2004* defines "insured service" by referring to the *Health Insurance Act*, where we find the following definition: "prescribed services of hospitals and health facilities rendered under such conditions and limitations as may be prescribed". "Prescribed" is defined as "prescribed by the regulations".[20] In understanding "prescribed", we need to consider both in-patient and out-patient services, although most patients will be seeking to have new cancer drugs infused on an out-patient basis. As discussed further below, the regulations do not decisively resolve the issue in the context of in-patient care. With respect to out-patient care, it is reasonably clear that there is no impediment to the sale by hospitals of uninsured drugs.

1. *In-patient Services*

With regard to in-patients, section 7 of the *General Regulation*[21] states that

> …the in-patient services to which an insured person is entitled without charge are all of the following services:
>
> …
>
> 2. Necessary nursing service, except for the services of a private duty nurse who is not engaged and paid by the hospital.
>
> 3. Laboratory, radiological and other diagnostic procedures, together with the necessary interpretations for the purpose of maintaining health, preventing disease and assisting in the diagnosis and treatment of any injury, illness or disability.
>
> 4. Drugs, biologicals and related preparations that are prescribed by an attending physician … in accordance with accepted practice and administered in a hospital.…

If the Ontario government wanted to allow the private sale of cancer drugs in public hospitals to in-patients the most problematic provision is subsection 7(4). Its broad wording seems to entitle a patient to any drug administered in a hospital and prescribed by an attending physician. Thus, arguably, as long as a doctor prescribes the drug in question, and the patient is in a hospital, the drug must be publicly insured. In contrast, subsection 7(2) speaks of "necessary" nursing services, opening up the possibility of classifying some nursing services as "necessary" and thus publicly insured, and others as unnecessary and thus not publicly insured.

Our interpretation of the existing regulation (section 7 of the *General Regulation*) supports the argument that residents of Ontario are entitled to full coverage of all drugs prescribed by an attending physician in a hospital. In our view, it is necessary to amend Ontario's *General Regulation* if the government wants to allow public hospitals to charge in-patients for these new cancer drugs.

2. *Out-patient Services*

The situation with respect to the provision of private-pay drugs on an out-patient basis in public hospitals is clearer. Subsection 8(1) of the *Regulation* lists the out-patient services to which an insured person is entitled without charge, but specifically excludes *"visits solely for the administration of drugs, vaccines, sera or biological products."*[22]

If a patient goes to an out-patient clinic solely for the administration of cancer drugs, then there appears to be no barrier to the hospital selling uninsured drugs to her. It could be argued, however, that because these new cancer drugs must be infused, and nursing services are thus required, the patient is not presenting solely for the purpose of receiving a drug. But this interpretation likely will not be persuasive—after all, even providing an out-patient with a tablet to ingest requires some additional services in addition to the drug itself.

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20 *Supra* note 18, s. 1.

21 R.R.O. 552.

22 *Ibid.*, s. 8(1)(5)(iv) [emphasis added].

B. The *Canada Health Act*

If Ontario's legislation is interpreted to allow the sale of private drugs in public hospitals or amendments are made to facilitate this sale, then we must address whether these changes will comply with the *CHA*. The *CHA* protects and requires first-dollar public coverage for "insured health services". If a province chooses not to provide public coverage then the federal government may withhold payment. The *CHA* defines "insured health services" by reference to "hospital services", which are:

> …any of the following services provided to in-patients or out-patients at a hospital, if the services are *medically necessary* for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability, namely,
>
> …
>
> (b) nursing service,
>
> (c) laboratory … and other diagnostic procedures, together with the necessary interpretations,
>
> (d) drugs, biologicals and related preparations when administered in the hospital,
>
> (e) use of … case room … facilities, including necessary equipment and supplies,
>
> (f) medical and surgical equipment and supplies….[23]

The *CHA* thus requires that all "medically necessary" drugs be provided when administered in a hospital. However, "medically necessary" is not defined, with the result being that whatever is covered in a province's insurance plan is typically regarded as medically necessary. In other words, the term "medically necessary" does not substantively drive coverage decisions but rather is a label applied *ex post* to coverage decisions.[24]

Because Ontario has chosen *not* to insure the cancer drugs at issue, then it is likely that these drugs will *not* be considered "medically necessary" for the purposes of the *CHA*. However, although it largely lies with a provincial government to determine what is and is not "medically necessary", it is still possible that the federal government could contest a classification of one or more of these cancer drugs as not medically necessary and thus not publicly insured. It is feasible that the federal government, given evidence of effectiveness and the fact that other provinces and other countries fund these same cancer drugs, could claim the drugs are in fact "medically necessary" for the purposes of the *CHA*. But rare indeed are examples where the federal government has challenged a provincial government's decision-making in this regard and, as Choudhry notes, provinces are frequently not penalized for what seem to be more blatant breaches of the *CHA*.[25]

We also note that the sale of these drugs in public hospitals will reinforce public perception that the drugs truly are "medically necessary", which in turn will put pressure on both the federal and provincial governments to treat the drugs as medically necessary and to publicly insure them.

In conclusion, it seems that under existing Ontario legislation it is not permissible to sell cancer drugs to in-patients, but it is permissible to sell cancer drugs to out-patients. With respect to the *CHA*, all turns on the definition of "medically necessary". If the drugs are considered medically necessary, they must be publicly funded within public hospitals; if not, then there is nothing in the *CHA* that would prevent their sale in a public hospital. There is no established process for deciding what is and is not medically necessary, and there is a large grey area in which a judgment has to be made; further, the federal government has historically been wary of trumping provincial decision-making in this regard. It is unlikely, except in circumstances where Ontario is a clear outlier from other provinces in terms of a decision not to insure a drug publicly, that a federal government would object to a province's own assessment of what is or is not "medically necessary". If a drug is not considered medically necessary, there is nothing in the *CHA* that would seem to prevent the private sale of such a drug within a public hospital.

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[23] *Supra* note 11, s. 2 [emphasis added].

[24] See Flood, *Just Medicare*, *supra* note 1.

[25] Sujit Choudhry, "Bill 11, the *Canada Health Act* and the Social Union: The Need for Institutions" (2000) 38 Osgoode Hall L.J. 39 at 51–59.

III
WHAT THE ONTARIO GOVERNMENT SHOULD DO: POLICY CONSIDERATIONS FOR AND AGAINST ALLOWING THE PRIVATE SALE OF CANCER DRUGS IN ONTARIO'S PUBLIC HOSPITALS

Having discussed what the Ontario government is presently permitted to do under statute and regulation vis-à-vis the sale of private drugs in public hospitals, we now turn to what it should do. We do this through exploring the policy arguments for and against the sale of private drugs in public hospitals. First, we look at arguments against such sale, including concerns about unequal treatment within public hospitals and the possibility of negative effects on the public system. We then turn to look at favourable arguments, particularly concerns for safety of those who are attempting to buy cancer drugs in inappropriate venues, given that they are not permitted to purchase them in public hospitals.

Both the *CHA* and Ontario's *Commitment to the Future of Medicare Act, 2004* speak to important values underlying the health care system: in particular, a commitment to access on the basis of need rather than ability to pay, and a commitment to one-tier Medicare through bans on extra billing and user charges. The difficulty with these governing pieces of legislation is that it is not clear *why* they prohibit extra billing and user charges. There are two possibilities. The first is that it is always wrong for there to be unequal treatment vis-à-vis health care (or at least "medically necessary" hospital and physician services). The second possibility is that these governing pieces of legislation are in place because they are necessary to ensure a robust and reasonable standard of care for all in the public health care system (for example, by ensuring sufficient doctors working in the public system).[26] One's stance with regard to this central question of justification significantly affects how one will respond to the government's proposal to allow public hospitals to sell uninsured drugs.

A. Unequal Treatment in Health Care

Let us look at the first argument, namely, that it is wrong for there to be unequal treatment vis-à-vis health care. Access on the basis of need rather than ability to pay is a defining principle of Medicare, and equality *within* Medicare is an extremely important value. However, there are necessary limits to Medicare and thus to the extent of the equality principle. Equality under the *CHA* is only with respect to "medically necessary" hospital and physician services. Provinces are not required to provide other kinds of services although they may be "medically necessary"—prescription drugs outside of hospitals, home care, long-term care, dentistry, etc.[27] Even with respect to medically necessary services, there are no outright provincial prohibitions vis-à-vis their purchase by private-pay patients. There are, instead, many indirect regulations that suppress the flourishing of a private tier for "medically necessary" hospital and physician services (for example, regulations that require doctors to opt out of the public system if they wish to bill privately for "medically necessary" care and regulations that limit what doctors can charge private-pay patients).[28] The end result is that there is, across Canada, a very small private sector for medically necessary hospital and physician services. Compared to many other jurisdictions, there is a sharper division between the privately and publicly financed sectors. The privately financed sector stands somewhat separate from the public sector. This isolation is both symbolic and value-oriented in nature, as well as having substantive implications that we address further below.

The argument that unequal treatment is always wrong, taken to its extreme, would mean that if a treatment is not publicly funded for every Canadian, then it cannot be provided at all. There would be few, if pressed, who would agree that this notion could be the foundational basis for our (public and private) health care system. For example, a provincial government, having decided that it will not publicly fund a particular treatment like *in vitro* fertilization services, would not conclude that because of the need for equality the provision of these treatments should also be banned in the private sector. In other words, there is a limit to equality, and equality is only required within Medicare. The problem is that the boundary or limits of publicly funded Medicare are determined by the vague and often unsatisfactory process for deciding what is and is not "medically necessary".[29] The social consensus has been that

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[26] For a general summary of some of the manners in which the private sector can impact the public sector negatively, see e.g. *Romanow Report*, *supra* note 1 at 6–8.

[27] However, with the deinstitutionalization of medical care and the corresponding increase in the importance of pharmaceuticals and home care, some advocate for the inclusion of these services within the *CHA*. See e.g. *ibid.* at 171–210.

[28] See Colleen M. Flood & Tom Archibald, "The illegality of private health care in Canada" (2001) 164 Canadian Medical Association Journal 825.

[29] See Flood, *Just Medicare*, *supra* note 1.

services left to the private sector are not as important as those that are publicly funded. This consensus will be increasingly challenged as new technologies—judged to be not sufficiently cost-effective to be publicly funded, but still of value—are left to private markets. The boundary of what should be public and should be private will, to many people, start to seem much less clear.

If we accept that equality is limited to the extent that we speak of allocation of publicly funded health care within Medicare (i.e., care that has been determined to be "medically necessary"), should public hospitals be able to sell private services? Accepting the existence of limits on equality and the fact that services not defined as medically necessary may be sold in private markets, should we be concerned if public hospitals sell these services too?

In terms of symbolic values, Canadians view public hospitals, although technically privately owned, not-for-profit institutions, as public institutions benefiting all citizens, rich or poor. Although Canadians may access private services, they generally do so in facilities that are independent of the public system, in clinics that are in separate locations, and from physicians that are not employed in the public system. One claim may then be that although some unequal treatment is tolerated within the system broadly, such inequality is not acceptable within public hospitals. This claim is linked to the symbolic notion of the public hospital as a community facility for the benefit of all. The power of this argument is diminished by the fact that private payment is allowed in public hospitals for some services (for example, private nursing staff). On the other hand, the fact that the drugs in question are life-prolonging might be viewed as sufficient to distinguish them from the caring or comforting types of nursing that are allowed to be provided on a private basis in public hospitals. Another argument in favour of allowing private payment is that presently there is unequal access within public hospitals to the drugs in question. For example, as we understand it, Alimta is already provided to qualifying patients within a hospital through the Workplace Safety and Insurance Board, if their cancer is related to workplace exposure.[30] However, pointing out the existing inequalities in the provision of cancer drugs risks falling into the fallacy of arguing that one form of inequality can justify another. Also, let us recall that an important principle of Medicare is access on the basis of need and not of ability to pay. All patients, whether rich or poor, qualify for workplace safety coverage. Their coverage depends on how they acquired the cancer from which they suffer and not on their ability to pay.

The issue of unequal treatment within a public hospital likely engages ethical issues that are beyond the scope of this paper. We would note, however, that regardless of whether such unequal treatment is theoretically tolerable (on the grounds that the drug in question has been deemed "not medically necessary"), Ontarians may not view it as acceptable. While they may tolerate different treatment across the system as a whole, they may be unwilling to tolerate it within public hospitals particularly with respect to life-prolonging treatments.

B. Impact on the Public System

Legislation limiting the private health care sector is also rooted in concerns about the potential impact of the private tier on the public system. A commonly expressed concern (for which there is an evidentiary basis) is that in a two-tier system, the private tier will pay physicians more to do less arduous work (treating less needy patients), resulting in a migration of manpower from the public to the private tier.[31] For example, the New Zealand Medical Council reports that in New Zealand (which has a two-tier system and allows doctors to work simultaneously in both the public and private sectors) specialists spend just 48.9% of their time in public hospitals. Most of the rest of the time is devoted to their private medical activities.[32]

The supply of drugs in a two-tier system does not raise this kind of capacity concern because it is usually possible to manufacture more drugs in a short time-frame. By comparison, it is never possible to manufacture doctors in a short time-frame. If a private-pay patient buys a hip operation, then it is more

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30 Personal discussion with Terrence Sullivan, President and CEO, Cancer Care Ontario [April 2006].

31 Charles Wright, "Different Interpretations of 'Evidence' and Implications for the Canadian Healthcare System" 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) 220 at 221–222 discusses a number of studies which outline these concerns. See also Colleen M. Flood, "*Chaoulli*'s Legacy for the Future of Canadian Health Care Policy" (2006) 44 Osgoode Hall L.J. 273 at 289–293.

32 Medical Council of New Zealand, *The New Zealand Medical Workforce in 2000* (Wellington: Medical Council of New Zealand, 2000) at 14, online: Medical Council of New Zealand <http://www.mcnz.org.nz/portals/0/publications/workforce%202000.pdf>.

likely that a surgeon will be spending time treating the private-pay patient, time that could have otherwise have been spent with a public patient. In contrast, imagine a patient in a private clinic being infused with cancer drugs. Because there is no shortage in the supply of cancer drugs, buying cancer drugs in private markets will not detrimentally affect the ability of public patients to access drugs. The consumption of uninsured drugs (whether in private clinics or in public hospitals) has no direct effect on the availability of drugs for public patients. Thus, the strongest argument in favour of one-tier medicine (i.e., that allowing a second tier will divert scarce human resources from the public to the private tier) does not apply in the case of drugs.

This is not to say that allowing hospitals to sell uninsured drugs may not have some negative effect on human resources within the public system, as the time spent by doctors or nurses in the prescription or administration of uninsured drugs is time that may have been spent supplying "medically necessary" services to public patients. The resources devoted to blood work and imaging are also resources that could have been used for other public patients requiring medically necessary care. The extent of this harm is an empirical question that has yet to be answered; the effect may not be particularly large if the cancer patients in question would use other public resources in substitution. If a hospital could charge the patient for the other costs of treatment associated with administering a private-pay drug,[33] concerns about cross-subsidization from public patients to private-pay patients would be negated. There may, however, be barriers—not the least of which are political—to such an approach, as it would seem that the government was treating cancer patients even more harshly than it would if it simply did not allow public hospitals to sell the drugs in question.

There are two further arguments against allowing the sale of cancer drugs within public hospitals. First, the sale by public hospitals of uninsured cancer drugs may further undermine confidence in publicly funded Medicare. It may be hard for Ontarians to accept that these drugs are not important and are not "medically necessary" if public hospitals sell them to patients who are able to pay, particularly if other provinces are publicly funding the drug. Allowing public hospitals to sell these cancer drugs may be viewed as an implicit endorsement of the true importance of these drugs and may undermine trust in the process of decision-making about what drugs to publicly fund and what drugs not to, and more broadly undermine trust that Medicare is really covering that which is "medically necessary". Second, and more importantly, allowing the sale of uninsured drugs in public hospitals may erode political support for ensuring a high standard of care in the public system and make it easier to delist (or not list in the first place) services or drugs from the universal public plan. The middle-class and the wealthy—able to pay privately for the drugs they want within public hospitals—may not use their political clout to lobby for public funding of new drugs. Potentially, this situation makes it easier for future governments not to add new therapies and technologies to the basket of services that attract universal public funding. This stasis may be a good thing from the perspective of ensuring sustainability but of concern from the perspective of ensuring a robust standard of care in the universal public system.

Although this concern of diminished political support in a two-tier system is one that is often expressed in the literature, it is not one that has yet been conclusively proven on an empirical basis. Some work has suggested that increases in private spending will result in overall reductions in public spending over time, providing some basis for the concerns expressed here.[34] It should be noted that in the *Chaoulli* decision, a majority of the Supreme Court did not find a sufficient evidentiary basis for the concern that allowing a two-tier system would degrade political support for a robust publicly-funded system;[35] this decision, however, has been severely criticized.[36]

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[33] This charge could include, for example, the cost of the nursing services required to administer the drug, of blood work, of occupying the room where the drugs are administered, and of needles and tubing through which the drugs are administered. It could also include charges for more ancillary services, such as post-drug imaging to evaluate whether the drugs were effective in reducing the tumor, and anti-nausea or other medications required to counteract the side-effects of the intravenous cancer drugs.

[34] See Carolyn Hughes Tuohy, Colleen M. Flood & Mark Stabile, "How Does Private Finance Affect Public Health Care Systems?: Marshalling the Evidence from OECD Nations" (2004) 29 J. Health Pol. 359.

[35] *Chaoulli v. Quebec (A.G.)*, 2005 SCC 35, [2005] 1 S.C.R. 791 at paras. 68, 83–84 [*Chaoulli*].

[36] For a more detailed discussion in this regard, see e.g. Christopher P. Manfredi, "Déjà vu All Over Again: *Chaoulli* and the Limits of Judicial Policy-Making" 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 and the other chapters in this volume; Joan M. Gilmour, "Fallout from *Chaoulli*: Is It Time to Find Cover?" (2006) 44 Osgoode Hall L.J. 327; Marie-Claude Prémont, "L'affaire *Chaoulli* et le système de santé du Québec: cherchez l'erreur, cherchez la raison" (2006) 51 McGill L.J. 167; and Amélie Quesnel-Vallée *et al.*, "In the aftermath of *Chaoulli v. Quebec*: Whose opinion prevailed?" (2006) 175 Canadian Medical Association Journal 1051.

C. Patient Safety and Access

To be balanced against the concern over erosion of the public system is the issue of patient safety and the emotional distress caused by having to travel for private treatment. There are dangers associated with being treated by multiple practitioners and having multiple sets of medical records at different locations.[37] There are stories about desperate patients trying to get these drugs infused in a family doctor's office or by untrained staff in a public hospital. Such situations are of concern, as the attendant risks require the drugs to be infused in a hospital setting by appropriately trained staff.[38] Another issue may arise when patients require the administration of both an uninsured and an insured drug. Despite the fact that it may be recommended that the two drugs be infused simultaneously, under the current regime, patients are receiving them separately—the uninsured drug at a private clinic and the insured drug at a public facility. With respect to distress, cancer patients may simply not be well enough to travel to the only private clinic in Toronto or to another jurisdiction. Even if a patient is well enough, there will be hardships involved in having to make this kind of journey for treatment, including possible separation from her family and supports.[39] If public hospitals sell uninsured cancer drugs, patients will be able to access the drugs they wish (if they have the resources to pay for them or have private insurance) at any of the 14 regional cancer centres in Ontario.

D. Balancing the Arguments For and Against Funding Cancer Drugs

The Ontario government has made a decision not to publicly fund some of these new cancer drugs; this is obviously a tough call, given the fact that at least three other provinces have elected to fund these drugs. In our view, the Ontario government must either uphold their tough decision, or contradict it and fund the cancer drugs. The middle-ground option of allowing the sale of private-pay drugs in public hospitals for those who are insured or able to fund the drug from their private resources would, in our view, likely cause political backlash on equity grounds (even though inequity has always been tolerated to some degree within the system). Moreover, allowing the sale of private cancer drugs in public hospitals further legitimizes the drug treatments in question—undermining the government's stance that these drugs are not sufficiently beneficial to be publicly funded. In addition, we have concerns in the longer term about how private payment may compromise the decision-making process about what is in and out of Medicare. However, these arguments are not cut and dried and, frankly, we find it difficult to decide between the two opposing viewpoints on this particular issue. There is not here the same strong argument that exists against two-tier medicine in the case of physician services, where there are incentives for scarce medical manpower to be diverted from the public to the private sector. There is more robust supporting evidence against a two-tier system for physician services than there is against a two-tier system for drugs.

We turn now to explore if a frustrated patient could launch a successful section 7 *Charter* claim against the Ontario government for refusing to allow the sale of new cancer drugs in public hospitals.

IV
WHAT THE ONTARIO GOVERNMENT MAY BE FORCED TO DO: CHALLENGES UNDER THE *CANADIAN CHARTER OF RIGHTS AND FREEDOMS*

Do patients have a constitutional right to pay privately for cancer drugs in public hospitals? Recall that we are addressing cancer drugs that are unquestionably of some therapeutic benefit but that are not considered sufficiently beneficial given their cost to warrant public funding. However, because of a lack of private hospital and clinic facilities in Ontario, it is difficult for a patient wishing to purchase the drugs to access a private facility for their administration. Could the Ontario government be effectively forced

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[37] An inquiry into a number of paediatric cardiac surgical deaths in Britain is perhaps the best illustration of the concerns with multi-site treatment: U.K., *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995* (London: Secretary of State for Health, 2001), online: The Bristol Royal Infirmary Inquiry <http://www.bristol-inquiry.org.uk/final_report/the_report.pdf>.

[38] Personal discussion with Terrence Sullivan, President and CEO, Cancer Care Ontario [April 2006].

[39] However, as will be discussed at greater length in the section addressing the *Charter*, this psychological stress would have to be severe in order to invoke section 7 legal protections. We would differentiate between the emotional distress discussed in this case, namely the difficulties private-pay patients would have in accessing the cancer drugs at any other venue apart from a public hospital, and the psychological stress discussed in *Chaoulli*, *supra* note 35. In the latter case, the stress in question resulted from long wait times in the public sector coupled with an inability to purchase private insurance. However, as discussed below, this differentiation would not necessarily bar a section 7 claim relating to cancer drugs.

through a *Charter* challenge pursuant to section 7, which guarantees the right to life, liberty and security of the person, to allow patients to access private-pay cancer drugs in public hospitals?

A. Section 7

Section 7 of the *Charter* provides that "[e]veryone has the right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice".[40] There are three elements to this provision: a life, liberty, or security interest must be engaged; an individual must suffer a deprivation of this interest as a result of governmental action; and this deprivation must be contrary to the principles of fundamental justice. We address these elements in turn below.

To clarify, we are not considering whether the government's failure to *insure* these drugs publicly constitutes a breach of section 7, but rather whether Ontario's laws or other governmental action that prevents public hospitals from selling uninsured cancer drugs to patients are in breach of section 7 (for further details as to the existing laws, see section II(A) above). The courts have been very clear that there exists at present no positive right to publicly funded health care under section 7.[41] For example, the majority in *Chaoulli* found that "[t]he *Charter* does not confer a freestanding constitutional right to health care".[42] More recently, the Ontario Superior Court of Justice, Divisional Court, in *Flora* found that provision of health care does not require that the "government must do everything possible to save the lives of the citizens in every circumstance".[43] To put it bluntly, section 7, to date, has been used to prevent governments from taking actions that affect individual rights, but not directly to require governments to spend money.[44] If the government chooses to fund a health service or other treatment, then it cannot do so on a discriminatory basis under section 15 of the *Charter*. However, there is, to date, no free-standing constitutional right to health care in the context of section 7.

1. *Life, Liberty, Security*

As discussed, the cancer drugs in question are of some therapeutic benefit and may extend life by several months. As such, deprivation thereof would seem clearly to engage one's life or security interests. More specifically, being forced to travel to a private clinic may be found to violate the psychological aspect of security of the person. For example, in *R. v. Morgentaler*, the Supreme Court took the view that administrative procedures causing a delay in the provision of abortion services constituted a violation of both the physical and the psychological aspects of security of the person. Dickson C.J.C. specifically dealt with the issue that abortion services are available in other jurisdictions, finding that notwithstanding this option "the emotional and financial burden"[45] of travelling long distances and the potential for increased risk of complications, meant that security of person was engaged.[46]

2. *Governmental Action*

A claimant will have to demonstrate a clear nexus between the inability of a public hospital to sell private cancer drugs and a breach of a section 7 right. A claimant's difficulty is that section 7 does not generally protect economic rights;[47] thus she would need to show a connection between the prohibition on public hospitals selling cancer drugs and her suffering.

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[40] *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [*Charter*].

[41] *Supra* note 35 at para. 104 and para. 173; *Flora v. Ontario Health Insurance Plan*, 2007 CanLII 339 at 200 (Ont. Sup. Ct. Div. Ct.) [*Flora*].

[42] *Supra* note 35 at para. 104.

[43] *Flora, supra* note 41 at para. 227.

[44] This is subject to the possible exception of the Court's decision in *New Brunswick (Minister of Health and Community Services) v. G. (J.)*, [1999] 3 S.C.R. 46, in which the Court imposed an obligation on the state to provide legal aid in a custody hearing.

[45] *R. v. Morgentaler*, 1988 1 S.C.R. 30 at 71 [*Morgentaler*].

[46] Stanley H. Hartt & Patrick J. Monahan, "The *Charter* and Health Care; Guaranteeing Timely Access to Health Care for Canadians" in *C.D. Howe Institute Commentary* (May 2002) at 9–23, online: C.D. Howe Institute <http://www.cdhowe.org/pdf/commentary_164.pdf>.

[47] For example, the dissent in *Chaoulli, supra* note 35 notes: "The argument that 'liberty' includes freedom of contract (in this case to contract for private medical insurance) is novel in Canada, where economic rights are not included in the *Canadian*

In *Chaoulli*, a majority of the Court accepted the nexus between the prohibition of the purchase of private health insurance and long waiting times in the public system.[48] For people who could not travel to the U.S. for treatment or pay out-of-pocket to opted-out physicians, a majority of the Court (in the context of the Quebec *Charter)* found a deprivation of their life and security interests. The sale by public hospitals of uninsured cancer drugs raises different issues from those at stake in *Chaoulli*. With respect to the sale of drugs, there is no issue of a governmental ban on private insurance or otherwise on private financing. Legislative barriers focus on the inability of patients to pay privately for the drug *within* a public hospital. The facts are more in line with those in the *Morgentaler* case where administrative barriers prevented women from accessing timely abortions.[49] As in *Morgentaler*, there is theoretically the option of getting treatment elsewhere—at a private clinic or in another jurisdiction—but the stress associated with accessing those options is high. The obvious difference between *Morgentaler* and the facts under discussion is that in *Morgentaler*, abortion services were publicly funded. Here Velcade, Alimta, and Zevalin are specifically not publicly funded in Ontario. It is not clear whether this difference is substantive vis-à-vis a section 7 analysis although the fact that in the present discussion we are speaking of a right to buy drugs (as opposed to a right to have administrative impediments to public treatment removed) underscores the economic aspects of this claim.

In order to be able to demonstrate a sufficient nexus between government policy and a deprivation of a section 7 right, a claimant would have to show that being required to buy the treatment at a private clinic rather than in a public hospital jeopardizes a life and/or security interest. This hurdle would be much more difficult to cross than that crossed in *Chaoulli*. A patient *may* be able to demonstrate a connection between the prohibition on the sale by public hospitals of uninsured drugs to in-patients and an infringement of life or security by the government in two circumstances. In the first, there would be serious safety concerns associated with requiring a patient to travel from a public hospital to a private clinic for infusion of a cancer drug. In the second, a patient would have to rely upon demonstrating serious psychological stress associated with having to travel unreasonably long distances to receive treatment (as the only private clinic providing the drug is in Toronto) or show that, as was recently the case for Zevalin, only public hospitals were able to provide the drug in question.[50] McLachlin C.J.C. and Major J. in *Chaoulli* quoted *Rodriguez v. British Columbia*, stating that "security of the person encompasses 'a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress.'"[51] Being effectively forced to travel to a private clinic and the psychological stress associated with such travel, in conjunction with safety concerns, might create the necessary nexus to engage section 7.

3. *Principles of Fundamental Justice*

The third requirement under section 7 of the *Charter* is for a claimant to prove that any deprivation of his or her rights is not in accordance with the principles of fundamental justice.[52]

In *Chaoulli*, the three judges who determined that there was a breach of section 7 found that one of the principles of fundamental justice was a requirement that the law not be arbitrary.[53] In order to establish arbitrariness, a claimant would have to show, on a balance of probabilities, that preventing

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Charter...." at para. 201.

48 Moreover, the majority judgment is only in respect of the Quebec *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12 [Quebec *Charter*] and not with respect to the Canadian *Charter*. With respect to the latter, the court was split 3:3 on whether the prohibition on the sale of private health insurance in Quebec was in breach of section 7. Consequently, the extent to which the *Chaoulli* decision will serve as a precedent is questionable, but we can nonetheless extrapolate from some of the findings in that decision to inform our analysis here.

49 *Supra* note 45.

50 This is because the administration of Zevalin requires a nuclear medicine licence, which, until recently, no private facilities had been granted.

51 *Rodriguez v. British Columbia (A.G.)*, [1993] 3 S.C.R. 519 at 587–88 [*Rodriguez*], cited in *supra* note 35 at para. 122.

52 Although there are a number of definitions of what constitutes a principle of fundamental justice, one of the broader definitions is: "principles which have been recognized by the common law ... and by the very fact of the entrenchment in the Charter, as essential elements of a system for the administration of justice which is founded upon the belief in the dignity and worth of the human person and the rule of law". *Reference Re B.C. Motor Vehicle Act,* [1985] 2 S.C.R. 486 at 512.

53 As mentioned above, this is not a majority decision, so its value as a precedent is limited. However, in another case the court stated that "[w]here the deprivation of the right in question does little or nothing to enhance the state's interest (whatever it may be), it seems that a breach of fundamental justice will be made out, as the individual's rights will have been deprived for no valid purpose." *Rodriguez*, *supra* note 51 at 594.

public hospitals from selling uninsured drugs did not achieve the government's goal of protecting the public health care system. A claimant could argue that the sale of uninsured drugs in public hospitals does not affect the supply of drugs to public patients. She could also argue that hospitals are free to charge for any ancillary nursing services and blood work, thus negating any concern with diverting public resources to private patients. In fact, a claimant might argue that allowing these services to be provided within public facilities would help retain nurses in the public system by not increasing demand for their services in private clinics. Claimants could also suggest that the legislation allowing the sale of cancer drugs on an out-patient basis but not on an in-patient basis is arbitrary (the reader is referred back to section II(A) above for a discussion of the different approaches to funding treatment on an in-patient as opposed to an out-patient basis).

The Ontario government, in response, would have to point to at least some evidence that to allow the sale by public hospitals of uninsured drugs would either undermine support for the public health care system or result in untenable inequities. For example, the government could argue that the sale by public hospitals of uninsured drugs depleted resources from the public system that should be directed to patients in need of "medically necessary" care. Additionally, the government may argue that such sale could open the floodgates to privatization of public hospitals, undermine public trust in decision-making about what is and is not "medically necessary", and erode political support for single-tier Medicare. As *Chaoulli* illustrates, however, arguments in principle or political theory will not be sufficient alone, and the government would have to compile strong comparative evidence from other jurisdictions in order to be successful.[54]

B. Section 1

If the court is satisfied that there has been a breach of section 7, then it must consider whether the breach is a reasonable limit "prescribed by law as can be demonstrably justified in a free and democratic society".[55] Although the burden of proving a section 7 violation is on the claimant, once this burden has been met, the state must prove that the breach is justified pursuant to section 1. This burden is rarely met where a section 7 right has been violated.[56] We will be brief in our discussion of section 1, as this discussion involves many of the same considerations contemplated under the "principles of fundamental justice" and our policy discussion in section III above.

The test for considering whether the government's burden under section 1 has been discharged is set out in *R. v. Oakes*: the legislative objective must be pressing and substantial; the means chosen must be rationally connected to the objective; the legislation must be minimally impairing; and the means chosen must be proportional to the resultant breach of rights.[57]

1. *Pressing and Substantial Objective*

It will be relatively easy for the government to meet this part of the test by arguing that the objective of the impugned legislation is to create an insurance plan that fosters equality regardless of ability to pay. This objective is furthered through protecting the public system. These types of broad objectives were accepted in *Chaoulli*, for example, with Deschamps J. finding the legislative objective was "to promote health care of the highest possible quality for all Quebeckers regardless of their ability to pay".[58]

2. *Rational Connection*

This part of the test will prove more difficult for the government to meet. Although the courts have traditionally deferred to governments, particularly in areas of complex social policy, *Chaoulli* may signal a shift in this attitude. In *Chaoulli*, faced with competing and inconclusive policy and social science evidence, three of the seven members of the Court who ruled on section 7 refused to defer to the Quebec government's chosen means of protecting public Medicare. The defendant government will, as discussed earlier, have to provide evidence supporting well-established theories about the negative impact of public

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54 *Supra* note 35 at para. 64, Deschamps J., and at para. 136, McLachlin C.J.C. and Major J., dissenting.

55 *Supra* note 40, s. 1.

56 Patrick J. Monahan, *Constitutional Law*, 2d ed. (Toronto: Irwin Law Inc., 2003) notes at 426 that out of 35 successful section 7 claims between 1991 and 2001, only two were saved under section 1.

57 [1986] 1 S.C.R. 103 [*Oakes*].

58 *Supra* note 35 at para. 49.

hospitals providing private-pay drugs; it will not be sufficient merely to lay out these theories. There is presently a paucity of empirical evidence on the effects of the sale of uninsured drugs within public hospitals.[59] If the claim reaches this stage before a court, then the government will be in a difficult position. In addition, patients could argue that any drain on the public system could be compensated by patients paying for the nursing time and other costs ancillary to the administration of the drugs. Most importantly, as discussed above, if a court concludes that the provisions are "arbitrary", then, as noted in *Chaoulli*, it is questionable whether an arbitrary provision would ever meet the rational connection test.[60]

As discussed above, if the government allows the sale of cancer drugs to out-patients and does not allow such sale to in-patients, it will strengthen the claim that the provisions are arbitrary. In turn this claim will strengthen the argument against the existence of a rational connection between the objective (protecting the public system) and the measures taken.

3. *Minimal Impairment and Proportionality*

The last two parts of the test may also prove difficult for the government to meet. Arguably, there are alternative means by which the government could protect the public system, such as charging cancer patients who buy uninsured drugs a fee for nursing, administration, diagnostic, and other services. In addition, a claimant may argue that provinces, such as Alberta, that allow for the sale of enhanced services within public hospitals arguably do so without jeopardizing the integrity of the public system.[61] Patients who have to travel unreasonably long distances for treatment as a result of the prohibition on the sale of uninsured drugs at public hospitals may argue that minimally impairing legislation would generally prohibit charging for uninsured services within hospitals, except in cases where it would effectively deny patients living in remote and rural areas the ability to obtain treatment because of a lack of access to private facilities.

Given the foregoing analysis of minimal impairment, the government would also have difficulty meeting the fourth requirement of proportionality. The underlying purpose is to ensure that there is "proportionality between the <u>effects</u> of the measures which are responsible for limiting the *Charter* right or freedom, and the objective which has been identified as of 'sufficient importance'".[62] The objective of the regulation requiring all drugs be funded publicly that are provided within public hospitals is to ensure equality in treatment within public hospitals. The effect of the measures on some patients may be viewed as onerous and therefore might not be proportional. The court in *R. v. Oakes* notes that "[t]he more severe the deleterious effects of a measure, the more important the objective must be if the measure is to be reasonable and demonstrably justified in a free and democratic society."[63]

C. Conclusion on section 7

We think it unlikely that a claimant will establish a *prima facie* breach of section 7, *but if* such a breach is proven, the government will then have an uphill battle. First, it will need to show that the breach is in accordance with the principles of fundamental justice. Second, if the government fails in this first step, then it will need to demonstrate that the breach is justified under section 1 as being a reasonable limit demonstrably justified in a free and democratic society. As we have already illustrated in our discussion of the relevant policy options, the evidence of a negative effect on the public system is relatively weak as it lacks a strong empirical base. Consequently, proving these adverse policy consequences to the satisfaction of a court may, as in *Chaoulli*, be difficult.

CONCLUSION

There are increasingly tough choices for governments to make in the face of an influx of expensive new health care technologies, particularly of new drugs. In Ontario, a decision has been made not to fund publicly a number of new cancer agents on the basis that they are not sufficiently cost-effective. These drugs are, however, of therapeutic benefit, and many patients and their physicians will consider these

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59 Because of the novelty of the issue of selling uninsured drugs in public hospitals in Canada, there has been no opportunity to collect data on the effects of such a policy. In addition, we were unable to find international data on this point that is important.

60 *Supra* note 35 at para. 155, McLachlin C.J.C. and Major J., dissenting.

61 For a discussion of Alberta's legislation in this regard, see Choudhry, *supra* note 25.

62 *Oakes*, *supra* note 57 at 139 [emphasis in original].

63 *Ibid.* at 140.

drugs crucial to cancer treatment. Accordingly, patients with means (and/or private insurance) will want to buy these drugs.

Having made a decision not to publicly fund these drugs, the Ontario government now faces pressure from those who can afford to pay privately to facilitate their access to these drugs in public hospitals. The reason for this pressure is that presently there is only one private clinic in Ontario at which these cancer drugs can be safely accessed outside of a public hospital. This paucity in private delivery options results in safety concerns, with patients anxious to receive these new cancer drugs approaching untrained staff in inappropriate sites (for example, urging their family doctor, untrained in the complexities of these drugs and their administration, to provide the infusion).

The resolution of this problem is extremely difficult and fraught with political complexities. In this paper, we explored the Ontario government's dilemma in three parts: what it could do (in terms of what statutes and regulations limited the private sale of cancer drugs in public hospitals); what it should do (considering the pros and cons of this policy); and what it may be made to do (if a frustrated patient, who wanted to buy cancer drugs in public hospitals, could successfully bring a section 7 *Charter* challenge).

First, with respect to what it can do, it seems that under existing Ontario legislation, it is not permissible to sell cancer drugs to in-patients, but it is permissible to sell cancer drugs to out-patients. Turning to federal legislation, with respect to the *CHA*, all turns on the definition of "medically necessary". If the drugs are "medically necessary", then in order to qualify for federal funding, a province must ensure that such drugs are fully publicly funded within public hospitals. The catch is that there is no established process for deciding what is and is not medically necessary, and there is a large grey area in which a judgment call has to be made. The federal government has historically been wary of trumping provincial decision-making in this regard. It is therefore unlikely, except in circumstances where Ontario is a clear outlier from other provinces, that the federal government would object to a provincial government's own assessment of what is "medically necessary". If a drug is not classified as medically necessary, there is nothing in the *CHA* that would seem to prevent the private sale of such a drug within a public hospital.

Second, with respect to what it should do (i.e., the advantages and disadvantages from a policy perspective), the Ontario government is in an unenviable position. There are real concerns about the sustainability of Medicare and the threat that the cost of new drugs pose. However, having made the tough call not to publicly fund a new cancer drug, there is the question of how to respond to cancer patients who have sufficient private financing to buy the drug but cannot readily access a private provider. Although the cancer drugs in question may be judged cost-ineffective and thus not "medically necessary" from the perspective of the public plan, many patients and many doctors will nonetheless view them as necessary. Resolution of these issues turns on how one justifies the various regulations prohibiting a two-tier system. We argue that there are two basic approaches to answering this question. The first is that it is wrong for there to be unequal treatment vis-à-vis health care. The second is that unequal treatment is acceptable, provided that it does not result in derogation from a robust and reasonable standard of care for all in the public health care system. We reject the first approach and accept the second approach; it is acceptable to allow others to buy private care *provided that* it does not undermine achieving the goal of a reasonable standard for all in the public health care system.

Looking first at the equality argument, there has always been inequality in our system to the extent that every publicly funded system has limitations and beyond those limitations patients are free (if able) to access private markets. However, this acknowledgment does raise the question of whether *within* public hospitals there should be equality in treatment. There may be more sophisticated ethical answers to this question than we are able to provide here; we would simply note that allowing patients to access cancer drugs on a private-pay basis within public hospitals will likely be viewed by the public to be in breach of a commitment to equality in Medicare even if such permission can be justified in theory.

Turning to consider the impact on the public system, we raised the concern that over time if patients with means (or private insurance) are able to buy private-pay drugs in public hospitals, they will no longer be as committed to ensuring a robust (in terms of access, quality, and timeliness) universal public system. This result may be good from the perspective of cost containment and perhaps the fiscal sustainability of Medicare; however, it is of concern from the perspective of ensuring a robust standard of quality in universal public Medicare. Another potential negative impact on the public system is that the sale of these drugs in public hospitals may undermine the government's position that these drugs are not sufficiently beneficial to warrant public funding. If they are not sufficiently beneficial, the public may question why the government is taking steps to facilitate access on the part of patients who can afford to pay for them. However, the arguments against the sale of uninsured drugs in public hospitals are not as strong as the

arguments and supporting evidence against two-tier medicine in the case of physician services, where there are incentives for scarce medical manpower to be diverted from the public to the private sector. In contrast, there is little empirical data addressing the concerns associated with the sale of uninsured drugs by public hospitals.

Balanced against concerns of increased inequalities within public hospitals and the flow-back effect on the universal public system is the fact that patients who wish to access these cancer drugs presently have very few private delivery options and that travelling to the one private clinic that exists in Toronto may further compromise patients' health and add to the financial and other burdens they already face.

The decision not to publicly fund some cancer drugs was likely a difficult one, given that at least three other provinces fund these same drugs in their respective public plans. In our view, weighing the pros and cons, the Ontario government should either continue not to publicly fund these drugs for all or change its policy and fund the drugs for all. The government should eschew the temptation to take the middle ground of facilitating access on the part of private-pay patients in public hospitals.

Notwithstanding our view of what the right policy choice is, the government may be forced to take action as a result of a section 7 *Charter* challenge. The first hurdle for a claimant is that section 7 does not protect economic rights and so one needs to show a nexus between the inability to purchase private care (seemingly an economic claim) and the suffering endured (as was done in *Chaoulli*). Here, in contrast to the circumstances of *Chaoulli*, a patient is at liberty to carry private insurance to cover the cost of the cancer drugs and to go to a private clinic in Canada to be infused with uninsured cancer drugs. Thus, a claimant would likely need to demonstrate that the physical and/or psychological stress of having to go to a private clinic, rather than to a public hospital, is such that one's life or security of the person is engaged. Such a case was made in *Morgentaler* vis-à-vis access to abortion services. The key difference between *Chaoulli* and the fact scenario under examination here is the claim to be able to pay privately for drugs in public hospitals. The claim to be able to privately pay for drugs in public hospitals is economic in nature compared to the claim in *Morgentaler*.

We envisage only two situations where a successful section 7 challenge *may* be possible. The first would arise when having to go to a private clinic for infusion would demonstrably jeopardize a patient's safety. The second category of potentially successful claimants would be those who would suffer significant psychological stress as a result of having to travel an unreasonably long distance to receive treatment in Toronto, the location of the only private clinic. However, assuming the number of private clinics increases, this second category of potentially successful claimants could diminish.

Although we think a plaintiff's chances of establishing a *prima facie* section 7 violation are limited, if such a breach is proven, we argue that the government will have a difficult battle demonstrating that the breach is in accordance with the principles of fundamental justice, or justifying the breach under section 1 of the *Charter*. Due to the lack of empirical evidence on the negative effect of selling drugs in the public system, proving adverse policy consequences may prove difficult, as in *Chaoulli*.

We conclude that, provided limits are drawn in a fair and transparent way, it is difficult to challenge conceptually a decision not to publicly fund a particular drug or treatment even if the drug or treatment is of some clinical benefit; it is also difficult to contest that such a drug should not be subsequently available in private markets, given the limits on what the public system can insure. The only real issue that arises is whether there are any negative effects on allowing the private sale of these drugs or treatments *within* the public system (i.e., within the walls of a public hospital). In the case of cancer drugs, the pressing concern is whether, over time, decisions not to fund new drugs and therapies will be taken more lightly, given that those with means and insurance will still be able to access these drugs in a public hospital. Will this policy ultimately erode a high standard of care for all Ontario citizens in the public system? This is a tough call. Allowing this policy may make future political decision-making about the limits of public-funding easier but this outcome should cause government to pause, as arguably these decisions should *not* be easy. Decision-makers should agonize over such close calls. The potential for this policy to lead to more unprincipled decision-making is the tie-breaker for us in resolving this extremely difficult dilemma, but, as discussed, at least some readers of this article and a court in a *Charter* challenge may not be so persuaded.