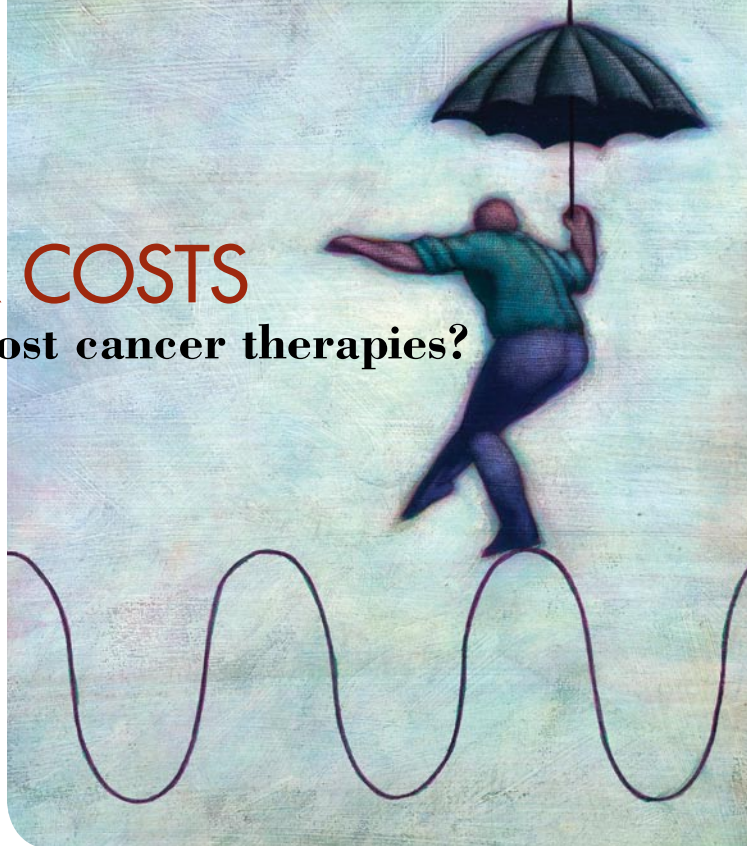


FACING CANCER COSTS

How will we afford high-cost cancer therapies?



The challenge

Brent Zanke, MD, PhD, FRCPC

The war on cancer has proven to be protracted and expensive. Real advances in chemotherapy over the last decade have juxtaposed burgeoning populations of sufferers and unprecedented prices, resulting in public payment for only the most effective agents. Private payment for effective but unfunded agents is fueling a growing debate over a perceived increasing trend towards privatization.

CANADIAN PRINCIPLES OF PUBLIC EXPENDITURE

In principle, public expenditures are driven by our shared values. Implicit in these are egalitarian principles compelling the collective to provide infrastructure and operating expenses for all. These public expenditures are determined by medical evidence and a loose assessment of cost-effectiveness. While evidence-based measures of medical usefulness such as prolonged survival or relief of symptoms are widely accepted, the acceptable price for medical benefit is unknown. Approval of agents that have some medical benefit is sometimes delayed or refused based on a perception of unreasonable cost to society.

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THE FUTURE OF PUBLIC FUNDING FOR ANTINEOPLASTIC AGENTS

While an evidence-based approach to approvals and reimbursements has worked well in the past, a different approach to the introduction of new agents may be needed — one that recognizes that timely funding may not be consistently available for every patient who could benefit. Policies are needed to address access to a growing list of unfunded drugs that do not meet a certain level of public “cost effectiveness” — which is based largely on the size of budgets in relation to demand. Some patients are very willing to pay drug acquisition costs for such unfunded drugs, recognizing that their personal attitude toward funding drugs they perceive they need is more liberal than that of public policy makers.

Currently, we do manage to provide the vast majority of new agents to all who need them. The challenge is to preserve an excellent public system in the face of very heavy usage while improving the transparency and timeliness of decision-making.

A WORKSHOP TO ADDRESS ISSUES IN CANCER COSTS

The following opinions were among those presented at a Cancer Care Ontario sponsored workshop on chemotherapy cost in Canada in October, 2005. The speakers emphasized the inevitable future availability of efficacious new treatments but also their unattainably high cost. Throughout the proceedings it was clear that all innovations should be considered and that the political, bureaucratic, administrative and medical communities remain committed to excellence in Canadian health care.

The legal obligation for government funding

Pamela C. Spencer, BSocSc, LLB, MHSoc

Is there a legal obligation for the Ontario government to fund effective high-cost cancer drug therapies that are not funded through the existing provincial and/or hospital formularies? “Effective” cancer drug therapies refers to those that are generally accepted by the medical community as the recommended form of treatment, when no equally effective alternative is available. It is assumed that these therapies have received Health Canada regulatory approval.

This issue is especially topical given the questions that have been raised concerning the application of the Supreme Court of Canada’s decision in *Chaoulli v. Quebec (Attorney General)* (Chaoulli) to guarantee patient access to healthcare services in general, and, more particularly, the role of provincial health plans in providing timely access to effective therapies that treat or prevent serious illness or death.

ONTARIO HEALTHCARE INSURANCE LEGAL FRAMEWORK

An overview of the key federal and Ontario legislation regarding patient access to funded drug therapies demonstrates that there is no legislative requirement to ensure universal access to drug therapies as part of our publicly funded system. Further, there is no legislative barrier to patients being directly charged for drug therapies that are not provincially funded or funded under hospital formularies.

Canada Health Act

The Canada Health Act (CHA) serves as the foundation for the examination of issues concerning the scope of provincially funded services and a patient’s right to access these services. Indeed, the stated purpose of the CHA is to establish the criteria for insured health services provided under provincial law that must be met before a full cash contribution from the federal government will be made. These criteria include ensuring that provincial health insurance plans are universal, comprehensive and accessible, as well as publicly

administered and portable. Facilitating reasonable access to health services, without financial or other barriers, is enshrined in the CHA as a primary objective of Canadian healthcare policy.

The CHA provides little guidance on the required scope of provincially insured services. This is expected as hospital insurance and medicare programs fall within the exclusive jurisdiction of the provinces. Provinces are only required to guarantee that their health insurance plans insure all “insured health services” provided by hospitals and medical practitioners, and services of certain other healthcare practitioners in limited circumstances. This is commonly referred to as the provincial requirement to ensure that physicians and hospitals provide “core” services, the specifics of which are undefined by the CHA.

Provinces are afforded considerable discretion in meeting the transfer funding criteria under the CHA. Provinces unilaterally determine which services will fall within their health insurance plan, and there is no guidance within the CHA as to the meaning of “reasonable access” to health services without financial barriers.

With respect to the provincial determination of the scope of insured drug treatments, the CHA provides for coverage of “insured health services,” including drugs administered in hospital that are “medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability.”

“Insured health services” also includes “any medically required services rendered by medical practitioners,” which provides little guidance as to its intended scope.

The phrase “medically necessary,” which underpins the notion of what constitutes an “insured service,” is not defined in the CHA or in the corresponding provincial health insurance legislation. By not defining medical necessity, the federal government allows each province to establish its own definition. Provinces have not

provided a substantive definition — thereby allowing medical necessity to be determined by the provinces based on their individual policy considerations. The courts have repeatedly taken the view that the scope of “medically necessary” services is a matter of social policy and healthcare planning to be determined by provincial governments with the assistance of healthcare experts. Given the practical reality of limited resources in the public healthcare system, “medically necessary” services do not include all medical services or treatments that are generally accepted by the medical community as the recommended form of treatment.

Ontario Health Insurance Act

Health insurance in Ontario is governed by the Health Insurance Act (HIA). The HIA provides that every person is entitled to receive those “insured services” in the amounts (and subject to any conditions and copayments) that are prescribed in the Regulations. Similarly, physician services are deemed “insured services” if they are referred to in the Schedule of Benefits. Physicians are limited to charging the fees for services stipulated in the Schedule of Benefits.

Under the HIA, “insured services” include prescribed hospital services and prescribed medically necessary services rendered by physicians. “Prescribed” means that they are set out in the Regulations to the HIA.

Insured drug therapies

Insured hospital services are provided on either an inpatient or outpatient basis. Inpatient hospital services include drugs prescribed by an attending physician in accordance with accepted practice and administered in a hospital. The scope of coverage under the HIA for drug therapies provided on an outpatient basis is limited to the supplying of drugs that are prescribed in accordance with accepted practice by a physician on the medical staff and that are administered in the hospital. Medications provided to patients to take home are

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excluded from this scope, including oral drugs, and likely also intravenous cancer drugs that the patient could administer at home. Also excluded are outpatient visits to hospital solely for the administration of drugs. Therefore, any drug therapies provided to outpatients that do not require ancillary hospital services (e.g. nursing assessment

or physician monitoring) are arguably not insured under the HIA unless they are explicitly listed as insured outpatient services in the Regulations.

Even if a cancer drug therapy meets the criteria for coverage under the HIA, whether to an inpatient or an outpatient, some drugs are not included in the hospital drug formulary (i.e. listed as

a drug for which the hospital will cover the cost out of its government global funding) or reimbursable through the provincially administered New Drug Funding Program (NDFP). As such, these drugs are effectively uninsured.

Hospitals retain the discretion to determine which drugs they will include on the hospital formulary

Determining a fair price for cancer drugs

Christopher J. Longo, MSc, PhD

A BALANCE AMONG OBJECTIVES

Pharmaceutical companies are in business to make a profit. Some key factors that determine drug prices are the current price of the market leader, the size of the market, the likely duration of exclusivity, and the current and future market competitors. Additionally, pharmaceutical companies have to consider price on a global basis, generally incorporating price bands based to some degree on ability to pay within each of the countries, and ideally to maximize social welfare — that is, to ensure that financial barriers do not impede drug access in lower-income jurisdictions.¹

For a new therapy to be considered innovative it should offer a therapeutic advantage over current treatments or strategies. If no meaningful benefit exists, parity with current therapies might be the “maximum acceptable price” for the new therapy in many of the restricted markets. If the price is too low, however, the sustainability of the innovative companies may be at risk, or they will be discouraged from initiating new research.^{2,3} For rare diseases there would be little incentive to develop new therapies if the ability to recoup costs were compromised by a ceiling on prices. A recent round table discussion undertaken by the U.K.’s National Institute for Clinical Excellence (NICE) Citizen’s Council suggested that larger price premiums should be accepted by the public payors in recognition of the fact that otherwise “...no-one will invest in finding cures.”⁴ A fair price would be one that does not result in access limitations but that ensures industry sustainability. As these outcomes may often be mutually exclusive, and choosing one over the other creates an ethical dilemma, the challenge is how best to balance all of these perspectives.

THE PROBLEM OF RARE DISEASES

In cancer care, the debate on public reimbursement is most likely to occur over therapies that provide life extension or quality of life improvement, rather than curative treatments. The business perspective is challenging. Many therapies have small target populations, and to recover their costs of development the unit cost of these drugs must be higher, often exceeding the economic threshold set by those undertaking economic evaluation — even in cases where no other therapy exists. If the thresholds applied to economic analysis are the same regardless of disease, many useful therapies for rare cancers will never be made available to patients through public financing. Such a denial of treatment as a result of the economics associated with a rare disease raises issues of ethics and equity.

An ideal process would establish clinical usefulness before undertaking an economic evaluation. A predetermined cost threshold could then be applied to determine whether reimbursement would occur. Different thresholds could apply when no therapy is available or when the clinical benefit is particularly remarkable (although this could compromise objectivity). The perfect solution that satisfies all perspectives likely does not exist, necessitating some tradeoffs. Political pressures will arise despite the best effort to use transparent, rational, pragmatic policies anchored in science — the most rational and defensible policy solution.

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within the categories of services they have been approved to provide under the Public Hospitals Act. Thus, hospital formularies for cancer drug therapies may differ within Ontario.

Commitment to the Future of Medicare Act

This act, known as the CFMA, prohibits hospitals and physicians from accepting direct patient payment for insured services under the HIA, unless permitted by the government. To date, the only such permitted circumstance for hospitals is the ability to accept copayments for certain hospital accommodations. While the CFMA prohibits physician extra-billing for insured services, it is silent on physician practices for uninsured services, such as those that may be offered by physicians in private oncology infusion clinics. Hence, the CFMA does not prohibit physicians from providing and determining the appropriate fees for uninsured cancer drug therapies.

So far there have not been any successful legal challenges against hospitals or physicians for breach of the CFMA for accepting payment from a patient for a drug treatment not included under the hospital formulary or reimbursable through the NDFP. Nothing in the CFMA appears to prohibit a hospital from establishing a private oncology infusion clinic and charging patients for the administration of drugs that are currently unfunded.

CHARTER CHALLENGES

This section analyzes the strengths of available arguments based on the scope of protections of individual healthcare rights afforded under the Canadian Charter of Rights and Freedoms (Charter) to require Ontario government funding of effective cancer therapies. It is important to note that, despite popular thinking, the Charter does not provide an explicit right to healthcare. This reflects the fact that our publicly funded healthcare system does not guarantee that all needed or recommended services will be provided within its scope.

As discussed below, the courts have recognized the limitation of access to health services within the public system, and will, for the most part, defer

Allocating available resources to fund public services

Maurice McGregor, MB, BCh, MD, MRCP

Do the health gains of some cancer treatments justify the high costs involved? This is not just a cancer therapy problem — it is our healthcare system's major problem. Healthcare is costing more than we wish to pay, at least as expressed by the decisions of our politicians. We do not really know why the cost keeps rising.

GROWTH IN SERVICES

While there is clearly waste, such as overuse of drugs and services, most of the increase in the cost of health services is not the result of increases in waste, growing inefficiency or rising labour costs. It is due almost entirely to the annual increase in the volume and cost of new services resulting from successful new technologies. Each year we introduce new diagnostic and therapeutic procedures, drugs and population-wide interventions. They usually cost more, most give positive health benefits (although sometimes quite small) and they rarely save money. If new technology is the principal cause of the cost increase, only reducing the rate of acquisition — or the cost of these technologies — will achieve lasting control and assure sustainability. Increasing efficiency and reducing waste will of course reduce costs, but their effect can only be temporary. As long as we continue to expand the services offered by our system, costs will continue to increase.

ADVISING DECISION-MAKERS

So what can be done? There is no simple answer, but the areas of responsibility are clear. Those who work inside the system have first of all the responsibility to eliminate waste and maximize efficiency. Society and its governments are responsible for deciding how many resources it wishes to commit. Once given a predictable, non-fluctuating budget, it is clearly also our responsibility to advise society how to achieve the greatest health gain from whatever resources it decides to commit.

to the discretion of the government to determine which services fall within the basket of insured services. The Chaoulli case however, represents a shift in judicial thinking, in that the issue is reframed in terms of patient rights to access funded services for programs that the government commits to deliver and fails to provide — especially when such programs treat or prevent serious illness or death. Within this context, the focus is on the scope of protected individual rights within

the Charter and whether the government's healthcare choices and programs respect these rights.

Failure to provide medically necessary treatments

The case that is most analogous to a consideration of whether the government is required to fund a specific cancer drug therapy as a medically necessary service is the Supreme Court of Canada's 2004 decision in *Auton v. British Columbia* (Attorney General)

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(Auton). The issue was whether the B.C. government's refusal to fund a treatment for pre-school-aged autistic children amounted to an unequal and discriminatory denial of benefits under the B.C. healthcare plan, so as to violate the children's right to equality under s.15 of the Charter. The Court considered the fact that the B.C. government funded certain programs for young autistic children, but not the one requested by the families in Auton (i.e. intensive, universal ABA/IBI [applied behavioral analysis/intensive behavioral intervention] therapy for ages 3 to 6). Further, some provinces funded ABA/IBI therapy and some did not. The Court ruled that the government's failure to provide ABA/IBI therapy to autistic children did not violate s.15 of the Charter. The ruling acknowledges the Court's deference to the government's determination of what particular benefits the public health system should provide, and its recognition that the legislative scheme providing insured services is not designed to provide all medically required treatment. Given that the Court found that the law did not confer a benefit to all medically required treatment, the Court ruled that it need not consider whether access to a specific benefit had been denied in violation of the Charter. If there is no benefit, there can be no Charter violation.

The Court also considered the larger issue of when, if ever, a province's public health plan under the CHA is required to provide a particular health treatment outside the "core" services administered by doctors and hospitals. In this regard, the Court stated that:

"...the [Canada Health Act and the B.C. Medicare Protection Act] does not have as its purpose the meeting of all medical needs. ... its only promise is to provide full funding for core services, defined as physician-delivered services. Beyond this, the provinces may, within their discretion, offer specified non-core services. It is, by its very terms, a partial health plan. It follows that exclusion of particular non-core services cannot, without more, be viewed as an adverse distinction based on an enumerated ground [under the Charter]. Rather, it is an anticipated feature of the legislative scheme."

To apply the reasoning in the Auton case to the issue of cancer therapy, the particular therapy would have to be considered a core physician-delivered service within the language previously cited under the CHA (i.e. medically necessary to maintain health, prevent disease or diagnose or treat an injury, illness or disability). Thus, it would arguably have to be the only available therapy to treat the cancer at issue. It is questionable whether cancer therapies in the category of end-of-life therapies would qualify as core healthcare services, given that they are not curative in nature. Further, the success of such an argument would depend upon the weight of the medical evidence regarding the role of the cancer therapy in maintaining health or treating the disease. Even if such evidence was accepted by the courts, it would still be challenging to overcome the Auton principle of deference to government determinations of medically necessary treatments — especially when such determinations are made by medical experts who weigh many competing interests in their decision-making, including fiscal capacity, economic benefit and clinical criteria.

Failure to appropriately exercise statutory authority

Another potential argument to compel government funding for certain drug therapies is based on a consideration of whether the provincial government has violated the Charter in appropriately exercising its statutory authority to determine what benefits will be provided as insured services. This issue was considered by the Supreme Court of Canada in *Eldridge v. British Columbia (Attorney General)* (*Eldridge*).

At issue in *Eldridge* was whether the B.C. government violated the right to equality in the Charter in its decision not to provide sign language interpreter services for the deaf as an insured service. As in *Auton*, the Court did not examine whether the legislation violated the Charter by failing to provide the benefit, as it was determined that this was a matter of provincial government discretion. However, it considered whether the decision of the government not to provide the benefit was constitutional-

ly suspect by failing to provide a benefit to a disadvantaged group (i.e. the deaf) that would allow them equal access to healthcare that is afforded to those without hearing impairments. It was argued in the case that the lack of insured interpreter services resulted in an inability to effectively communicate healthcare decision-making — a disadvantage that is not shared by the hearing population accessing the same core health services.

The Court determined that while hospitals are unilaterally responsible for determining the extent of services to be provided within their government-funded budgets, the effect of such decisions cannot be to deny equal access to healthcare. Since sign language services are the means by which deaf persons receive the same quality of medical care as the hearing population, the Court found that the government's failure to take positive steps to ensure deaf persons received such services violated individual s.15 Charter rights to equally benefit from healthcare services provided to the general public. The Court noted that the government in this case was not being asked to provide a specific healthcare service, such as hearing aids. Rather, it was being asked to ensure equal access to deaf persons to publicly available health services.

To apply the *Eldridge* reasoning, it would have to be established that the drug listing decision-making process was discriminatory in nature. This would be difficult given that the decision-making process is performed by medical and government experts who take into consideration many complex competing interests. One would have to establish that the decision-makers blatantly failed to appropriately exercise their duties and developed drug funding policy that discriminated against patients within the enumerated Charter grounds. Otherwise, it is unlikely that the courts would interfere with funding determinations — thereby respecting the judicial deference established in *Auton*. In any Charter argument, the Court must also consider whether the government's violation of the Charter is justified as a minimal impairment of the appellant's constitutional rights — for

example, the Court would consider whether the violation is justified as part of the government's need to manage healthcare resources or implement reasonable healthcare policies. In

Eldridge, the Court considered whether the \$150,000/year costs to the government of implementing an interpreter services program justified the impairment to the appellants' con-

stitutional rights. It was found that the refusal to expend such a relatively insignificant sum could not possibly constitute a minimum impairment of the appellants' constitutional rights. In

When and how cancer chemotherapy should be privately funded

Anthony Culyer, CBE, BA, DEcon, FRSA, FRCP, FMedSci

GOOD HEALTH AND INCOME ARE POSITIVELY CORRELATED

As with many other diseases, the incidence and prevalence of most cancers is associated with a social class gradient. Typically, the less fit are also less well-off, and those more in need of care have fewer resources at their disposal to obtain it. Moreover, in any risk-calibrated insurance system, the poorer are at higher risk of disease, so they have higher premiums but are less able to pay for insurance coverage.

WE KNOW HOW TO DETERMINE WHEN PUBLIC FUNDING IS REQUIRED

All healthcare technologies whose cost-effectiveness meets a socially agreed-upon threshold level for at least some uses and some patients ought to be publicly funded and should be provided and funded fairly. The ability to implement any cost-effective strategy depends on acceptable outcome measures and cost categories that enable comparisons across patient groups and healthcare technologies. In cancer care, this approach asks how the cost per unit of additional beneficial outcome compares with other available procedures. Techniques exist to do this analysis and address uncertainties about the basic science as well as the economics.

PRIVATE HEALTHCARE IS ETHICAL

For treatments not provided through the public system, can private sector participation be ethically introduced? In particular, should Ontarians be allowed to privately purchase expensive drugs or other treatments that are not in the medicare basket of insured services? Ontarians already have the option of buying care privately in the United States. Provided that the basket granted publicly in Ontario under medicare meets the conditions outlined above, it seems hard to justify denying people the right to purchase drugs that are not very effective or whose modest benefit can be had only at great cost (or insurance to enable

such purchases). Nor do I see it as a great ethical issue if the provision of cost-effective care comes from private "for profit" providers — provided it accords with best-practice protocols and the ethical requirements of the Ministry of Health and Long Term Care. There is a question of whether such private patients should pay for all associated costs and not just the drugs. My own view is that "going private" should mean just that and that private purchasers should in principle pay the full costs of all the care they receive in conjunction with the use of relatively cost-ineffective drugs that are not in the public bundle, because otherwise they will drain resources in the healthcare budget away from procedures that have more favourable ratios of benefit to cost.

IMPROVEMENTS ARE NEEDED

A system that discriminates sensibly between publicly and privately funded care must be able to differentiate between the efficacy, effectiveness and cost-effectiveness of clinical procedures. There is often an inadequate knowledge base for identifying cost-effective procedures with confidence in the public system and professionals do not always follow best-practice guidelines. The Ontario government does not currently have a mechanism for the independent assessment of the cost-effectiveness of drugs — it relies on manufacturers' evaluations. This is an unnecessary handicap to the creation of an efficient and fair way of funding a modern public healthcare system. Its lack of transparency does not inspire confidence, and it builds in biases that may be hard to detect and even harder for agencies like the Committee to Evaluate Drugs to rectify. Reasonably accurate assessment of the relative costs and benefits of health technologies are therefore necessary not only to determine what ought to be in the public medicare basket but also to determine what might be outside it but available for private purchase. Perfect accuracy will rarely be necessary — but the direction of bias ought always to be detectable.

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the event that one could establish a government requirement to fund certain cancer therapies as a Charter right, the courts may likely find that the high costs associated with such therapies are a reasonable impairment to the rights, especially if such therapies do not treat cancer — only prolong life. If courts mandate high-cost publicly funded healthcare services, judicial deference to the scope of provincial healthcare plans will be lost and the courts have not indicated a willingness to go this far.

In addition, the Court in *Eldridge* refused to determine how the government must provide interpreter services (i.e. it was not required to list them as an insured service), only that it must be provided. Applying this reasoning to the issue of cancer chemotherapies, in the unlikely event that the courts compelled delivery of particular therapies, governments would still be afforded the discretion to determine how to provide the services — for example, through private healthcare insurance methods, special access drug programs, catastrophic drug programs, etc.

Failure to provide services for serious illness or death prevention


The Supreme Court of Canada's decision in *Chaoulli* has received a great deal of scrutiny for the principles affirmed in the decision that may impact on the integrity of a public health system and government healthcare delivery obligations. These principles include:

- State prohibitions against private health insurance for services available in the public system are contrary to the Charter when the government fails to deliver publicly funded services in a timely manner.
- Delays in receiving treatment may breach a person's s. 7 Charter right to life and security of the person.
- Where the lack of timely healthcare can result in death, the s.7 Charter protections of life itself is engaged.
- A prohibition against a private parallel health insurance system is not justified on the basis that it negatively impacts on public healthcare systems.

- The courts will not defer to a government's choice of measure to deliver healthcare when it does nothing in the face of a violation of a person's right to security.
- The courts will show deference to government healthcare decision-making only where the government establishes that it has assigned proper weight to each of the competing interests in making such decisions.

If the Court agreed that the denial of funded cancer drug therapies was a denial of "vital healthcare" that results in serious physical or mental suffering or death, there is a possibility that the Court would explore whether such services must be provided in order not to violate an individual's Charter right to security of the person. It must be noted, however, that the scope of application of the *Chaoulli* decision is entirely uncertain. *Chaoulli* was primarily concerned with the constitutionality of Quebec legislation which prohibited private insurance for publicly insured services. The application of the decision may be restricted to constitutional interpretations of legislation in the context of which the government may be seen to be insufficiently responding to a general service inadequacy (as opposed to not providing a particular drug therapy).

SUBSTANTIAL CHANGE NOT LIKELY

Following the *Chaoulli* decision, more Charter litigation is expected regarding access to healthcare services, such as effective high-cost cancer therapies. This is also consistent with rising patient expectations about the quality of healthcare, as well as increased public awareness of available treatments. However, the threshold of proof in establishing a Charter claim to a particular treatment as an insured service remains extremely onerous — especially in cases requesting particular treatments for diseases that are relatively well serviced within the public system and come with extremely high costs to provincial plans. In these circumstances, even in the aftermath of *Chaoulli*, overall judicial deference to provincial definitions of medically insured or necessary services will likely be preserved. 

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Towards a hybrid system

Brent Zanke, MD, PhD, FRCPC

As cost and utilization rates of cancer drugs press budgets beyond provincial comfort levels a new approach to cancer care funding is clearly needed. Uniform access to effective healthcare is a value that defines Canada. Drug prices are largely outside of our national control. Few avenues to active agents that fall below public funding thresholds exist other than private funding. Our collective challenge will be to maximize the health of Canadians in an increasingly hybrid system. Efficacious drugs — irrespective of their cost — must clearly not be available only via private care, since this would discriminate against individuals unfortunate enough to have a rare disease. Treatments that provide expensive but minimal benefit should continue to not be reimbursed through the public system. The current "crisis" is an opportunity to redefine the use of public dollars to maximize value while allowing individuals to exercise their right to acquire any agents privately that may improve their health.