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Delivered by email to: DSSecretariat@moh.gov.on.ca

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Helen Stevenson
Drug System Secretariat
Ontario Ministry of Health and Long-Term Care
Hepburn Block, 11th Floor
80 Grosvenor Street
Toronto, ON
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Dear Ms Stevenson:

The Cancer Advocacy Coalition of Canada is pleased to offer this submission to the Secretariat in the hope that urgently needed reforms to the provincial drug approval process are forthcoming.

The most significant drug problems facing cancer patients are access to treatment. Ontario has constructed a rigid system that effectively denies care to cancer patients even when delays can mean the difference between life and death. The gap in care between federal approval of new oncologics and Ontario's decision to pay for them is a gap that prevents oncologists from preserving life.

Today, hundreds of Ontario cancer patients who urgently need treatment are receiving nothing while they wait for action from the Ministry. Others who are fortunate enough to have substantial financial resources are leaving the province to buy their own cancer care in the U.S. This is not the health system promised to Ontario citizens. On their behalf we urge you to alleviate the unnecessary suffering and death caused by blind adherence to process, and start putting patients first.

Sincerely,

Colleen Savage
President & CEO

About the Cancer Advocacy Coalition of Canada

The CACC is Canada's only full-time, registered, non-profit cancer group dedicated exclusively to advocacy. The CACC is not a charity and operates on unrestricted grants from sponsors based on guidelines that ensure the organization's autonomy. The CACC publishes Canada's only independent evaluation of cancer system performance, the annual *Report Card on Cancer*. The Board of Directors is comprised of unpaid volunteer oncologists, health sector executives and patient advocates from across the country.

Our Vision for the Cancer System

An effective, comprehensive, evidence-based cancer system that offers Canadians the best chances for preventing and treating this disease, and addresses the emotional, physical and financial needs of patients and survivors.

Our Goals, to benefit cancer survivors and all Canadians

System	Human
Consistent adherence to best practices in cancer care and prevention, making best use of financial and human resources	Reduction of the emotional, physical and financial distress associated with a cancer diagnosis
Accountability to patients, survivors and taxpayers	Access to best practices in disease prevention and timely, effective treatment options
Transparency of decision-making, priority-setting and performance measurement	Increased awareness of prevention choices



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SUBMISSION TO ONTARIO DRUG SYSTEM SECRETARIAT

DECEMBER, 2005

Identify the most significant concerns or challenges in the current provincial drug system, particularly as they relate to you or your organization.

Access generally

When all other treatments have failed, a cancer patient does not have time for decision-making about a new oncologic agent to be held up at the Ministry. Simply put, the decision does not belong there. It is too far from the point of care to respond to an emergency.

We're going to throw everything we can behind our effort to improve health care for Ontarians.
- Premier McGuinty, May 18, 2004

A cancer patient who ceases treatment that has been ineffective is in a life-threatening crisis. The cancer has not been controlled, the disease is growing and spreading, and a series of debilitating complications are on the immediate horizon. Some of these complications, if allowed to develop, will prevent the use of any other oncologics, making the urgency of another treatment choice a clear question of life or death.

The Ministry took ownership of the hospital-based chemotherapy reviews in September 2004, theoretically so the review process would “have the benefit of pharmacoeconomic expertise within the Drug Quality and Therapeutics Committee (DQTC).” The clear intention was to add a layer of cost-benefit to the review process so that bang-for-the-buck would become part of the decision-making. In theory nobody has any problem with that. Nobody has any problem with the need for Ontario to be prudent about where our money goes, to be sure taxpayers are getting the best possible deal. In practice, it all falls apart for cancer patients whose disease has not responded to older treatments.

Ministry officials claim that the review process for new oncologics can routinely produce a decision in three months. At best that timeframe is a guess and a hope, while the Velcade example shows that things do go wrong. Blaming the manufacturer might relieve the conscience of people at the Ministry but it does nothing to help people in need. Letting cancer patients deteriorate and suffer because the Ministry is ticked off with drug companies is surely not in anyone’s best interest.

When the Ministry has problems with drug companies, it is unacceptable to conclude that denying care to patients is a rational way out. Whenever patients become pawns in the battles that governments and drug companies have with each other, you will hear from the patients. Cancer patients do not care who is right, or how hard it is to manage the health budget. They are not responsible for these situations and have absolutely no power to influence or resolve any of those issues. They paid their taxes, they are gravely ill and they want the health system to live up to all the promises: care as close to home as possible, nobody going bankrupt in this country because of illness, a health system that puts the patient first, and a system that delivers the highest standards of care.

The large majority of phone calls we receive at the CACC are from people who lost their jobs because of their disease and are in severe financial difficulty trying to buy their own treatments. If they have assets to sell, they find their way to a U.S. clinic, typically spending at least twice what the same treatment would cost in Canada. If they cannot raise at least \$50,000 they wait for death, wondering where our health system went.

We are absolutely determined to make the essential investments in our health care system. More than just a matter of money, we're determined to get real results.

- Premier McGuinty, May 11, 2004

Historical basis of the problem

The basis of the problem seems to be an unexpected convergence of two separate policy decisions.

- The first is Bill 8, the *Commitment to the Future of Medicare Act*.

Cancer Care Ontario (CCO) reports that at least half of all chemotherapy in Ontario is delivered in community hospitals, outside the regional cancer centres/host hospitals. Before Bill 8, hospitals would usually pay for whatever the cancer patient needed if the oncologist believed in a reasonable chance for survival or extending life. If saving a life meant creating a deficit, hospitals would still choose to save the life.

After Bill 8 not a hospital in the province is willing to risk a deficit. None of them have a slush fund large enough to cover cancer drugs the Ministry will not reimburse. The recent example of a St. Catharines hospital refusing to cover the cost of a leukemia treatment that is routinely covered by other local hospitals is telling.

Apparently, the hospital has decided that if the cancer centre does not have to pay for that drug, why should they? The irony of this “commitment to the future of medicare” is painful.

We are building a public health care system that's committed to accessible, top-quality patient care, and is accountable to the people of Ontario.

-George Smitherman, June 18, 2004 upon passing of the *Commitment to Medicare Act*

- The second is the new review process, i.e., Ministry control over the approval process for hospital-based cancer drugs.

When the reviews rested with CCO, the organization would occasionally take a risk and spend, which explains why they had used up the entire \$60 million budget for new drugs by Christmas in the 2003-2004 fiscal year. The Ministry reacted by demanding that CCO withdraw one of the new drugs they had already started using and not add any others until a new process could be put in place. That reduced the over-expenditure for the fiscal year, but also withheld vital treatments and sparked an outcry from cancer patients spending their own money to go to the U.S. The Ministry's revenge was to pull the entire process away from CCO. The Ministry is now responsible for the approval process for hospital-based chemotherapy and is not doing very well.

The oncology sub-committee of the DQTC is said to be a joint Ministry-CCO review, but it seems obvious that burying hospital-based oncology decisions in the underbelly of ODB was unwise.

These two policies converge to place the decision making so far away from the point of care that life-saving decisions cannot be made in time to save lives. Oncologists have no room to move. Hospitals have no room to move. CCO has no room to move. Only the Ministry has any maneuverability and they choose not to use it. Failure to supply a treatment that would increase the chance of a cure must leave the Ministry open to litigation.

Navigating the Ministry

At present, cancer patients who need newer drugs not yet approved by the Ministry are caught in a maze. Take the example of Erbitux and Avastin, two new colorectal cancer treatments that are administered in a hospital setting. Both were approved by Health Canada in September, 2005. Neither one has been approved for use in Ontario hospitals, i.e., no Ontario hospital is funded to provide these treatments, and in order to avoid a deficit, they simply do not let their oncologists use these drugs.

Because federal Notice of Compliance (NOC) has been issued, OHIP will not approve out of country travel to receive the treatments in the U.S. Indeed, the letters of rejection are fast – it only takes two days to be turned down. The letters are stunning, stating that out of country treatment is unnecessary because the treatment is available in Canada, although not available in Ontario as an insured service. In practical terms, that means the treatments are not available in Ontario at all, because hospital-based chemotherapy cannot be anything else but an insured service: no third party is allowed to pay for hospital care. The staggering absurdity of the OHIP position can only be interpreted as a ruthless determination to say No. The appeal takes 45 days. We have to wonder what other medical emergency would be neglected for 45 days.

So we've called upon the people of Ontario to make an investment in their health care system, which was not an easy thing to do, but we maintain it was an absolutely essential request for us to make to the people of Ontario. What we intend to do, of course, with that premium is to invest generously in our health care system.
- Premier McGuinty, June 4, 2004

Again, it is important to reiterate our central point that the Ministry has no capacity to respond to the life-threatening needs of cancer patients in a timely manner.

Section 8

When John Emerson received individual approval for Velcade at Princess Margaret Hospital, both Peter Finkle and Sandy Nuttal (hospitals branch) said it was because the hospital based system needed something similar to the Section 8 that is available for drug benefit (ODB) patients. That made sense because the Ministry's website says Section 8s are available during the review process for ODB drugs. It has taken months for the Ministry to admit (Susan Paetkau in drug programs branch and Abid Malik in the Minister's office) that Section 8s have not been allowed during the review process for

years. Ms Paetkau implies the secret switch in policy was done before her time, therefore at least three years ago, apparently after concluding that drug companies were taking advantage of Section 8 and not bothering to submit new products for approval.

We note that the Ministry website still claims that Section 8s are available during the review process and would appreciate receiving some clarification of the facts on this point.

The entire process of Section 8 as a mechanism to respond to unusual circumstances has unraveled. We do not pretend that we know why, although certain characteristics indicate that the current system is Ministry-centred not patient-centred.

- The application is onerous and time consuming for oncologists who are already overwhelmed by a growing caseload of cancer patients. Oncologists estimate they spend up to 25 per cent of their time trying to get new drugs for their patients. This is a huge waste of specialist time, especially given the shortage of oncologists.
- Precious weeks can evaporate between the application and approval for Section 8. Although the approvals are retroactive to the date of the application, most cancer patients cannot afford to buy their drugs up front and be reimbursed later. In effect, their disease goes untreated during this time.
- No exception mechanism is available for hospital-based cancer treatments, representing more than half of all cancer treatments in Ontario.

In the case where the disease had progressed to the point where the drug would no longer be effective, patients would be justified in seeking legal redress were they so inclined. Given the nature of some cancers and the effectiveness of the newest generation of drugs, this is not an unlikely scenario.

Human services need flexibility; there has to be a way to address the unique needs of individual patients because there is no such thing as an average patient. Decision-making within branches of the Ministry tends to operate on the mainstream: the typical, the most likely, and the most common scenario. Cancer doesn't fit in that kind of thinking.

One of the cancer patients, a young woman who has not yet told her story publicly, has been advised by her oncologist that when her multiple myeloma returns, as it inevitably will, it could kill her in four weeks. The disease is that fast. What we need is a capacity to respond in days to that kind of crisis. The remote process of Ministry review and approval is too far away to save her life. She needs somebody, somewhere to have the capacity for rapid response. Whether the Ministry can build that capacity as an exception mechanism is a question yet to be answered. If they cannot, then the exception has to be handled elsewhere, preferably much closer to the point of care.

Recently the Minister told reporters it would not be fair to provide exceptional access during the review process, because if the drug is eventually rejected for funding it would not be available to other patients in the same circumstances. This train of thought reinforces our fear that the Ministry increasingly works to serve itself, forgetting the patients. Why, for example, would the Ministry say no to any cancer patient with

imminently life-threatening disease whose oncologist believes a new treatment could stop or slow the progress of disease? Whether that happens during the review process or afterward, even after a funding rejection, why would the Ministry assume that every answer must start with No? Are we in the life-saving business or not?

Confusion about the nature of the review

All the clinical evidence needed for Ontario's review process has already been widely published in peer reviewed journals and presented at medical conferences that every oncologist in Canada reads and attends.

There are five new highly effective cancer drugs approved by Health Canada this year; and every oncologist in the country knows the evidence for them. Their safety and effectiveness have been established along with the most appropriate use for the drug i.e., which tumour site, which stage of disease, even the sequence and combination of therapies. Is there one example of an Ontario review for a cancer drug that found Health Canada's approved indication to be wrong? Ontario's review is about whether or not to pay, not about clinical evidence of effectiveness.

In the Legislature on November 17th, the Minister was proud to leap to the defense of people who work in our cancer system and dedicate their lives to the care and treatment of seriously ill patients. We would do the same. The difference appears to be that we also have confidence in their clinical judgment.

Pharmacoeconomics – cost of illness

Ontario's review of oncology products is said to be driven by the need to determine the clinical evidence of effectiveness. This misrepresents the facts, as Health Canada typically spends years conducting the review of safety and efficacy before granting its Notice of Compliance. The NOC clearly states the approved indication and we have not found one example of an Ontario review that disproves the federal indication.

The analysis of cost-benefit is currently based on a pharmacoeconomic review that looks only at potential future expenditures vs. an estimate of potential lives extended or saved. The element that is missing from this analysis is called Cost of Illness evaluation, which calculates the direct and indirect costs attributable to the disease. Instead of comparing the costs of alternative treatments, it provides a picture of all existing costs from the disease, which is already being treated with some standard of care. Looking at the cost of illness would be a practical way to form an opinion on the importance of any new expenditure. Looking at the cost of not treating the illness is a preferable measure of how much investment is appropriate.

The Canadian Medical Association and indeed Premier McGuinty have frequently commented on the value of health care to the economy. A high quality health system keeps citizens active, productive and paying taxes as well as attracting new business investments.

According to Health Canada, the loss to the Canadian economy – not the cost of care, but the lost productivity from premature cancer deaths – was \$10.6 billion in 1998. We are losing talented people who die before they should, before their potential contribution to this country, to their communities and families can be realized. This loss is not factored into the present method of assessing whether or not to pay for a new drug.

Confusion about who should pay

This problem materializes in different ways. In some cases, patients are pushing their insurance companies to pay for treatments that would otherwise be considered insured services under the *Canada Health Act* (i.e., administered only in a hospital setting); in other cases patients are going to a private clinic or to the U.S. for treatments that are recommended by their oncologists but not covered by the Ministry. Patients without money simply wait helplessly for the disease to kill them. We have interviewed such patients.

Medicare is the best expression of Canadian values. It's an essential social program that ensures every person in this province has access to the publicly funded health care they need, regardless of their economic means, their age or ethnicity, or where they live.
- George Smitherman, June 18, 2004

The anxiety associated with these financial demands exacerbates the disease. Just when oncologists tell their patients to avoid stress, the health system collapses under their feet.

The Ontario government repeatedly affirms its commitment to principles of the *Canada Health Act* which promises that insured services are fully covered and no third party will pay for them.

In this province, today, several hospitals are in breach of the *Canada Health Act* by telling cancer patients to buy their own cancer drugs and bring them to the hospital to be administered. The direct cost to cancer patients can be overwhelming, especially since many lose their jobs and third-party insurance benefits during the course of the disease.

A province that refuses medically necessary care to cancer patients cannot claim to be in compliance with the *Canada Health Act*.

Participating in the process – the issue of transparency

While the Ontario Government insists that not everything can be covered and that tough choices have to be made, there is no opportunity for taxpayer, let alone patient, involvement in those decisions. Ultimately, when Ontario refuses to cover a drug that Health Canada has approved, it is because of a decision that the outcome is not worth the cost. It is not because Ontario believes the NOC was incorrect, it is not because Ontarians are uniquely immune to the disease, and it is not because the drug is demonstrably useless. It is about cost vs. impact.

We're making some choices. We will not shrink from our responsibility to make difficult choices. We cannot be all things to all people. We're investing in those kinds of things which we think warrant greater priority -- like cardiac care, cancer care, hips and knees, family doctors and nurses -- and we're proud to do it.
- Premier McGuinty, November 16, 2004

In these circumstances, the values of citizens are not represented at the table. Only the values of the payer are at the table. Societal values about the relative merits of paying for this treatment and not paying for that one cannot be represented in a system that locks the patient out of the discussion.

Recently, the BC Cancer Agency was found to have paid for some of the cost of using Herceptin by canceling two treatment programs for other cancers. The two programs in question were for treatments with inconclusive evidence of effectiveness, but they had been previously approved for funding and would affect 108 patients with rare cancers. It seems most likely that the same types of decisions and priority-setting happen in Ontario.

What is different about BC is that the information was accessible through a Freedom of Information request and therefore open, belatedly, to public scrutiny. That opportunity does not exist in Ontario. Nonetheless, it is clear from the number of cancer treatments that Ontario does not cover, years after these treatments are used in BC, that somewhere at the Ministry unknown advisor(s) is (are) making those choices.

Ontario taxpayers are entitled to greater transparency in how those choices are made and whose values drove the decision. Only by involving patients and taxpayers in the decision can we expect to have any confidence that the system is working in the best interests of patients. The choices have to be in the hands of the citizens paying for, benefiting from or suffering from such decisions and the rationale must be open to public scrutiny. Furthermore, it must be said that any patients denied care because of these decisions must be assured of another reasonable alternative to extend their lives.

Recommend possible solutions to meet these challenges and improve the drug system.

The Ministry is expecting an old process to give a new answer; a more rational approach would be to look at the answer and make the process work to deliver that answer. The place to start is by asking “What is the cost of not using this treatment?” and then devise a drug program that truly responds to the needs of Ontarians.

Recommendations

1. Start with a statement of values: that when a life can be saved, it should be.
2. An exception mechanism is urgently needed to allow oncologists access to the new drugs and highly effective drugs approved by Health Canada but not yet approved by the Ministry.
3. Exceptions need to be available for imminently life-threatening cancer, where other treatments have failed and the patient has no other reasonable treatment choices.

4. The response capacity for approving exceptional access cannot be longer than three days. Someone with a rapidly growing tumour cannot wait weeks for a decision about her life. If the Ministry cannot deliver, this mechanism has to be managed closer to the point of care. The basic principle is that in a life-threatening situation, the treating oncologist must be allowed to provide what is needed, without delay.
5. The terms for exceptional access ought to allow an oncologist to use the new chemotherapy for sufficient treatment cycles (usually two or three) to determine if the drug is working. After that, if there is evidence the chemotherapy has worked the exceptional access should continue; if it has not worked, the exceptional access would stop.
6. The exception mechanism must be rapid up front, given that the critical questions really happen after the treatment – it worked or it did not work. This would be consistent with the usual practice by oncologists, testing to see whether the tumour has reacted to initial cycles of treatment; it does not place new burdens on the oncologist or the health system.
7. Even if a drug has been rejected by the Ministry’s review, there will always be the unusual patient whose unique needs can be answered only by this treatment. The exceptional access mechanism should remain in place after the review process.
8. The review process should involve patients at the point where a decision will take place to choose one therapy over another, to invest in one disease over another or to fund one treatment only by rejecting others.
9. Transparency and public scrutiny are required so that the “tough decisions” can be seen to be in the interests of society as a whole.
10. Pharmacoeconomic analysis should include the Cost of Illness model as a practical method of assessing the merits of investing, or not investing, in new treatments.

Propose how you or your organization could contribute to the solution.

The Cancer Advocacy Coalition would be pleased to help the Ministry execute a plan to expedite better access to cancer treatments.

We have committed our support to the cancer patients who are, today, receiving no treatment as their disease advances and who have (or had) a reasonable prospect of recovery with one of the new drugs already approved by Health Canada. Some have deteriorated past the point where they can be saved, some are anxious and scrambling to pay for U.S. cancer care, some have died.

We are a small group of dedicated unpaid volunteers experienced in delivering oncology treatments, receiving oncology treatments, or administering the treatment and care delivery systems. Our collective expertise gives us unique insights into the problems faced by patients, relatives, and health care administrators, and what is equally important,

experience in delivering the practical solutions that need to be implemented. From that perspective, we stand ready to offer expert advice at all three of the above levels with no personal gain to be derived by any of us in any instance.