

**PRESENTATION TO THE SOCIAL POLICY COMMITTEE ON BILL 102
MONDAY, MAY 29, 2006**

**Presenters: Dr. Kong Khoo, Vice-Chair of the Board of Directors
Colleen Savage, President & CEO**

Cancer patients in Ontario have less access to cancer drugs than most other provinces and substantially less than British Columbia, where cancer outcomes are the best in the country.

Bill 102 and its related package of policies and regulations help to address that problem. We stand by our early commentary on Bill 102, on April 13th, when CACC expressed eager support for the intentions announced by Health Minister Smitherman to improve access to effective treatments. In meetings since then, with Helen Stevenson and with the Deputy Minister and with the Minister, we have been impressed with the openness, candour and spirit of collaboration that has given us several opportunities to describe the issues facing cancer patients and what those patients need to see in the future.

Specifically, we are pleased to see Ontario finally creating an exceptional access mechanism for hospital-based cancer drugs, as every province west of here has had in place for many years. We fully support and encourage the Ministry's desire to monitor the outcomes from real-world use of cancer drugs that would be funded through conditional listings while a new drug is under review. Cancer patients in every part of the province are relieved and hopeful that the promise of rapid review for breakthrough drugs will improve their odds of surviving cancer.

We are all too aware that intentions can be squeezed during implementation. Somewhere between the Minister's promises and the reality for cancer patients, many things can go wrong. If this Committee and the groups appearing before you do not anticipate and clarify the details, we will all be responsible for the results.

Cancer patients have asked us to remind you as clearly as possible that time is not an option for people with a potentially fatal disease. At every step in the implementation of

Bill 102, they expect to see commitments to efficient, timely responsiveness and accountability for meeting those commitments.

In the annual reports from the Committee to Evaluate Drugs, we would hope to see an evaluation of whether this new process is working in the best interests of patients.

Therefore the Cancer Advocacy Coalition asks you to watch for details that are still a matter of concern to us. Some are policy questions, not described in Bill 102 but nonetheless critical to understanding the intentions. Some are questions that will only be answered in the Regulations but these future directions can make a difference.

Section 16 – Exceptional Access Mechanism

The Section 8 process for special exception has been a disaster of paperwork and frustration; its demise is welcome. Section 16 of the proposed legislation permits a much more efficient system but the details are missing. The CACC asks for your help in creating language that will benefit cancer patients.

1. The new process should not limit the number of drugs that are available for exceptional access. Any drug that a physician has evidence could benefit a patient should be available through this mechanism.
2. Oncologists are qualified and knowledgeable about cancer drugs and can easily figure it out in a matter of minutes. If untrained individuals are going to make these decisions, we need to know who they are and what guidance they are following.
3. When other treatments have failed, a cancer patient is in dire need of a new choice and cannot wait for an answer.
4. An online application is the most efficient way to handle exceptional access. A simple one page form that the oncologist can use to fill in the data and click to send would be preferred to fax, telephone or any other process.
5. The best process would give an immediate approval and require the oncologist to report on results in two months. If the treatment has been successful, it should continue. If not, the exceptional access can stop.
6. If one of these drugs is used successfully and the patient has improved, the better health status should not lead to rejection of a renewal. Evidence of benefit could be a criterion for continued use.
7. Ontario does not pay for many cancer drugs that are proven effective and are widely used elsewhere. Apparently, cost is the deciding factor. The only condition that should apply to use of a cancer drug is whether it is effective.

Conditional Listing During the Review Process

It is especially welcome news that this part of the proposed reforms involves outcome surveillance. We understand the Ministry will enter into written agreements with manufacturers to cover off this point along with pricing and other related matters. Everything the Ministry can do to promote surveillance of treatment outcomes in the real world, post clinical trials, benefits patients. We recommend that these studies also be applied to all drugs used by exceptional access.

Therapeutic Substitution

We now understand the language of “same-similar” is being revised and clarified to eliminate therapeutic substitution. Without those changes, “same-similar” would mean a pharmacist could dispense an alternative drug with similar pharmacology to the one prescribed. Therapeutic substitution by the pharmacist would be an unacceptable intrusion into the physician’s medical judgment and knowledge of the patient’s clinical status. A pharmacist does not have either of those essential qualifications to change a prescription. We have not yet seen the language, but we take the word of Minister Smitherman that he has no intention of permitting therapeutic substitution at the pharmacy.

Competitive Agreements

CACC remains concerned whether competitive agreements will be used to accomplish therapeutic substitution. If we find ourselves in a situation where the Ministry enters into contracts, through competitive bidding, to select one drug that will be the only one covered from an entire group of similar drugs, then the Ministry is creating therapeutic substitution even farther away from the point of care.

In these circumstances, it is true the physician would know up front what the deal is: prescribe this one and your patient has it covered, prescribe the other one and your patient has to pay. But the dilemma is the same for the patient – if something about his or her clinical status makes that one drug unacceptable – either because of the risk of adverse reactions or because it is pharmacologically different enough to mean it will not be effective – then that disease condition is not treated equally for all patients. This would inevitably lead to complaints to the Ombudsman about the equitable application of health policy.

Appeal Process

We anticipate three types of appeal for decisions from the Executive Officer or the Committee to Evaluate Drugs.

1. **Appeal for exceptional access**
An appeal process is essential for cases where the initial response is negative and the oncologist believes the patient’s circumstances demand more consideration. This appeal should be conducted for a response by an oncologist within 48 hours. Whether in oncology or other diseases, there are bound to be disputes about a negative decision, and the process for handling them must involve a qualified practitioner.

2. **Response to citizen concerns**
Cancer patients want to have assurances that the Ministry will take their complaints seriously. Many cancer patients tell us their complaints over the past year have never been answered. On their behalf, we ask this Committee to ensure that the Ministry develops a respectful approach to patient concerns, including an appropriate investigation if necessary.

3. **Rejection of the initial drug submission**
When a drug is about to be rejected for funding, we propose that a cross-check should kick in automatically to ensure the decision meets a test of fairness. We recommend a process that involves the new Citizen's Council so that social values, on top of the clinical evidence and cost-benefit analysis, are part of the decision. This third factor has been missing from reviews although it is significant in cancer care and probably many other diseases.

Clinical Trials

It is absolutely necessary for Ontario's hospitals and community cancer clinics to be involved in clinical trials. Ample evidence has been published demonstrating that where community cancer clinics are involved in clinical trials, the patients involved in the trials and those who are not involved in trials all do better. Anything that makes it more difficult for Ontario hospitals or community cancer clinics to participate in clinical trials would reduce quality of care and reduce the outcomes for patients.

Transparency

Disclosure of the rationale for rejecting a new drug needs to be complete and not cryptic: merely stating that a drug is too expensive will not be sufficient. Patients want exposure of the cost analysis that puts a price on extending life and cuts off that opportunity without explanation at some mysterious number of months or price. The problem of so few cancer drugs being approved in Ontario compared to other provinces will only be understood if these factors are fully disclosed.