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Joint Oncology Drug Review  
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Manitoba Health

Kevin Wilson, Co-Chair  
Joint Oncology Drug Review  
Executive Director, Drug Plan and Extended Benefits Branch  
Saskatchewan Health

Dr. Anthony Fields, Chair  
Joint Oncology Drug Review Advisory Committee  
Vice President of Medical Affairs and Community Oncology  
Alberta Cancer Board

Dear Sirs:

The Cancer Advocacy Coalition of Canada recognizes the important opportunity represented by Joint Oncology Drug Review and strongly supports the development of an ethical framework for shared decision-making.

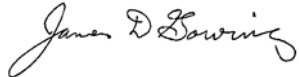
We also appreciate the opportunity to attend stakeholder information sessions, but were disappointed that time constraints at the June 22 meeting left insufficient time for discussion of several critical issues. This letter is to elaborate on points of particular interest to the CACC in the hope these matters can be discussed in more detail at the next meeting.

The cancer patient whose life hangs in the balance is by far the most important stakeholder in decisions about access to cancer drugs. Thus, we are encouraged by the positive response for a patient representative on the JODR Advisory Committee. However, one million Canadians stricken by hundreds of varieties of cancer across 14 health care jurisdictions are unlikely to sing in perfect harmony through such representation. It is therefore imperative to maintain ongoing consultation with this wider community. CACC would not support any move by the Advisory Committee to delegate its responsibility for communication with stakeholders to a single patient representative

or even two. It would be helpful for the Advisory Committee to clarify its intentions in this regard.

The proposals that follow are intended as constructive advice to help JODR design a more acceptable, complete and fair review process. CACC will be sharing this document with the other groups in attendance at the last stakeholder meeting. If you have any questions, please feel free to contact me.

Sincerely

A handwritten signature in cursive script that reads "James D. Gowing".

James D. Gowing, MB, FRCPC  
Chair

# ISSUES FOR FURTHER DISCUSSION

## 1 Oversight of the joint oncology drug review (JODR) process

- 1.1 Best practices:** The interim JODR is not based on best practices.

Recommendation:

JODR should be looking at the best process for drug review that can be constructed from the experience of all provinces, meeting and surpassing the review standards of G8 countries.

- 1.2 Equality of provinces:** The interim JODR appears to operate on the premise that eight other provinces have much to learn from the Ontario Committee to Evaluate Drugs (CED), and that Ontario does not need to hear from those provinces during a drug review. Given the past performance of the Ontario CED in comparison to the results of similar processes in other provinces, we strongly disagree with this premise.

Recommendation:

During drug reviews, a mechanism should be instituted that permits full discussion with other provincial jurisdictions in attendance.

- 1.3 Evaluation:** There is no indication how the promised one-year evaluation will be conducted. As it stands now, JODR is required to make a recommendation in November to the Provincial/Territorial Deputy Ministers of Health, but the questions to be answered at the time of evaluation have not been disclosed. Of special interest will be the impact on patients when one province funds a recommended drug and another province does not, as well as the degree to which provinces act on JODR decisions.

Recommendation:

Terms and methodology for the evaluation of the interim JODR need to be established immediately, with input from patients and other stakeholders. These include:

- (a) Impact on patients and health system(s),
- (b) A comparison of the degree of acceptance of JODR recommendations province by province,
- (c) Evaluation of JODR's effectiveness by an independent body that does not have responsibility for drug purchasing or drug reviews.

## 2 Ethical Framework

- 2.1 Undeclared considerations:** It is unacceptable to have non-scientific factors discussed during drug reviews and influence decisions in a way that is not open to public scrutiny. These factors are not being identified in the submission process or

declared as considerations to be ranked in the review. This is in violation of normal government policies ordinarily followed for procuring goods and services.

Recommendation:

Normal government policies should be followed, including:

- (a) Prohibition of assumptions about information not offered in the submission,
- (b) Declaration of all factors to be considered in the review,
- (c) Disclosure of the rating to be used for various elements under review,
- (d) Performance of the review by a body that is not also the primary purchaser.

A description also should be included about how non-scientific factors are validated, including:

- a) The present dollar cap being used per quality-adjusted life year,
- b) Assumptions about societal priorities and taxpayers' willingness to spend,
- d) Government spending preferences (drug budget vs. programs/services).

- 2.2 Accountability:** Accountability for health policy, priorities and budgets cannot be delegated to a committee of advisors. Provincial governments and their officials must be accountable for these items. Despite the fact that not one jurisdiction claims individuals chosen for review committees were selected for ability to create health policy, place a maximum dollar value for extending life, or establish spending priorities for the health system, these are the decisions for which they are currently being held responsible.

Recommendation:

- a) Appointees to the drug review committee must be explicitly relieved of any responsibility for health policy or management of health spending.
- b) A political decision about affordability – in which spending on cancer drugs is ranked relative to other expenditures – should be clearly separated from drug review committees, as it is the exclusive responsibility of government and its executive officials.
- c) Decisions to fund new cancer drugs by reducing other cancer expenditures should be disclosed and justified by health ministers.

### 3 Competence

- 3.1 Expert reviewers:** Individuals (or sub-committees) conducting clinical and pharmacoeconomic analyses are not identified, and their instructions are unknown. Historically, clinical and pharmacoeconomic reviews done by the experts in various provinces have started with the same core information but somehow have come to substantially different conclusions. The resulting possibility for bias remains, and is clearly evident in the West-East gradient in guideline discrepancies (see CACC Report Card 2004, “Guidelines”). Yet there has not been an insistence that these discrepancies be explained.

Furthermore, scientists who had performed the pivotal trials (and are among those most competent to judge the results of these trials) have been explicitly excluded from contributing to CDR reviews (and CDR still conducts reviews for Ontario), on the questionable premise that their testimony would be so tainted and biased as to be unusable.

Recommendation:

- a) Interprovincial workshops (open to the public) should be held for all the reviewers used by the provinces, in an effort to design an optimal analytic approach, including methodologies and reporting formats
- b) The names and qualifications of expert reviewers, including all external reviewers, should be open to public scrutiny
- c) The clinical scientists who have conducted the pivotal trials should be allowed to both testify to the review committee and to contribute to its deliberations

- 3.2 Clinical evidence:** We are told the Ontario CED will accept nothing short of Phase 3 randomized controlled trials showing overall survival benefit as acceptable clinical evidence for recommending public funding. This prevents, for example, a sensible response to situations where pivotal trials were stopped for ethical reasons due to highly significant patient response rates, or freedom from relapse, before any overall survival benefit could be documented. In such cases, for ethical reasons, cross-over from the control to the test arm is routinely permitted, and thereafter it would be unethical to try to conduct another trial to prove survival benefit. Yet in such instances the drugs have been recklessly rejected by reviewers (specifically the CDR), on the untenable premise that entirely new Phase 3 trials are required for final approval. This effectively delays Canadians' access to important new drugs.

Recommendation:

JODR needs a practical mechanism for dealing with important new drugs and should be transparent in reporting its reasoning. When trials are stopped due to significant patient response rates, or improved freedom from relapse or progression, but short of overall survival differences, the drugs in question should receive a more balanced appraisal. Common sense should prevail from the outset rather than be forced by public hindsight.

- 3.3 Cost-benefit analysis:** One of the more egregious arguments used to reject funding for newer cancer drugs is that extending life for a median of three to six months is not worth the cost of the drug. Yet, when these new drugs are effective – in some cases due to the right match of patient and drug – they may extend life by years not months in individual cases. Statistically such instances are buried in an expression of overall effect on the group. When the new cancer drugs are not effective, this usually becomes apparent to the oncologist within the initial few cycles of treatment and the drug can be discontinued. It is not correct to assume that a full year of drug cost is incurred in those cases, or that all responding

patients each have only a few months of benefit, or that the many months and years of extended life for individual patients do not exist.

Recommendations:

a) The best match of patient and drug will occur through investment in biomarkers measured during Phase IV trials (post-approval trials), to more precisely identify the patients who benefit from those who do not. Provinces should set aside two to four per cent of their drug budgets to finance the necessary research (See Report Card 2006, “Research Saves Lives”)

b) Value judgments about the worth of an extended life have no basis in science, should not be offered by a drug review committee, and should remain in the purview of the elected officials who have created the committee (see above).

- 3.4 Pharmacoeconomic model:** Limitations of the pharmacoeconomic model used by the Ontario CED have frustrated logical attempts to analyze the cost-effectiveness of cancer treatments. These models should not continue in use by JODR

Recommendation:

Incorporate “the cost of not treating” into assessments of the cost-effectiveness of a new cancer treatment. As well, the economic benefit accruing to the society at large from the patients who respond to the new treatment should be taken into consideration

## 4 Credibility

- 4.1 Transparency:** Appointing a patient representative to the JODR Advisory Committee, while a necessary and important step, is not a surrogate for transparency. One or even two sets of eyes on behalf of a million Canadians, with a confidentiality agreement that prevents disclosure of the Committee discussions, do not meet the expectations for transparency. Disclosure allows performance evaluation and leads to public confidence in the process.

Recommendation:

All stakeholders should be invited to be kept informed on an ongoing basis about issues being discussed and priorities being established by JODR. To accomplish this, the analyses and rationale from all drug reviews should be published as written reports and on a searchable web-based system.

- 4.2 Assessment of Performance:** Transparency as described above will produce the substrate which will allow ongoing assessment of performance and discourse on how to maintain constant quality assurance.

Recommendation: As decisions are made by JODR, guiding principles should be a matter of ongoing discussion with stakeholders to allow development (and revisions) of an appropriate set of measures to be tracked and disclosed.