

> Cancer Advocacy Coalition

Canada

Grassroots Action for Cancer Care

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**Presentation to the House of Commons Standing
Committee on Health**

April 30, 2007, Ottawa, ON

**Dr. William Hryniuk, MD, FRCPC, Past Chair
Cancer Advocacy Coalition of Canada**

Thank you for inviting the Cancer Advocacy Coalition of Canada to comment on the important matter before you. First of all, we congratulate the Government for transferring the cancer drug portfolio from the CDR to the Joint Oncology Drug Review (JODR).

Let me place our credentials before you. The Cancer Advocacy Coalition of Canada, or CACC, is a non-profit organization comprised of cancer survivors, physicians, scientists, and cancer system administrators drawn from coast to coast across the 10 public cancer systems of Canada. CACC board members have personally received cancer treatments and services, or delivered those services to individual patients, or administered cancer services on a regional basis, or organized and conducted clinical cancer research on a national basis, or studied cancer prevention on an international basis. Not one of us is paid for our work on CACC. We contribute our time solely because we each believe that by developing a collective view from our varied perspectives and sharing that collective view with others we can make a difference. Board members are listed at the back of the presentation. For my part, I am the immediate past chair of CACC, and formerly a practicing medical oncologist, a cancer researcher, and a director of university-based cancer centers both in Canada and the United States.

CACC is dedicated to ensuring that the spectrum of cancer control activities in Canada proceeds in optimum fashion. Each year we investigate various aspects of cancer prevention, screening, treatment, supportive care, and research in Canada, and publish the results in our Report Cards on Cancer. We consistently observe marked differences between the Canadian provinces in the effectiveness of their cancer control. We have shown how these differences translate into substantial differences in cancer mortality among provinces, how those differences relate to provincial government funding for cancer control, and how access to important new life-saving cancer drugs is very unequal and inconsistent across Canada. Many constructive activities have recently been catalyzed to address this latter issue of cancer drug access. We are especially grateful for your attention to the process for cancer drug approval.

We are also gratified that the Government of Canada has established the Canadian Partnership Against Cancer, which we, along with others, have been espousing for years as a means of redressing these inter-provincial differences through knowledge sharing at the national level. CACC looks forward to watching the working of this new agency.

Let me get to the point of this hearing: why was the CEDAC committee of CDR unable to comprehensively evaluate oncology drugs and how can JODR do better?

First of all, CEDAC was not well suited to deal with the complexity of the oncology problems presented. In the first instance, committee members were prevented from accessing the best knowledge about each new treatment and were therefore unable to judge data in context. Let me explain.

There are well over 150 types of cancer. For each type there are several stages. For each stage there can be several treatment options, depending in part on the molecular markers on the cancer cells. These options constantly change as new data pours in every day from the hundreds of cancer clinical trials testing revolutionary new medicinal treatments aimed at the different markers. It is becoming increasingly difficult to maintain the knowledge level required to adequately judge what is the state-of-the-art medicinal

treatment in any given situation at any given time. The requisite knowledge applying to each unique situation is arguably best held by the investigators who actually did the clinical research establishing the drugs effectiveness in the applications before CEDAC. Yet the CEDAC has been prohibited from accessing the detailed knowledge of these investigators. As I understand it, this prohibition was based on the premise that the judgment, and therefore the advice, of such investigators would be tainted by their affinity for the trial results or their affiliation with the drug company who sponsored the trial showing the drug was effective. This presupposes that in a significant number of instances there would have been such an adversarial relationship between the trial investigators and the committee members that there could have been no trust between the different parties as they exchanged knowledge in cases before the committee. Granted the various parties would have had somewhat different perspectives. But surely the main knowledge exchange that could have occurred would have been of benefit to the Canadian public. After all, the investigators are physicians who not only have the requisite knowledge to place the treatment results in proper context, it is safe to assume they also have the interests of their patients at heart and the commitment to improve treatment for their patients. Otherwise they would not have done the study in the first place.

You will probably hear of examples of where CEDAC might be accused of having judged wrongly because of lack of knowledge about context because of this prohibition. You will decide how much weight to give these examples.

We strongly urge that the investigators who conducted the pivotal studies be allowed to contribute to the process of adjudication of drugs by JODR

The JODR is a process in which eight other provinces allow the Ontario Committee to Evaluate Drugs (CED) to conduct all the oncology drug reviews on their behalf. The CED has an oncology sub-committee providing expert advice that is otherwise not adequately present on the CED itself. The oncology subcommittee is comprised of an equal number of oncology experts from Cancer Care Ontario and other representatives from the CED and the Ministry. There now arises a transparency problem as the responsibility for adjudicating cancer drugs is transferred to the CED. You should know that the identity of members on the oncology subcommittee is shielded from the public. Among the reasons for this is concern that subcommittee members may be subjected to undue pressure or even bodily harm if they render negative judgments about particular drugs. If that is the reason, it would be an entirely unique one in the annals of public service in Canada. I am sure you can judge the weight to be given to such a premise compared to the need to know the credentials and competencies of committee members engaged in such an important public service.

We ask that the identities and credentials of JODR oncology sub-committee members be readily available to the public.

The third concern we have about the process followed by the CDR committee is the lack of transparency surrounding its judgments. We do not have the detailed reasons and by what criteria was a particular drug submission turned down. We suspect that the JODR, left to its own devices will follow the same path. That certainly has been the habit of the CED in its role as adjudicator of oncology drugs for the province of Ontario.

We ask that you ensure that JODR make public the detailed explanations of why it renders particular judgments.

Central to the issue of lack of transparency is the lack of a robust economic model whereby the cost-effectiveness of each drug is being judged. I am not criticizing the members of the CDR committee who were charged with judging this aspect. They were well suited based upon their credentials and their individual track records for the task before them as presented in the committee terms of reference. However, regardless of whether it is CDR or JODR that is rendering the judgment, it is regarding the reference frame within which cost issues are addressed that we take issue.

The new cancer drugs each result from huge efforts in basic and clinical research. They are very expensive, and cost-effectiveness must factor into their deployment. Cost-effectiveness has usually been expressed in terms of the incremental cost per quality-adjusted life year gained. However, better methods of expression must now be developed to allow judgments in a larger context so that the tensions among efficiency, equity, and opportunity costs can be resolved. To adequately judge the cost-effectiveness of a particular drug, additional factors must be taken into account including the cost of alternative, older and less effective but still expensive treatments, the cost of not treating the condition which results in more doctors' visits, emergency room visits, hospitalizations, the cost to society in the lost tax base and loss to the GDP from failure to adequately treat otherwise functioning cancer victims, the loss to the community from loss of its leaders, and above all the heavy emotional and economic cost to family from loss of loved ones. To put it more simply, a new drug might increase a cancer agency's budget, but it might reduce overall health care cost, or even produce a net gain to the economy.

We hasten to add the area of cost-effectiveness of drugs is one of great controversy. The entire Western World is wrestling with the issue of drug costs. However, somehow almost all other jurisdictions have come to very different conclusions compared to the CDR committee and have released many more drugs for general public use after going through the exercise of judging cost-effectiveness, as you will undoubtedly hear from other presentations. On page 34 of our 2004 Report Card you will find we gave a detailed, broadly-based, and comprehensive suggestion about how to approach this critical aspect.

We strongly urge that the JODR embrace much more broadly-based economic models when deciding whether or not a cancer drug is cost-effective.

That immediately raises the next area of concern, which is the relative lack of representation by patients on the committee. Individuals must participate in the process who can give strong voice to the millions of past, present and future cancer victims in Canada. I would remind the committee that the risk of each of us developing cancer is now over 40%. That means almost one in two Canadians will develop cancer in their lifetime. Surely, these are the stakeholders whose voice must be most strongly heard. My own experience with committees in thirty-five years of academic medicine has taught me at least this: when well informed patients are present, the tone, content and direction of discussion, and final conclusions are very different than when patients are absent. Undoubtedly, many of the judgments of CEDAC would have been different had patients

been strongly represented. We see that this deficit in committee membership is being redressed by CDR, but it still promises to be a deficit for JODR.

We ask that well informed and effective cancer patient representation be on the oncology subcommittee of JODR.

Next, there arises the issue of the type of evidence about drug effectiveness that guides the deliberations of CDR and JODR. We strongly support the need for results from properly conducted studies before each new drug can be approved. Insistence on data from well designed randomized trials has been the main driving force behind continued progress in cancer treatment. In fact, one of our own board members, Dr Tony Miller, initiated and developed the National Cancer Institute of Canada Clinical Trials Group over three decades ago. This group has achieved international recognition for its competency, productivity, and reliability in conducting randomized cancer drug trials. However, you should be aware that in Canada, as elsewhere, in the case of the adult cancers these randomized trials are conducted on a highly selected and small subset of patients drawn from the community at large. Only 3% of patients participate in these trials yet the results are extrapolated to many of the remaining 97% who are not participants for a variety of reasons. We submit that in almost all cases after a drug has been approved based on randomized trial results, there needs to be monitoring of its effectiveness in cancer patients in the community at large. The effectiveness in the general population could be quite different from that predicted by the randomized trial results, and, given the expense of the new cancer drugs, post-approval adjustments in use indications will have to be made.

We ask that community-based follow-up studies be routinely conducted after approval by JODR to determine whether the results are those predicted from pre-approval studies

Finally, we would like to raise an issue related to the deliberations before us today but not explicitly stated in the terms of reference. We have investigated and published on the fact that across Canada there is wide variation in the guidelines advising doctors on cancer treatment. The differences are marked even though the guidelines were all ostensibly based on the same body of evidence. There is a pressing need for Canada-wide guidelines for cancer treatment, for monitoring whether they are being adhered to, and whether they are having an impact. The province with the most comprehensive approach to this aspect of cancer control is BC which also has the best treatment outcomes and the lowest cancer mortality. In fact, BC is recognized as a leader in cancer control in the Western world, and the rest of Canada would do well to follow its lead. Cancer treatment guidelines could be developed at the national level through the newly created Canadian Partnership Against Cancer. Your attention and encouragement would greatly help to ensure that the Partnership proceeds in this direction. If national guidelines were established, the loop will then be closed because the provincial pick-up of drugs approved by JODR would be greatly enhanced. As it stands now, without national guidelines, even when JODR approves a drug, the provinces do not have to pay for it, based on their own biases. In such cases, as far as the cancer patients in that province are concerned, the JODR may as well not exist.

Thank you for your attention.

CANCER ADVOCACY COALITION BOARD OF DIRECTORS

Jack Chritchley BA, MD, MSc, FRCPC, is one of the founding members of the CACC. He practiced Internal Medicine and Medical Oncology for 25 years in the Interior of British Columbia before joining the BC Cancer Agency as a Vice President leading the provincial Communities Oncology Network.

Geoff Eaton a graduate of Memorial University of Newfoundland's business faculty, is a two-time cancer survivor, professional speaker and founder of RealTime Cancer. He lives in St. John's, NL with his wife Karen and daughter Adia.

Douglas Emerson has spent the last decade working in communications, public affairs and government relations. He lost his father to cancer in 2005.

James Gowing (Chair) BA, MB, BS, FRCPC, founded the community cancer clinic in Cambridge, ON and established the National Conference on Community Cancer Clinics. He has been an advocate for community cancer care and cancer control throughout his 40-year medical career.

William Hryniuk (Past Chair) MD, FRCPC, has practiced in Canada and the US as a medical oncologist, taught at medical schools, developed and directed major cancer centres and regional cancer control programs. He remains active in basic and clinical research and is currently Medical Director of CAREpath Inc.

Linda Jalbert is a breast cancer survivor living in Montreal. She is currently on the board of Jump for Hope an organization that raises funds for the emotional needs of breast cancer patients and their families. She is also the Executive Assistant Manager of Loews Hotel Vogue, with more than two decades of experience in the local hotel industry.

Darwin Kealey (Vice Chair) BA, MA, is a former executive public servant and international entrepreneur with extensive advocacy experience.

Kong Khoo (Vice Chair) MD, FRCPC, is a medical oncologist based in the Southern Interior of British Columbia in Kelowna.

Eric MacEwen is a recent cancer survivor and is also a founding director of the East Coast Music Awards and has been a singular voice for the music of Canada's East Coast through his weekly syndicated radio program.

Anthony Miller MD, FRCP, is Professor Emeritus in the Department of Public Health Sciences, University of Toronto. After a long career devoted to cancer epidemiology and screening, he is now a consultant to the World Health

Organization on Cancer Control and to the US National Cancer Institute on cancer screening.

Robert Pearcey MA, MBBS, FRCR, FRCPC, is a practicing academic Radiation Oncologist and Professor of Oncology in Edmonton. He also has 14 years of previous administrative experience in Radiation Oncology and is the current chair of the specialty committee in Radiation Oncology for the Royal College of Physicians of Canada.

Joseph Ragaz MD, FRCP, is Professor, Clinical Medicine at McGill University and medical oncologist at McGill University Health Centre. Previously, he spent 27 years as a senior Medical Oncologist and nationally and internationally recognized breast cancer researcher at the BC Cancer Agency.

Jack Shapiro Order of Canada, is presently the Co-chair of the Canadian Cancer Action Network and Board Member for the Canadian Cancer Research Alliance.

Sandi Yurichuk BS, MBA, is a cancer advocate and management consultant in the field of oncology.