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**PRESENTATION TO THE STANDING COMMITTEE ON
HEALTH**

Post-Market Surveillance of Pharmaceutical Products

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Dr. James Gowing, BA, MB, BS, FRCPC, Chair
Dr. William Hryniuk, MD, FRCPC Past Chair

Cancer Advocacy Coalition of Canada

Thank you for recognizing the importance of post-market surveillance and for providing the opportunity for many groups like ours to present suggestions for improvements. We are very grateful that you have seen fit to act on one of our previous recommendations when we presented our views to you during your hearings on Common Drug Review last year.

Please accept our congratulations on your December 2007 report regarding CDR. In our view your recommendations, if implemented, will substantially improve the cancer drug approval process in Canada.

The Cancer Advocacy Coalition of Canada is a full-time, registered non-profit group comprised of physicians, patients and business executives from across the country who are all unpaid volunteers. We publish the annual Report Card on Cancer in Canada, which is the only independent evaluation of cancer system performance in the country. In the 2007 Report Card released last month, we examined the allocation of research funds, the needs of young adults with cancer, the clinical trial research process, health human resources, access to diagnostics and drugs and the role of nurses in supportive care.

We publish these reports to identify barriers to better cancer control and to offer constructive solutions that are also realistic and implementable. For the past three years, the articles about access to cancer drugs have recommended Phase 4 (post-approval) trials to confirm treatment results in the cancer population at large and for two years in a row we have recommended increased translational research to identify the subsets of patients who benefit from the new drugs.

Post-market surveillance is an appropriate portal to initiate these proposals, and could encompass a more comprehensive system of information that is analyzed, shared and disseminated to benefit patients.

When a new cancer drug is approved, the only obligation at present is reporting of unexpected adverse events and even this is not done comprehensively. From the physician's perspective, lack of effectiveness is an adverse event when the treatment has added toxicities and other health risks to the patient for no good result.

The information available to physicians about a new cancer drug is often not very helpful in the real world. Patients in pre-approval clinical trial represent at best three percent of the wider population and when patients at late stages of disease are treated in these trials they generally achieve a response rate of 20 percent or less. Evidence suggests that response rates in the real world can drop to 10 percent. But for responders, the outcome could be cure. There are notable exceptions such as Herceptin, where a tumour marker has been identified to improve patient selection and in such cases the response rate is impressive and can include a cure. However, most drugs do not have biomarkers and for the majority of patients who do not respond we are subjecting them to a drug with potentially severe adverse effects with no hope of benefit.

The objective then, is to use every means at our disposal to identify the patients who will benefit and to spare those who will not from the wasted time and avoidable adverse effects.

If post-market surveillance were formalized to capture information on positive results as well as adverse events, then the characteristics of responders and non-responders could be captured for analysis. The immediate benefits would be remarkable. Better patient selection for the use of these new, expensive drugs would save a huge amount of the money that is otherwise fruitlessly spent.

To accomplish that goal, post-market surveillance must collect additional reporting and much of this must come from physicians who can offer the important clinical detail necessary for further analysis. Reports ought to be submitted on every patient treated with a newly approved cancer drug, within 12 weeks of initiating the treatment to ensure the accuracy of the information.

Physicians and others will not cooperate with an onerous paperwork exercise that produces nothing useful for their knowledge or their patients' well-being. The reporting we envisage could be done on a single computer screen. Indeed the proposal is undermined by anything more time consuming. The information system required has to be linked to appropriate research by qualified entities such as the National Cancer Institute of Canada, and have some assurance of timely outputs that are readily available online, and then the effort is worthwhile.

Data gathered should be readily available online and presented in a manner that offers greater meaning than a mere compilation of reported events. Indeed, if this undertaking is to serve its intended purpose, physicians and health administrators would find many other valuable uses for the data, including guideline writing and biomarker research.

In the final analysis, as this new knowledge became available and the true potential of each cancer drug is realized, patient access would be increased and treatment results improved.

The Cancer Advocacy Coalition encourages you to focus on what is possible and needed, rather than what is already done. A robust post-market surveillance system could be an integral system providing valuable information and education that benefits all Canadians – and saves money.

Thank you for your time and for your interest in this important subject.

CANCER ADVOCACY COALITION (CACC) 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.

Dauna Crooks PhD RN is Dean of Nursing at the University of Manitoba. She has also practiced as an oncology nurse, has conducted original research in the area of supportive care, and taught at the nursing schools of several Canadian universities

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 as a medical oncologist, conducted peer-reviewed basic and clinical research, taught at medical schools, and has developed and directed major cancer centres and regional cancer control programs in both Canada and the US. He remains active in clinical research and is currently Medical Director of CAREpath Inc.

Linda Jalbert is a breast cancer survivor and hotel industry consultant, now living in Toronto. She has been an active advocate on behalf of cancer patients and survivors, with a special interest in services that meet the emotional needs of breast cancer patients and their families.

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. He has conducted studies in access to and payment mechanisms for cancer drugs.

Eric MacEwen is a recent cancer survivor, 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.

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 a Clinical Professor, Medicine and Oncology, at McGill University in Montreal and outgoing Director, Oncology Program, McGill University Health Centre (2003-2007). Previously, he spent 27 years as a senior medical oncologist and a nationally and internationally recognized breast cancer researcher at the BC Cancer Agency in Vancouver (1977-2003).

Sandeep Sehdev MD FRCPC is a community focused Medical Oncologist at the William Osler Health Centre in Brampton, Ontario – one of Canada’s largest community hospitals – where he has worked since 1992. He is past chair (five years) of the Pharmacy and Therapeutics Committee.

Jack Shapiro, Order of Canada, is Chair of the Canadian Cancer Action Network and board member of the Canadian Cancer Research Alliance.

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