From: Anne Dooley [mailto:annemd@shaw.ca]
Sent: Sunday, September 16, 2007 4:47 PM
To: Sylvie Dupont
Subject: PMPRB Working Groups

Dear Dr. Benoit and Ms Dupont,

Thank you for both accommodating CAPA representation by teleconference and permitting me to provide a few (written) comments that I was unable to contribute by phone to the PMPRB public/patient stakeholder meeting of September 12th in Ottawa.

First, we very much appreciate your determination to include patients as stakeholders in this process to ensure we have a voice in the working groups. It is our belief that patient input is critical to successfully resolve some of the questions the Excessive Price Consultations have raised.

From the brief we prepared in August 2006 in anticipation of the Excessive Price Consultations, and our participation in consultations, you may have noted that the Canadian Arthritis Patient Alliance (CAPA) is one of the few volunteer organizations that have consumers who are very well informed. We have substantial knowledge of the Canadian drug approval process, are familiar with the many provincial and federal jurisdictional issues that prevent equitable access to medications across Canada and recognize patent drug pricing as one of many access to medication and barrier to treatment issues. Many of us are reliant on multiple patented &/or generic drugs to keep our disease(s) in check and enable us to care for ourselves and families, and economically contribute to society. We understand and participate in research as collaborators and advisers, as well as subjects in clinical trials. Ours is first-hand knowledge and our input will be valuable to the working groups being formed.

PMPRB's narrow mandate to determine excessive pricing is beneficial in some instances, however the recent advances in medical care and treatments, and greater use of generics suggest that perhaps it may be too restrictive. For instance, because generic medications are increasingly part of the 'real world' that patients and physicians occupy, costs and profits of generics must become part of the equation.

The characterization of 'effectiveness' of a drug is of great interest to patients. We know clinical trials, we participate in them and we know how trials are constructed. Jay Fiddler mentioned the lack of 'head to head' trials to determine efficacy, and someone else mentioned the tightly controlled inclusion specifications for trial participants so trials are not representative of the 'real world'. I agree with these statements and many of the other comments made around this topic. I also think it is problematic that there must be a 'presumed drug' that is the first 'standard' by which a wholly new drug is compared, and that comparisons with placebo alone are allowed to determine drug effectiveness. Certainly the discussions at the jointly sponsored (Health Canada and CIHR) Placebo Conference in March 2002, raised these and many other challenges to the manner in which new drugs are tested and the ethical standards that apply. The debate continues. I was also in agreement on much of this discussion.

The subject of 'risk' was raised during the brief discussion on re-benching and range of price variability. In this instance it referred to the associated risks of a pharmaceutical company when bringing a drug from bench to market. I'd like to mention something that was not brought up at the table. No matter how much 'risk' is presumed or assumed by industry, the risk borne by the participants / subjects in human research is always greater; human subjects bear the risks of research. That risk also extends to individuals who are prescribed these drugs. It is only through good surveillance over many years that collects and processes reports of adverse reactions as

well as beneficial outcomes that we learn the real worth of a medication. We all need to keep this in mind.

While we are interested in all the working groups and believe their work is critical, CAPA input would be most valuable on the Working Group on Therapeutic Improvement. We would like to put forward Linda Wilhelm to be a member of this working group. As the CAPA Chair of the Access to Medications Committee, CAPA representative on BMC, and experience as a Health Canada Expert Witness, among other qualifications, she will be well able to represent the consumer perspective. I believe you have her contact information, but I have also included it below.

With best regards,

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