Drs. Jean Gray, Mitchell Levine, James McCormack (HDAP)

Dr. Brian Benoit, Chair
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West
Ottawa, ON K1P 1C1

February 21, 2008

Dear Dr. Benoit:

Re: Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines

The Human Drug Advisory Panel (HDAP) has reviewed the document entitled "Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines" and would like to raise one small issue with the Board.

On page 6 of the Discussion Paper, item #2 indicates that medications will be reviewed "When the scientific information/evidence available at the time the medicine was first introduced was not sufficient to determine with confidence its category of therapeutic improvement, or when new post-market evidence suggests the initial categorization was inappropriate". The HDAP supports this concept although it is not clear who or what will trigger this re-examination. Will HDAP and/or the Board have to monitor drugs available through the Progressive Licensing initiative of Health Canada and, if so, how will this take place? In discussing scenarios i, ii, and iii, and the paragraph about drugs sold in Canada for 3 to 5 years, HDAP wasn't sure if the request to re-examine such drugs would come from the manufacturer or would be automatically triggered when some as yet undefined benchmark was achieved.

As this initiative moves forward, we would ask that greater clarity be provided in outlining the circumstances surrounding a re-examination of drug category, including both the outline of the process as well as details of the triggers that would prompt such a re-examination.

Yours truly,

Jean Gray, CM, MD, FRCPC
Mitchell Levine, MD, MSc, FRCPC
James McCormack, Pharm D