Drs. Jean Gray, Mitchell Levine, Adil Virani

September 11, 2008

Dear Dr. Benoit,

Thank you for the opportunity to review and provide feedback on the proposed new PMPRB Guidelines and Procedures. HDAP members discussed this document at today's meeting and feel these new guidelines and procedures are appropriate and workable.

We do have one concern related to **Item 8. Selection of Comparable Medicines**. In particular, Section 8.6 states that "HDAP will identify all drug products that are either **superior** or inferior in treating the approved indication or use." If a drug is deemed to represent a *substantial improvement* or a *moderate improvement* in Therapeutic Improvement, there will be no difficulty in selecting products that are inferior for the treatment of the approved indication or use. However, we feel it is impossible to select products that are "superior", as the definitions of *substantial* and *moderate* improvement encompass the concept that there are no superior products. We request that the concept of "superior" medications be removed from section 8.6.

In arriving at this request, we considered several products that we reviewed in 2007 using the new guidelines. We are satisfied that the definitions will work and that equivalent or inferior products for the treatment of the approved condition can be identified. However, we quickly recognized that if the product is deemed to be either a "moderate" or a "substantial" improvement, there would be no scientific evidence HDAP could use to identify a "superior" product. These examples can be provided to you, if they would assist in completing these guidelines and procedures.

We recognize the hard work that has gone into updating and revising these Guidelines and Procedures and hope that these comments will assist in developing the final document.

Yours truly,

Current members of the HDAP
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