Drug Safety and Risk Management Advisory Committee

Questions to the Committee

Question 1: **FDA/NABP Study Findings**

What additional analyses of the FDA/NABP/Svarstad study do committee members suggest to answer remaining questions about the adequacy of patient information?

Question 2: **Additional Research Needs**

What additional research does the committee recommend to document the areas and means for improving written patient medication information handed out by pharmacists? The committee may wish to consider the following:

- Action Plan ("Keystone") criteria and subcriteria of usefulness and their ability to assure maximum impact on appropriate patient use of prescription drugs. For example, can individual criteria be analyzed to assess their impact on patient knowledge or behaviors?
- Methods to determine if Keystone criteria/subcriteria should be prioritized or others added / deleted
- The influence of overall length of written materials on consumer reading and comprehension of materials

Question 3: **Suggested Actions to Achieve 2006 Goals**

What actions do committee members suggest to improve consumer medication information to meet the 2006 goal of 95% of new prescriptions dispensed being accompanied by useful written information? Please provide opinion on relative importance (low, medium, high) and time frame for implementation (immediate, near-term, longer- term)

Sample topics that may be addressed include:

- Legibility and comprehensibility interventions
- Means to assure that technical content on warnings, precautions, and adverse events are complete
- Means to assure that data distributors understand what is "Keystone compliant"
- Processes for implementing improvements (eg. workshops, guidances)
- Critical stakeholders