

**Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee
Questions to the Committee**

June 11, 2003

QUESTION 1

Discuss the current controversies in the diagnosis and management of hyperbilirubinemia.

QUESTION 2

In the context of current medical practice, including phototherapy, should drugs be developed for an earlier intervention to prevent hyperbilirubinemia in newborn infants?

In answering this question, please discuss the following:

- Your understanding of the relationship between bilirubin toxicity and neurodevelopmental outcome;
- How you define the population at high risk for complications of hyperbilirubinemia;
- The intervention sequence (e.g., more screening, additional monitoring and assessments, phototherapy, hydration, pharmacotherapy, cessation of breast feeding, changes in infant nutrition, home nursing visit, etc.) and Why?

QUESTION 3

Assuming that hyperbilirubinemia only requires therapeutic intervention with phototherapy approximately 3 to 5 percent of the time, what safety information would you require from a sponsor for a new molecular entity before it could be introduced into the newborn population?

QUESTION 4

In today's healthcare setting, does the benefit of drug therapy to prevent hyperbilirubinemia in the newborn population as a whole outweigh the risk to individual newborns, the majority of whom require no intervention?