PREGNANCY LABELING SUBCOMMITTEE MEETING
March 28 & 29, 2000

A Sub-Committee of the Advisory Committee for Reproductive Health Drugs

QUESTIONS TO THE COMMITTEE

March 28, 2000: Pregnancy Registry Issues

1. Under what circumstances are registries most useful and when are they NOT? Please be specific regarding:
   - Type of drugs
   - Expected clinical use patterns of products
   - Types of maternal or fetal outcomes (e.g., maternal toxicities, congenital anomalies, cognitive development, infertility, etc.).

2. What are the most important data elements that should routinely be collected in a registry? (You may wish to refer to Attachment 1 in the "Draft Guidance for Industry: Establishing Pregnancy Registries")
   - Under what circumstances should a qualitative assessment (e.g., pathological) be incorporated to evaluate products of conception in cases of fetal loss in $2^{nd}/3^{rd}$ trimester?

3. The questions below consider several aspects of patient follow-up in registries.
   - In general, what is the minimum length of follow-up required to assess pregnancy outcomes? (e.g., 1 week post delivery?)
   - Under what circumstances is it most useful or appropriate to end data collection and follow-up immediately after delivery?
   - In considering alternatives, such as 30 days post-delivery or one year post-delivery, what additional types of information can be expected to be gained?
   - What factors should guide decisions regarding length of follow-up (e.g., drug pharmacology, animal findings, specific outcomes, class concerns)?
   - What strategies should registries consider to enhance patient recruitment and retention as well as facilitate follow-up?
   - Should an additional mechanism be put in place to re-contact subjects after extended time periods in case the need arises? If so, considering the practical aspects of conducting registries, under what circumstances should it be done?

4. What criteria should be used to determine when a registry should be closed down?

5. The questions below consider the use of information from a pregnancy registry.
   - Under what circumstances should information from a registry be incorporated into a product's labeling? For instance, what types of information from registries would be useful to include and at what point in a registry's conduct (e.g., after "x" number of patients enrolled)?
   - Many observers have expressed concern that if drug exposure experience from registries is included in labels there is a risk that patients and clinicians will perceive a false assurance of complete safety when the data lack the power to detect certain levels of risk. What qualifying information should be included in the labeling so that the registry data are understandable?

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March 29, 2000: Strategies for Monitoring Drug Risks in Pregnant Women

1. What are your thoughts on the role of some type of centralized pregnancy registry?

    - How could a centralized model help to overcome existing obstacles? Would additional obstacles be introduced?

    - What areas would need to be specifically addressed to ensure that useful information would come from such a centralized system?

    - How could a central registry be operated in order to maximize gains and minimize real or perceived obstacles to conducting a registry (e.g., public/private models, foundations, contracts, central control, funding, etc.).

2. How can systems and databases already in existence be better utilized in this effort? What has been learned from existing methods? How can they be improved upon?

3. In general, what other strategies might be helpful for collecting information relevant to the safe use of drugs during pregnancy (case control, pk/pd studies, randomized controlled trials)? Under what circumstances should such strategies be employed?