



PIC QUESTION OF THE WEEK: 6/13/11

Q: What are some of the major changes in the FDA's proposed guidelines for the pregnancy section of prescription drug labeling?

A: Since 1979, the FDA has utilized *Risk Categories* to identify the relative risk(s) of drug use during pregnancy. The categories designated A, B, C, D, and X rated drugs from those evaluated as safest (A) based on controlled studies to those considered contraindicated (X). The system has undergone frequent criticism because definitions for many of the categories were ambiguous, oversimplified, not based on specific dosage and the actual period of exposure, etc. The classic publication *Drugs in Pregnancy and Lactation* has abandoned this system of risk categories in its newest edition and provides its own series of definitions designating a drug's safety when used during pregnancy. In 2008, the FDA proposed revisions to product labeling that would provide more practical information and eliminate the current system of A- X categories. After an extensive comment period, the agency is in the process of developing and distributing its final ruling on the content of the pregnancy section of the product labeling. Revision of the labeling section on *breastfeeding* will also be included in the final ruling. The following is a summation of some components of the key subsections (*Risk Summary*, *Clinical Considerations*, and *Data*) of the revised labeling requirements for drug use in pregnancy. The reader is encouraged to review the entire list of proposed guidelines in the FDA link included in the references below.

- **Risk summary**- will begin with a one sentence statement that summarizes the potential of the medication to increase the risk of the following: structural abnormalities, fetal and infant mortality, impaired physiologic function, and alterations to growth. This summary will state if animal or human data was used. If human data was used, the summary will go into greater detail. In the event animal data was presented, only a risk conclusion statement would be provided.
- **Clinical Considerations**- will address situations in which a woman was inadvertently exposed to the drug, any effects the medication will have in labor and delivery, and decisions that clinicians may have to make while prescribing these medications to pregnant women including:
 - Dosing adjustments during pregnancy
 - Adverse reactions unique to pregnancy
 - Interventions that may be required while receiving the medication
- **Data**- this section will include all available data for the medication and its use in pregnant women. Human data will take precedence over animal data. It will describe the types of studies completed, which animals were used, dosage, the type of adverse events (if any) observed, and, if applicable, the relationship between drug exposure in animals and humans.

References:

- Briggs GG, Freeman RK, Yaffe SJ. *Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk*. 9th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.
- Food and Drug Administration. Summary of Proposed Rule on Pregnancy and Lactation Labeling. Accessed May 16, 2011
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093310.htm>

Emilee K. Hixenbaugh and Julianne Dykes, Pharm.D. Candidates

The PIC Question of the Week is a publication of the Pharmaceutical Information Center, Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA 15282 (412.396.4600).