

Clinical Lactation Studies-

Study Design

Data Analysis

Labeling



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November 29, 2007

FDA Pediatric Advisory Committee Meeting

Why Look at Drug Levels in Breast Milk?

- **Overwhelming evidence shows that breastfeeding is the most appropriate form of nutrition for babies, mothers should therefore be encouraged to breast feed.**
- **There is a paucity of information on medication use during lactation.**
 - **Lack of information and misinformation often lead to physicians advising mothers to discontinue breastfeeding because of medication use.**
 - **Many mothers may not take their prescriptions or quit breastfeeding because of medication use.**

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Increasing Medical Need

- **Increasing need:**
 - From 1996 to 2001, national rates of in-hospital breast feeding as well as breastfeeding at 6 months of age increased about 2% per year.
 - In groups historically less likely to breastfeed, this increase was even greater.
- **Breastfeeding women took significantly more medications per month than pregnant women.**
- **Over a third take medications rated possibly or probably unsafe, or have unknown safety.**

- STULTZ, STOKES, SHAFFER, PAUL, and BERLIN. Extent of Medication Use in Breastfeeding Women. BREASTFEEDING MEDICINE, Volume 2, Number 3;2007

Approach to Medication Use During Breast Feeding

- **Determine if medication is necessary**
- **Choose the safest drug available**
 - low milk:plasma ratio
 - safe when administered directly to infants
- **Where can a physician go to find this information?**



Addressing the Need

- **FDA's draft Guidance for Industry entitled "Clinical Lactation Studies--Study Design, Data Analysis, and Recommendations for Labeling"**
 - **Published in the Federal Register February 8, 2005 (70 FR 6697)**
 - **Many public comments received from experts in this field, industry**
- **As the Maternal Health Team reviewed the comments on the draft Guidance submitted to the public docket, as well as the draft Guidance, it became apparent that**
 - **Guidance needed updating based on more recent data.**
 - **Guidance needed to be restructure and reordered to incorporate recommended changes**

Addressing the Need

- **Hear and discuss information on:**
 - **Labeling of drugs for use by lactating women;**
 - **breastfeeding physiology, benefits, and current research;**
 - **the physiology and pharmacology of drug transfer into breast milk;**
 - **and ethical issues related to studying breastfeeding mother/infant pairs.**