The American Academy of Pediatrics (AAP) recommends breast feeding until 1 year of age

Women take an average of four medications during lactation


47.9% of drugs had no data on breastfeeding, 42.7% had some animal data, and only 4.7% had human data.

Accelerating scientific understanding of differences in lactating women can advance understanding of:

- The degree of drug transfer into breast milk
- The effects of drugs on milk production and composition
- The exposure of breast-fed infants to drugs in breast milk
- The impact of a woman’s physiological state due to hormonal changes, body fat proportion and changes in weight during lactation
- The effects due to changes in composition of breast milk over time (colostrum) and during a single session (foremilk vs hindmilk)
45CFR46 Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

- Regulations are focused on minimizing risks to the mother and fetus
- Addresses prospect of benefit and no benefit to the mother, fetus or both
- Includes language on research related to the placenta and fetal material

But there is no language addressing research with lactating women
FDA Guidance for Industry

Clinical Lactation Studies – Study Design, Data Analysis, and Recommendations for Labeling

Issued Feb 2005 for public comment and provided nonbinding recommendations

Goals were to (1) provide the basic framework for designing, conducting, and analyzing clinical lactation studies and (2) stimulate further research to assist in therapeutics for lactating patients.

FDA Workshop

“Evaluation of the Safety of Drugs and Biological Products Used During Lactation”

Goals:
- to review current safety data collection approaches
- to discuss and consider novel approaches
- to inform the public of the potential risks of medication use during lactation
- to create strategies to raise awareness and communicate safety information about medication use during lactation

National Cancer Institute

“Breast-feeding women may not be arbitrarily excluded from participation in clinical cancer treatment trials. Exclusion of breast-feeding women from a particular trial must be based on a clear and compelling rationale or justification that shows that inclusion is inappropriate.”
Steps Towards a Collaborative Plan

- Harmonize ideas for research in lactating women
  - Is regulation needed?
  - Ethical concerns?

- Activate stakeholders
  - Pediatrics
  - Obstetrics
  - Pharmacology
  - Statistics
  - Lactation researchers
  - Existing databases

- Consider incentives to obtain needed data
  - public-private partnerships
  - traditional grant funding
  - BPCA
  - FDA written requests

- Develop guidelines and recommendations

- Generate strategies for prioritizing research
  - most commonly used drugs
  - drugs with no available data
  - essential drugs with high risk profiles for infants
Input and Feedback

- What are your thoughts about regulations governing lactating women in research?
- What do you see as the most pressing priorities in this area?
- What are the best strategies for gathering safety data on lactating women?
- Are there existing resources that could guide our thinking?