

**'Pregnancy and Prescription Medication Use Symposium'**  
**FDA Office of Women's Health**

**May 17, 2011**

8:00 a.m. – 4:30 p.m.

FDA White Oak Facility

Bldg 31 Rm 1503

**Objectives:**

- Showcase completed PK and PD Pregnancy studies funded by OWH
- Provide opportunities for FDA scientists to network in order to collaboratively advance the Agency's public health mission
- Increase awareness regarding the use of prescription medications used during pregnancy and the need for ongoing studies to improve pregnancy labeling

**AGENDA:**

8:00-8:30      **Registration**

8:30-8:45      **Welcome and Overview of OWH**

Ameeta Parekh, PhD, OWH, FDA

8:45 – 9:30      **Keynote Address - Prescription Drugs and Pregnancy**

Don Mattison, MD, CAPT, USPHS

National Institute of Child Health and Human Development, NIH

**Q&A** - Emmanuel Fadiran, RPh, PhD, OWH, FDA

**Moderator** - Beverly Gallauresi, MPH, RN, OWH, FDA

9:30 – 10:15      **Use of ACE Inhibitors in Pregnant Women and the Risk of Congenital Heart Defects**

De-Kun Li, MD, PhD, Kaiser Foundation Research Institute, Kaiser Permanente, CA

10:15 – 10:30      **Break**

10:30 – 11:30      **Clinical Pharmacology of Drugs in Pregnancy**

Mary Hebert, PharmD, University of Washington, Seattle, WA

11:30 – 11:45      **Break to pick up box lunch - provided**

- 11:45– 12:45 **Lunchtime session**  
**Pregnant Women and Clinical Trials: Scientific, Regulatory, and Ethical Considerations**  
Sara Goldkind, MD, MA, FDA Office of Good Clinical Practice  
Karen Feibus, MD, FDA Maternal Health Team  
  
**Moderator/Q&A:** Beverly Gallauresi, MPH, RN, OWH, FDA
- 12:45 – 1:30 **The Pharmacokinetics of Antidepressants Across Pregnancy: The MADRE Study**  
Marlene Freeman, MD, Massachusetts General Hospital, Boston, MA
- 1:30– 2:15 **Labetalol Pharmacokinetics in Hypertension During Pregnancy**  
James Fischer, PharmD, University of Illinois at Chicago, IL
- 2:15 – 2:30 **Break**  
  
**Moderator:** Monica Yu, BS, OWH, FDA
- 2:30– 3:15 **Antibiotics PK/PD Study in Pregnant Women**  
James Fischer, PharmD, University of Illinois at Chicago, IL presenting for Gloria Sarto, MD, PhD, University of Wisconsin, Milwaukee, WI
- 3:15 – 4:00 **Assessment of Maternal Effects & Infant Outcomes Using Large Automated Healthcare Data Systems in Women Exposed to Prescription Medications During Pregnancy**  
William Cooper, MD, MPH, Vanderbilt University School of Medicine, Nashville, TN
- 4:00 – 4:30 **Round Table Discussion and Wrap Up**  
**Moderator:** Emmanuel Fadiran, RPh, PhD, OWH, FDA

The presentation slides and the web cast of the symposium will be available soon at:

**FDA Women’s Health Research Home Page**  
**[www.fda.gov/womenshealthresearch](http://www.fda.gov/womenshealthresearch)**

Please complete the evaluation sheet and leave at the registration desk – thank you!