

'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

- 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