Use of Medications during Pregnancy and Breastfeeding: Maternal, Fetal, and Neonatal Impact

March 11, 2016

CHAIRPERSONS

ANNE ZAJICEK, MD, PHARMD, FAAP, CHIEF OF THE OBSTETRIC AND PEDIATRIC PHARMACOLOGY AND THERAPEUTICS BRANCH AT NICHD

CATHARINE M.T. SHERWIN, PH.D., FCP., INTERIM CHIEF, DIVISION OF CLINICAL PHARMACOLOGY, DEPARTMENT OF PEDIATRICS, UNIVERSITY OF UTAH SCHOOL OF MEDICINE, SLC, UT
Topics

Pregnancy-induced changes in clinical pharmacology (Maged Constantine, MD)

Applications of pharmacometrics in pregnancy (Kevin Krudys, PhD)

Drug development in pregnancy (Christina Bucci-Rechtweg, MD)
Goals

Understand the pharmacoepidemiology of medication use in pregnancy and lactation.

Understand academic, regulatory, industry efforts in developing improved understanding of clinical pharmacology in pregnancy and lactation

Learn how NICHD’s MFMU and OPRU have developed knowledge in these areas

Understand need for clinical trial designs to enable gathering of these data in pregnancy and lactation
Take-Away Points

Most pregnant and breast feeding women take medications, some prescribed and some not.

Dosing, safety and efficacy information for drugs taken during pregnancy and lactation is lacking.

There is a need to develop methods to collect these data, on the pregnant women/ fetus and mother/neonate.
Speakers

Maged Costantine, MD
- Associate Professor, Dept of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, University of TX Medical Branch

Kevin Krudys, PhD
- Lead Pharmacologist, Office of Translational Sciences, CDER, US FDA

Christina Bucci-Rechtweg, MD
- Head, Pediatric & Maternal Health Policy, Global Drug Regulatory Affairs, Pediatric Therapeutic Area, Novartis Pharmaceuticals Corporation