Public Meeting
Food and Drug Administration (FDA)
Docket No. FDA-2014-N-0157

Study Approaches and Methods to Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting

May 28, 2014, 8:00 a.m. – 5:00 p.m.
May 29, 2014, 8:00 a.m. - 1:15 p.m.
White Oak Campus, Silver Spring, MD

Final Panel Roster

Jessica Albano, PhD, MPH
Sr. Director, Epidemiology, Post Approval & Strategic Services, INC Research LLC
Raleigh, NC

COL Trinka Coster, MD, MS
Director
Office of Surgeon General of the Army Pharmacovigilance Center
Falls Church, VA

Susan Andrade, ScD
Research Associate Professor/Senior Research Associate
Meyers Primary Care Institute/University of Massachusetts Medical School
Worcester, MA

Janet Cragan, MD MPH
Director Metropolitan Atlanta Congenital Defects Program (MACDP), National Center on Birth Defects and Developmental Disabilities (NCBDD), CDC
Atlanta, GA

Elise Berliner, PhD
Director of Technology Assessment Program, Agency for Healthcare Research and Quality (AHRQ)
Rockville, MD

Michael F. Greene, MD
Professor of Obstetrics, Gynecology and Reproductive Biology Harvard Medical School
Director of Obstetrics, Vincent Department of Obstetrics and Gynecology
Massachusetts General Hospital
Boston, MA

Christina Chambers, PhD, MPH
Professor of Pediatrics
University of California San Diego
OTIS Collaborative Research Group
La Jolla, CA

Craig Hansen, PhD
Senior Research Fellow
Kaiser Permanente, Georgia;
Sansom Institute for Health Research, University of South Australia

Ava Marie S. Conlin, DO, MPH
Medical Epidemiologist, Deployment Health Research Department,
Naval Health Research Center
San Diego, CA

Sonia Hernandez-Diaz, MD, DrPh
Director of the Pharmacoepidemiology Program,
Associate Professor of Epidemiology at the Harvard School of Public Health
Boston, MA
Panel Roster Continued

**Lewis B. Holmes, MD**
Director, North American AED Pregnancy Registry, Professor of Pediatrics, Harvard Medical School
Boston, MA

**Allen A. Mitchell, MD**
Director, Slone Epidemiology Center
Professor of Epidemiology and Pediatrics
Boston University Schools of Public Health and Medicine
Boston MA

**Margaret (Peggy) Honein, PhD, MPH**
Chief, Birth Defects Branch
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects & Developmental Disabilities
Centers for Disease Control and Prevention
Atlanta, GA

**Allison Naleway, PhD**
Senior Investigator
Kaiser Permanente Northwest
The Center for Health Research
Portland, OR

**Diana Johnson, MS**
Research Manager, OTIS Pregnancy Studies
University of California, San Diego Department of Pediatrics
MotherToBaby Pregnancy Studies, Conducted by the Organization of Teratology Information Specialists
San Diego, CA

**Rosenie Thelus, PhD, MPH**
Epidemiologist
Office of Surgeon General of the Army
Pharmacovigilance Center
Falls Church, VA

**Patient Representative**

**Julia Beck**
Founder of Forty Weeks

**Industry Representatives**

**Adel Abou-Ali, PharmD, ScD, MS,**
Deputy Director Pharmacoepidemiology and Risk Management, Global Pharmacovigilance, Sanofi-Pasteur
Toronto, Ontario, Canada

**Adrian Dana, MD**
Executive Director, Clinical Risk Management & Safety Surveillance
Merck & Co., Inc
North Wales, PA
FDA Representatives

**Hoda T. Hammad, MS, MPH**  
ORISE fellow,  
Office of Pharmacovigilance & Epidemiology (OPE), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER)

**Pamela E. Scott, PhD, MA**  
Director, Research and Development,  
Office of Women’s Health (OWH), Office of the Commissioner (OC)

**Solomon Iyasu MD, MPH**  
Director,  
OPE, OSE, CDER

**Judy Staffa, PhD, RPh**  
Director,  
Division of Epidemiology II, OPE, OSE, CDER

**Sandra Kweder, MD, FACP**  
Deputy Office Director,  
Office of New Drugs (OND), CDER

**Melissa Tassinari, PhD DABT**  
Senior Clinical Advisor,  
PMHS, OND, CDER

**Vicki Moyer, MS (Meeting Coordinator)**  
Senior Regulatory Project Manager,  
Pediatric and Maternal Health Staff (PMHS), OND, CDER

**Kimberly A. Thomas, MPH**  
Sr. Public Health Advisor,  
Health Communication and Outreach, OWH, OC

**Michael D. Nguyen, MD**  
CDR, U.S. Public Health Service  
Acting Director, Division of Epidemiology, Office of Biostatistics and Epidemiology, Center for Biologies Evaluation and Research

**Leyla Sahin, MD, FACOG**  
Medical Officer,  
PMHS, OND, CDER

**Lynne Yao, MD**  
Associate Director,  
OND, PMHS, CDER