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

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

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

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

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

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

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

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

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

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)

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

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

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

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

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

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

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

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

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

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