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.

BIOGRAPHICAL SKETCHES FOR PANELISTS

Adel Abou-Ali, PharmD, ScD, MS

Dr. Adel Abou-Ali is the deputy director of global pharmacoepidemiology at Sanofi Pasteur. He holds a doctorate degree in pharmacy from Massachusetts College of Pharmacy and Health Sciences, a master degree in health management and policy, and a doctorate degree in Epidemiology from University of Massachusetts. Before joining industry, he held competitive academic fellowships from several universities and institutes including; the University of Massachusetts, the National Institute for Occupational Safety and Health (NIOSH)/Harvard University, and the Oak Ridge Institute for Science and Education (ORISE). He worked for the Center for Drug Evaluation and Research (CDER) (FDA) where he led several projects investigating the association between antidepressant use and multiple adverse outcomes in adult, elderly, and pregnant populations. As part of his duty as a drug safety reviewer at FDA, he served as a consultant for Office of New Drugs (OND), reviewing post marketing requirements associated with submitted New Drug Applications (NDAs). He has extensive experience working with registries such as the mother-baby link of the U.K. Clinical Practice Research Database (CPRD) and The Health Improvement Network (THIN) database.

Jessica Albano, PhD, MPH

Dr. Jessica Albano is Senior Director of Epidemiology, Post Approval and Strategic Services, INC Research. She received her undergraduate degree in biochemistry at Earlham College, MPH at Emory University, and PhD from the University of Pittsburgh School of Public Health. She has conducted research as an epidemiologist with the American Cancer Society and the University of Pittsburgh Cancer Institute. For the past 6 years, her work as a pharmacoepidemiologist has focused on evaluating the safety of drugs in the post-approval setting utilizing observational research methods including registry study designs. Dr. Albano is currently Primary Investigator for the Antiretroviral Pregnancy Registry, an international collaborative pregnancy registry that has been ongoing for more than twenty years.

Susan E. Andrade, Sc.D.

Susan E. Andrade, Sc.D. is a Senior Research Associate at the Meyers Primary Care Institute and a Research Associate Professor of Medicine at the University of Massachusetts Medical School. As site investigator in the HMO Research Network Center and lead investigator for the HMO Research Network Food and Drug Administration (FDA) Epidemiology contract site, Dr.

Andrade has been involved in a number of multi-site studies evaluating use of prescription drugs in special populations including pregnant women, children, and the elderly. She has extensive expertise in the use of large automated health care databases for pharmacoepidemiologic research and in the study of adverse drug effects, drug adherence issues, and health services research.

Julia S. Beck

Julia S. Beck, Founder of Forty Weeks, is a prominent marketing strategist with a passionate and exclusive focus on the expectant and new parent market. It is a category which she developed, cultivated and in one which she continues to lead the conversation and the way. Julia has long connected brands with not only consumers but the whole of the pregnancy and parent market though ground-breaking public/private partnerships which both elevate brand and community. Most recently, Ms. Beck founded the Mothers @ Work project by Forty Weeks which helps private sector employers bring new mothers back to work with ease, as a matter of course and with a sense of pride.

Julia's twenty-year career can best be categorized as consistently vibrant, evolving and certainly exciting. Her signature enthusiasm, humor, natural leadership and genuine care for her clients and the world as a whole have led Ms. Beck on an exciting path. From her early days in magazine marketing and advertising sales, through her media consultant years and finally into her groundbreaking work with Forty Weeks, Julia has remained committed to her core ideals: finding ways to align the goals of the private sector with the ideals of social responsibility - ultimately bringing the for–profit and the philanthropic worlds together for greater good. Julia's skills in integration, connection and amplification are unparalleled and highly sought after by a diverse and loyal client base. Julia remains deeply dedicated to crafting game changing initiatives that meet and exceed the goals for all stakeholders involved.

Julia's work has been featured in such publications as the New York Times, Wall Street Journal, The Washington Post, In Style Magazine and many others. Her signature candid and well considered commentary has been featured on an array broadcasts outlets including: VH-1's The Fabulous Life, Good Morning America, and NPR.

Elise Berliner, Ph.D.

Elise Berliner, Ph.D., is the Director of the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ). The Technology Assessment program provides technology assessments to the Centers for Medicare & Medicaid Services (CMS) to inform Medicare coverage decisions and other policy issues. Prior to joining AHRQ, Dr. Berliner worked as a consultant to pharmaceutical and medical device companies on cost-effectiveness and outcomes research, technology assessment and reimbursement planning. Dr. Berliner also has several years of experience in research and development at a number of innovative medical technology companies. She was a Congressional Fellow at the Office of Technology Assessment. Dr. Berliner received her Ph.D. in biophysics from Brandeis University.

Christina Chambers, PhD, MPH

Dr. Chambers is a full professor in the Department of Pediatrics, Division of Dysmorphology and Teratology, and holds joint appointments in the Divisions of Epidemiology and Global Health in the Department of Family and Preventive Medicine and the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California, San Diego. She is the

Director of Research at Rady Children's Hospital San Diego and the Associate Director of the Clinical Translational Research Institute at the University of California, San Diego. She is a perinatal epidemiologist and teratologist, and specializes in research on the environmental causes of birth defects. She is the lead investigator on a number of U.S. and Canadian-based pregnancy exposure cohort studies (registries) as well as national and international studies on Fetal Alcohol Spectrum Disorders. She is the Director of the California Teratogen Information Service, past president of the U.S. Teratology Society, past president of the North American Organization of Teratology Information Specialists, and Deputy Editor of the journal Birth Defects: Clinical and Molecular Teratology. She co-Directs the Center for Promotion of Maternal Health and Infant Development at the University of California, San Diego – a multidisciplinary Center focused on research, education and service related to prevention of birth defects and other adverse child health outcomes.

Ava Marie S. Conlin, DO, MPH

Ava Marie S. Conlin, DO, MPH serves as a medical epidemiologist in the Deployment Health Research Department at the Naval Health Research Center in San Diego, CA. She provides physician expertise and oversight to the DoD Birth and Infant Health Registry, a surveillance system for birth defects and other infant health outcomes among military beneficiaries. She also leads the National Smallpox Vaccine in Pregnancy Registry and the BioThrax® (Anthrax) Vaccine in Pregnancy Registry, active registries which closely follow women inadvertently vaccinated while pregnant to evaluate their pregnancy outcomes.
Dr. Conlin received her Doctor of Osteopathy from Philadelphia College of Osteopathic Medicine. She completed an Obstetrics and Gynecology internship at Naval Medical Center San Diego and a Preventive Medicine residency at the University of California, San Diego and San Diego State University, where she concurrently received her Master of Public Health in epidemiology. She is a veteran of the United States Navy with extensive operational experience serving with the United States Marine Corps. She is board certified in Public Health and General Preventive Medicine and has been with the Center for more than ten years, publishing many peer-reviewed publications.

COL Trinka Coster

COL Trinka Coster is a medical entomologist, receiving a Master's of Science from the University of Maryland, College Park and a physician, receiving her medical degree from Tufts University School of Medicine. She completed her Internal Medicine Residency at the Walter Reed Army Medical Center in Washington, DC. She then worked at the US Army Medical Research Institute of Infectious Diseases where she served as the Chief of the Clinical Trials Department. Her department conducted Phase I and Phase 2 Clinical Trials for vaccine and drugs to treat malaria, small pox, shigella, cholera and Enterobacteriaceae. COL Coster then received training in medical informatics at Woods Hole, MA, and Stanford University, CA and successfully completed a Clinical Pharmacology Fellowship at Walter Reed Army Institute of Research where she worked with Dr. Ana Szarfman of the FDA. Following her Fellowship, she authored a Small Business Innovative Research (SBIR) Topic on Data Visualization and then on Data Mining the DoD's Medical Claims Data for adverse drug events. She successfully prototyped the product called the Pharmacovigilance Defense Application System or PVDAS that consists of medical and pharmacy data from the Military Health System, data visualization of individual patient data, and algorithms for drug utilizations in pregnant and non-pregnant patients, risk/outcome analysis for signal refinement and exploratory analysis for signals. In

2009, the US Army established the Pharmacovigilance Center and COL Coster continues to serve as the Director. The PVC's mission is to provide actionable medication safety data to improve the health outcomes of the forces and military beneficiaries who receive treatment in the MHS and further develop the PVDAS to support pharmacovigilance activities.

Janet Cragan, MD, MPH

Dr. Janet Cragan is a Medical Officer in the National Center on Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention. Since 2000, she has been the medical director of the Metropolitan Atlanta Congenital Defects Program (MACDP). Dr. Cragan, a pediatrician, began her career at NCBDDD as an Epidemiologic Intelligence Service Officer. Her work in the field of birth defects has resulted in numerous publications related to surveillance, prevalence, and risk factors for major birth defects. Dr. Cragan received her Bachelor's degree from Eckerd College and her Doctor of Medical and Masters in Public Health degrees from Emory University. She is a fellow of the American Academy of Pediatrics and serves as CDC liaison to the AAP Committee on Drugs and the Georgia Chapter of the AAP.

Adrian Dana, MD

Adrian Dana joined the clinical risk management group at Merck & Co. in 2004. While at Merck, she has taken roles of increased responsibility having had leadership of groups with accountability for products in therapeutic areas including vaccines, infectious diseases, and oncology. Her current role involves the strategic responsibility for the risk management and safety surveillance for vaccines and infectious diseases products. She manages a team of physicians, nurses, scientists and pharmacists. The team is involved in safety surveillance post-marketing and risk management activities from stage IIb or earlier through the product life cycle. As part of this role, she has been responsible for overseeing and developing post-marketing pregnancy registries for numerous vaccine and drug products. She has presented and published pregnancy registry data in prestigious meetings and peer reviewed journals.
Prior to joining Merck, Dr. Dana was in Global Medical Affairs at Wyeth, first as a director in anti-infectives, later as Therapeutic Area Director for Vaccines.
Dr Dana is a board certified pediatrician and a pediatric infectious diseases specialist. Prior to joining industry, she was Chief of Pediatric Infectious Diseases at DeVos Children's Hospital in Michigan. While in Michigan she served on the Michigan Advisory Committee on Immunizations, a committee which helped to set vaccine policy and recommendations for the state.

Michael F. Greene, M.D.

Dr. Michael F. Greene is a Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School and the Chief of Obstetrics at Massachusetts General Hospital. His residency and fellowship training were completed at the Boston Hospital for Women and Brigham and Women's Hospital respectively.
Dr. Greene's major academic interests are in medical complications of pregnancy and congenital malformations. He has chaired the Committee on Obstetrical Practice for the American College of Obstetricians and Gynecologists and was an Associate Editor of the 4th edition of "Guidelines for Perinatal Care". He is an editor of deSwiet's Medical Disorders in Obstetric Practice fifth edition and an Associate Editor of Creasy & Resnik's Maternal Fetal Medicine Principles and

Practice seventh edition. He is a Section Editor for Diabetes in Pregnancy topics in UpToDate. He served for four years (two as Chair) on the Advisory Committee for Reproductive and Urological Drugs of the Center for Drug Evaluation and Research of the Food and Drug Administration, and as a consultant to the FDA for 15 years. In those capacities, he advised the FDA regarding the conditions for final approval of Mifepristone (RU-486), and recommended changing the status of the prescription emergency contraceptive "Plan B" to over-the-counter. He serves as an advisor to the NIH, CDC and NIEHS. He is a Co-Chair of the March of Dimes Scientific Advisory Committee for preterm birth. He has served as an Associate Editor of the New England Journal of Medicine since 1996.

Craig Hansen, PhD

Craig Hansen gained his doctorate in environmental epidemiology at the University of the Sunshine Coast, Australia, where his research focused on the adverse effects of air pollution during pregnancy. Since then, Dr. Hansen has gained valuable experience working at the University of Queensland School of Medicine (Australia) – working in cardiovascular research, the United States Environmental Protection Agency (USEPA) – working in air pollution research, and the Centers for Disease Control and Prevention (CDC) – working in birth defects research as a lead epidemiologist. More recently Dr. Hansen was an investigator at Kaiser Permanente Center for Health Research, Georgia, where his research focused on pregnancy outcomes and maternal morbidity in relation to a variety of exposures including influenza, medications during pregnancy, and alcohol and drug abuse during pregnancy, as well as developing a pregnancy registry using administrative data from electronic medical records. He is the lead investigator for the multi-site FDA sponsored study (MEPREP) that examined maternal sulfonamide use during pregnancy and the risk of congenital anomalies. Currently Dr Hansen is a Senior Research Fellow at the Sansom Research Institute, School of Pharmacy and Medical Sciences, University of South Australia.

Sonia Hernandez-Diaz, M.D., Dr. P.H

Sonia Hernandez-Diaz, M.D., Dr. P.H. a physician and epidemiologist, is the Director of the Pharmacoepidemiology Program and Associate Professor of Epidemiology at the Harvard School of Public Health. Her research focuses on the evaluation of the comparative safety of pharmaceuticals, with a special emphasis in pregnant populations. She has collaborated in studies using Medicaid, GPRD, THIN and other large healthcare research databases, in addition to ad hoc case control studies and pregnancy registries.
Another area of interest concerns the application of causal structural approaches to define confounding and selection biases in ways that facilitate the identification, communication, and resolution of common analytical problems in non-randomized studies. Dr. Hernández-Díaz has served as a member of the board of directors of the International Society for Pharmacoepidemiology and as a Special Government Employee and Voting member for the Drug Safety and Risk Management Advisory Committee of the US Food and Drug Administration.

Lewis B. Holmes, M.D.

Lewis B. Holmes, M.D. has been the Director of the North American AED (antiepileptic drug) Pregnancy Registry since it was established in 1997. He and his associates have focused on developing the methodology of pregnancy registries, including a method for enrolling an

unexposed comparison group, a detailed list of inclusion and exclusion criteria and enrolling over 9,000 women , a sample size large enough to enable them to assess the frequency of specific malformations, a major goal of pregnancy registries. He and his associates have also carried out an active malformations surveillance program at Brigham and Women's Hospital from 1972 to 2012 , which has provided familiarity to the spectrum of physical abnormalities which must be assessed by a pregnancy registry. He is Emeritus Chief, Medical Genetics Unit at the Mass General Hospital for Children and Professor of Pediatrics at Harvard Medical School.

Margaret (Peggy) Honein, PhD, MPH

Margaret (Peggy) Honein, PhD, MPH is an epidemiologist and Chief of the Birth Defects Branch at the Centers for Disease Control and Prevention (CDC), and was credentialed as a Distinguished Consultant/Senior Scientist at the CDC in 2010. Dr. Honein received her B.S. degree in Biology from the University of California, Riverside in 1986, her M.P.H. from the University of California, Los Angeles (UCLA) in 1992, and her Ph.D. in Epidemiology from UCLA in 1995. Dr. Honein's research interests include understanding the role of smoking in birth defects, assessing the safety or risk of medication use and vaccine use during pregnancy, and evaluating the impact of infections during pregnancy. From 2001 through 2006, Dr. Honein was the lead epidemiologist on the National Birth Defects Case-Control Study, a large multi-site study of environmental and genetic risk factors for birth defects to advance understanding of the preventable causes of birth defects. She has recently expanded her public health research portfolio to include understanding longer term outcomes and costs associated with congenital heart defects and other birth defects across the lifespan.

Diana L. Johnson, M.S.

Diana L. Johnson, M.S**.** began working for MotherToBaby California in 1998 as a Teratogen Information Specialists and Research Coordinator. Currently, she is the Research Manager for the MotherToBaby Pregnancy Studies conducted by the Organization of Teratology Information Specialists (OTIS), with studies focusing on Autoimmune Diseases, Asthma and Vaccines in pregnancy.

Allen A. Mitchell, M.D

Allen A. Mitchell, M.D., is Professor of Epidemiology and Pediatrics at the Boston University Schools of Public Health and Medicine and Director of the Slone Epidemiology Center at Boston University. In 1972, following pediatric training at the Boston Floating Hospital for Infants and Children (Tufts-New England Medical Center), he joined the Boston Collaborative Drug Surveillance Program where he worked with Drs. Slone, Shapiro, and Heinonen in the analysis of Collaborative Perinatal Project data on birth defects and drugs in pregnancy. In 1973-75 he completed a fellowship in pediatric clinical pharmacology at Children's Hospital in Boston (jointly with the Center for the Evaluation of Clinical Procedures at the Harvard School of Public Health). He then joined Drs. Slone and Shapiro at the newly-created Drug Epidemiology Unit (now Slone Epidemiology Center--SEC) at Boston University where, following his interest in both pharmacoepidemiology and birth defects, Dr. Mitchell applied the concept of case-control surveillance to the study of teratogenesis, and in 1975 initiated the SEC Birth Defects Study (BDS) which continues to this time, having collected data on prenatal exposures for over 48,000 malformed infants (and controls) identified at over 90 hospitals and state birth defects registries in the regions surrounding Boston, Philadelphia, Toronto, San Diego, and Nashville. He also

serves as co-PI for the Massachusetts Center in the CDC's National Birth Defects Prevention Study (NBDPS) and its successor, BD-STEPS. The Slone BDS is one of two data collection components collaborating with the American Academy of Allergy, Asthma, and Immunology in a national systematic surveillance effort (Vaccines and Medication in Pregnancy Safety Surveillance—"VAMPSS") designed to evaluate the risks and safety of the wide range of medications taken by pregnant women. Dr. Mitchell also designed and conducted evaluations of pregnancy prevention efforts for risk management programs associated with isotretinoin (Accutane and generics) and thalidomide (Thalomid). Dr. Mitchell is the author of numerous publications in the fields of birth defects pharmacoepidemiology and serves on many editorial boards and advisory committees.

Allison Naleway, Ph.D.

Dr. Allison Naleway is a Senior Epidemiologist with the Kaiser Permanente Center for Health Research in Portland, Oregon. Her research focuses on the evaluation of vaccine safety and effectiveness, and the surveillance of vaccine-preventable or other infectious disease. Dr. Naleway is an investigator with the CDC-funded Vaccine Safety Datalink, a national project linking automated medical records data from several integrated health care delivery organizations to monitor vaccine safety. Additionally, she has collaborated with the CDC on studies to assess the effectiveness of influenza vaccination during pregnancy, influenza vaccine choice and effectiveness in health care workers, and the early impact of human papillomavirus vaccination on HPV-related outcomes. Dr. Naleway received her MS and PhD in Epidemiology from The University of Iowa's College of Public Health, and completed a post-doctoral fellowship in epidemiology at the Marshfield Clinic Research Foundation. Dr. Naleway also is an Affiliate Assistant Professor for the Oregon Health and Science University's Department of Public Health and Preventive Medicine.

Rosenie Thelus, PhD, MPH

Rosenie Thelus is a senior epidemiologist at the Pharmacovigilance Center at the Department of Army, Office of the Surgeon General. She currently serves as the primary epidemiologist on several pharmacoepidemiology projects assessing safety alerts for newly marketed medical products and leads the FDA mother-child drug surveillance collaboration. In this capacity, she is currently engaged with the FDA in the developing more robust methods to assess perinatal drug exposure and adverse pregnancy outcomes using validated endpoints and relevant methods to deal with claims-based data. She received her PhD in Epidemiology from the University of Texas Health Science Center in Houston, TX in 2010.