FDA Public Meeting
Study Approaches and Methods to Evaluate the Safety of Drugs and Biologic Products During Pregnancy in the Post-Approval Setting

May 28-29, 2014
Silver Spring, MD

Dear Speaker, Panelist or Moderator:

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Name of Meeting Participant _Adel Abou-Ali, PharmD, ScD, MS____________________________

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Adel Abou-Ali is an employee of Sanofi Pasteur. The views expressed in his talk are the speaker’s, and as such, the principles, ideas, and perspectives provided here don’t necessarily reflect those of the employer.

Signature ____________________________

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Name of Meeting Participant: Jessica D. Albano

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I am a salaried employee of INC Research, LLC, a contract research organization (CRO), which conducts post-approval studies under contract with pharmaceutical companies, including but not limited to assessments of fetal exposures during pregnancy to drug and biologic products.

Signature: Jessica D. Albano

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Name of Meeting Participant  ________________  Susan E. Andrade

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No conflicts.

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Signature  ________________________________  Susan E. Andrade

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Name of Meeting Participant __Christina Chambers, PhD, MPH

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Grant/contract funding received from the following pharmaceutical companies in the last 3 years:
AbbVie, Amgen, Bristol Myers Squibb, Sanofi-Genzyme, Pfizer, Roche-Genentech, CSL, Eli Lilly, Janssen, UCB, GSK and GSK Bio, Novartis, Teva, Sandoz, Apotex, Parr.

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Name of Meeting Participant __COL Trinka Coster, MD________________________

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No conflicts

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Name of Meeting Participant Janet D. Cragan

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I am a full-time federal employee with the Centers for Disease Control and Prevention (CDC). As a part of my official duties, I serve as a member of the Scientific Advisory Committee of the North American Antiepileptic Drug (AED) Pregnancy Registry which monitors the effects on the fetus of use of antiepileptic medications during pregnancy. Currently, the AED Registry is financially supported by Abbott Laboratories, EISAI, Novartis, Ortho-McNeil, Pfizer, and Sunovion. Over the past three years, I also have served as a member of the scientific advisory committees of the Sumatriptan and Naratriptan Pregnancy Registries, and the Lamotrigine Pregnancy Registry, all sponsored by GlaxoSmithKline. I do not now have, nor have I ever had, a financial interest in any of these registries, the companies that sponsor them, or the drugs that they monitor. I have never been reimbursed for my participation on any of these registry committees, and do not receive any personal remuneration for my participation.

Signature

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Name of Meeting Participant ____ Adrian Dana ______________________

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Full time employee of Merck and Co.

Signature ________________________________

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Name of Meeting Participant    Michael F. Greene, MD

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Name of Meeting Participant: [CRAIG HANSEN]

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Name of Meeting Participant  __Sonia Hernandez-Diaz__________________

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In the last five years, Dr. Hernández-Díaz has consulted for GSK, Biologics, Novartis and AstraZeneca for unrelated projects. She is the epidemiologists at the North American AED (antiepileptic drugs) Pregnancy Registry, which is supported by multiple manufacturers of AED drugs. The Pharmacoepidemiology Program at the Harvard School of Public Health receives funding from Pfizer, Millennium/Takeda, Bayer and Phrma.

Signature

Digitally signed by Sonia Hernandez-Diaz
DN: cn=Sonia Hernandez Diaz, o=H, email=shireen@pharma.harvard.edu,
c=US
Date: 2014.05.21.13:36:32 -05'00'

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Name of Meeting Participant **LEWIS B. HOLMES, M.D.**

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I receive salary support from the companies which sponsor and contribute to the North American AED Pregnancy Registry. The Sponsors are: Abbvie, Eisai, Novartis, OrthoMcNeil, Pfizer, Sunovion, UCB Pharma. The Contributors are: Aurobindo Pharma USA, Dr. Reddy’s Lab, Inc., GlaxoSmithKline, Sandoz, Inc., Teva Pharmaceuticals, Apotex.

Signature

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Name of Meeting Participant: Margaret A. Honein

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No conflicts

Signature: [Signature]

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Name of Meeting Participant: __Diana Johnson___________________________

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I do not receive any direct funding from pharmaceutical companies, however I manage pregnancy studies funded by the following pharmaceutical companies: AbbVie, Amgen, Sanofi-Aventis, Sanofi-Genzyme, Sanofi-Pasteur, Bristol-Myers Squibb, Roche/Genetech, Novartis, GlaxoSmithKline, UCB Pharma, Pfizer, and Jansen

Signature: __Diana Johnson___________________________

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Name of Meeting Participant Allen A. Mitchell, M.D.

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Research support: GSK, Novartis Vaccines and Diagnostics, CSL, Eli Lilly, Arbor.
Stock: J&J, <=$20,000, divested 8/2012.
Consulting: Biogen-Idec Pregnancy Registry Advisory Committees for Tysabri and Tecfidera

Signature

5/5/14

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Name of Meeting Participant: Allison Naleway

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Dr. Naleway has received research funding from GlaxoSmithKline for an unrelated study.

______________________________

Signature: Allison Naleway

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Name of Meeting Participant: Rosenic Thelus

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None

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