

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:

Please complete this form regarding disclosure of financial or other beneficial interests in matters that will be discussed at the assessment of the Public Meeting: Study Approaches and Methods to Evaluate the Safety of Drugs and Biologic Products During Pregnancy in the Post-Approval Setting. **This information will be posted publicly along with the transcript, slides and other material from the workshop in a fashion similar to disclosure statements in a scientific journal.**

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

Please list any financial arrangement or affiliation or other beneficial interest in the past three years with any products, or firms relevant to the discussions. Examples of potential conflicts of interest include financial investments or other beneficial interests in organizations involved in the development of relevant products, employee of a pharmaceutical company, consultancy for a pharmaceutical company, serving on speakers bureau or receiving funding, grants or contracts from a pharmaceutical company. If you have no conflicts of interest to report, please state "no conflicts", sign and return the form.

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 

Please email the form to Cherice Holloway (Cherice.Holloway) by May 5, 2014.

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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

Digitally signed by Jessica D. Albano
DN: cn=Jessica D. Albano, o=INC Research, ou=Post Approval
and Strategic Services,
email=jessica.albano@incresearch.com, c=US
Date: 2014.05.05 12:42:50 -04'00'

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Name of Meeting Participant Susan E. Andrade

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No conflicts.

Signature Susan E Andrade

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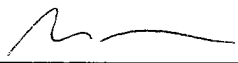
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Name of Meeting Participant Elix Bulow

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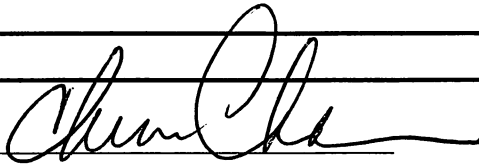
Name of Meeting Participant __ Christina Chambers, PhD, MPH

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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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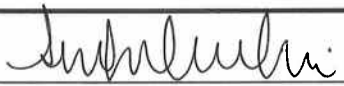
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Name of Meeting Participant Ava Marie S. Conlin, DO, MPH

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No Conflicts

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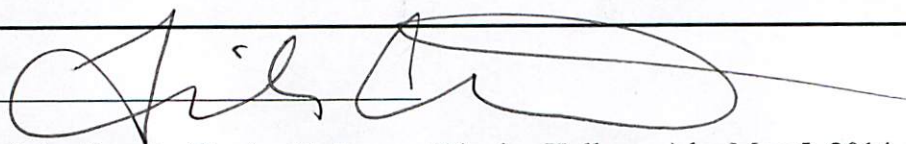
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Name of Meeting Participant COL Trinka Coster, MD

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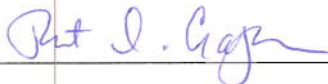
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Name of Meeting Participant Janet D. Cragan

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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.

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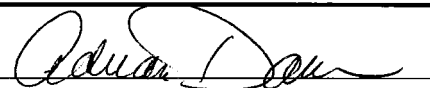
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Name of Meeting Participant _____Adrian Dana_____

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Full time employee of Merck and Co.

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Name of Meeting Participant Michael F. Greene, MD

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No conflicts

Signature

Michael F. Greene

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Name of Meeting Participant CRAIG HANSEN

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NO CONFLICTS

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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, ou, email=sherman@hsph.harvard.edu,
c=US
Date: 2014.04.21 17:38:39 -0400

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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

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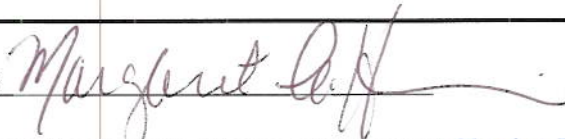
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Name of Meeting Participant Margaret A. Honein

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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 Jassen

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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 Allen A. Mitchell 5/5/14

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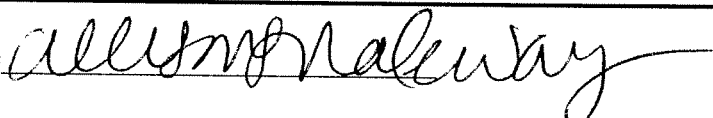
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Name of Meeting Participant: Allison Naleway

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

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Name of Meeting Participant Rosenie Thelus

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None

Signature _____

THELUS.
ROSENIE.
14004089
43

Digitally signed by: THELUS.ROSENIE.1400408943
DN: cn = THELUS.ROSENIE.1400408943 C = US
O = U.S. Government OU = DoD
Date: 2014.05.19 12:46:35 -0500

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