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	
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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 AM AMUMA

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

May 28-29, 2014 Silver Spring, MD

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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

Discre-Jessica D. Jahon, o-sINC Research, ou=Post Approval and Strategic Services, emall-Jessica. Jahon open Company of the Com

May 28-29, 2014 Silver Spring, MD

Dear Speaker, Panelist or Moderator:

Name of Meeting Participant \_Susan E. Andrade\_\_\_\_\_

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No conflicts.
Signature Susan E Andrade

May 28-29, 2014 Silver Spring, MD

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Name of Meetin	g Participant	Elix	Bulia			
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May 28-29, 2014 Silver Spring, MD

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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.

Signature

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

May 28-29, 2014 Silver Spring, MD

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

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May 28-29, 2014 Silver Spring, MD

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Name of Meeting ParticipantCOL Trinka Coster, MD
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.
No conflicts
Signature

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May 28-29, 2014 Silver Spring, MD

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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 Pet I. Gazz

Please email the form to Cherice Holloway (Cherice. Holloway) by May 14, 2014.

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 ParticipantAdrian Dana
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Signature Augus

May 28-29, 2014 Silver Spring, MD

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Name of Meeting Participant Michael F. Greene, MD

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

May 28-29, 2014 Silver Spring, MD

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Name of Meeting Participant CRAIG HANSEN

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May 28-29, 2014 Silver Spring, MD

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Name of Meeting Participant	Sonia Hernandez-Diaz	

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.

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=shernan@hsph.harvard.edu,
c=US
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May 28-29, 2014 Silver Spring, MD

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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 Lawis B Holman

May 28-29, 2014 Silver Spring, MD

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Name of Meeting	Participant _	Margaret A. Hon	ein		
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Signature Mi	Serit	Con Holloway (Ch	erice Holloway	) by May 5, 20	114

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

May 28-29, 2014 Silver Spring, MD

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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

Signature WWW MAN

May 28-29, 2014 Silver Spring, MD

Dear Speaker, Panelist or Moderator:

Stock: J&J, <\$20,000, divested 8/2012.

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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.
Research support: GSK, Novartis Vaccines and Diagnostics, CSL, Eli Lilly, Arbor.

Signature Celen Churcher 5/5/14

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

Please email the form to Cherice Holloway (<u>Cherice.Holloway</u>) by May 5, 2014. **Note to Speakers**: We also request that you include this information as the second slide of your presentations.

Consulting: Biogen-Idec Pregnancy Registry Advisory Committees for Tysabri and Tecfidera

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Name of Meeting Participant: Allison Naleway

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Name of Mee	eung Particip	ant Roseme Therus		
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