PREGNANCY LABELING SUB-COMMITTEE MEETING
March 28 & 29, 2000

A Sub-Committee of the Advisory Committee for Reproductive Health Drugs
Center for Drug Evaluation and Research (CDER), Food and Drug Administration
Hilton Hotel, 620 Perry Parkway, Gaithersburg, Maryland

Agenda

Tuesday, March 28, 2000

9:00 a.m. **Call to Order/Introductions**
Michael Greene, M.D., Sub-Committee Chair

Conflict of Interest Statement
Sandra Titus, Ph.D., Acting Executive Secretary, Preg. Lab. Sub. Comm., FDA

9:10 a.m. **Background Information, Update on the Pregnancy Labeling Proposal and Overview**
Sandra Kweder, M.D.
Co-Chair, Pregnancy Labeling Task Force
Deputy Director, Office of Drug Evaluation IV, FDA

9:40 a.m. **Preclinical Guidance Document – Status Report**
Joseph DeGeorge, Ph.D., Associate Director for Pharmacology and Toxicology, FDA

10:00 a.m. **NICHD Perspective on Needs for the Study of Therapeutic Drug Use in Pregnancy**
Cathy Spong, M.D.
Program Director, Maternal and Fetal Medicine Unit Network
National Institute of Childhood and Human Development (NICHD)

10:15 a.m. **Open Public Hearing**

Mary Teter, D.O.
Statement - Pharmaceutical Research and Manufacturer's Association (PhRMA)

10:30 a.m. **Break**

10:45 a.m. **Methodological and Operational Challenges in Running/Developing a Pregnancy Registry**
Elizabeth Andrews, Ph.D., M.P.H.
Director, Worldwide Epidemiology, GlaxoWellcome

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Agenda (cont.)

11:15 a.m. **Establishing Pregnancy Registries – Guidance for Industry**
Evelyn Rodriguez, M.D., M.P.H.,
Director, Division of Drug Risk Evaluation II,
Office of Post-Marketing Drug Risk Assessment (OPDRA), FDA

11:45 p.m. **Questions for Speakers**

12:00 noon **Lunch**

1:00 p.m. **Questions for the Committee & Discussion**

2:45 p.m. **Open Public Hearing**

3:00 p.m. **Break**

STRATEGIES FOR MONITORING DRUG RISKS IN PREGNANT WOMEN

3:15 p.m. **Charge to the Subcommittee Members**
Sandra Kweder, M.D.

3:20 p.m. **Overview: Current State of the Art**
Allen Mitchell, M.D.
Director, Slone Epidemiology Unit

4:00 p.m. **Informed Consent**
Audrey Rogers, Ph.D., M.P.H.
HIV/AIDS Research Network, NIH

4:30 p.m. **Questions for Speakers**

5:00 p.m. **Adjourn**

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Wednesday, March 29, 2000

8:00 a.m. **Welcome & Opening Remarks**
Michael Greene, M.D./Sandra Kweder, M.D.

8:15 a.m. **Regulatory Aspects**
Holli Hamilton, M.D., M.P.H./Dianne L. Kennedy, R.Ph., M.P.H.
Pregnancy Labeling Initiative, FDA

8:45 a.m. **Industry Experience & Perspective**
Robert Sharrar, M.D., M.Sc.
Merck and Company, Inc.

9:15 a.m. **Risk/Benefit Counseling of Patients: A Clinical Perspective**
Lewis Holmes, M.D.
Professor of Pediatrics, Massachusetts General Hospital

9:45 a.m. **Break**

10:15a.m. **Role of Surveillance**
Phillip Rhodes, Ph.D.
National Center for HIV, STD, and Prevention, CDC

10:45 a.m. **Considerations for Development of a Centralized Pregnancy Registry**
Jan Cragan, M.D.
Division of Birth Defects and Genetics, CDC

11:15 a.m. **Questions for Speakers**

11:30 a.m. **Questions for the Sub-Committee**

12:00 noon **Lunch**

1:00 p.m. **Open Public Hearing**

1:15 p.m. **Advisory Sub-Committee Discussion of Questions**

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Agenda (cont.)

2:30 p.m. **Break**

2:45 p.m. **Continue Discussion of Questions**

4:55 p.m. **Closing Remarks**
Sandra Kweder, M.D.

5:00 p.m. **Adjourn**