This one-day workshop is organized by the Teratology Society’s Public Affairs Committee to build on the efforts of the U.S. FDA to revise the content and format of the pregnancy component of the label for prescription drugs. The workshop panel is multi-disciplinary, representing clinicians, pharmacists, teratologists, epidemiologists, genetic counselors, and risk communication specialists. The primary objective of this panel is to develop a set of recommendations for improvement of labeling so that health care professionals may more effectively assess pregnancy risk for individual patients. Particular focus will be on the incorporation of animal data in a clinically relevant fashion. Topics for discussion include:

- How extensively and in what context should animal studies/data be presented?
- Would an interpretation of animal data be a useful addition?
- What format would be most useful for data or data summary presentation?
- Are there means of indicating/improving the quality of labeling information?
- What would be convincing evidence from animal data of potential risks to humans?
- When both human and animal data are available, how should they be weighted and presented?

**Workshop Schedule**

1:00 PM - 2:30 PM Invited background presentations
2:30 PM - 3:15 PM Panel Discussion I: Animal reproductive toxicity testing and inclusion in the label
3:15 PM - 3:30 PM Public comment
3:30 PM - 3:45 PM Break
3:45 PM - 5:30 PM Panel Discussion II: Communication of animal toxicity data in the label
5:30 PM - 6:00 PM Public comment
6:00 PM - 7:30 PM Dinner break
7:30 PM - 8:30 PM Panel Discussion III: Quality and accessibility of information for risk assessment and communication by clinicians
8:30 PM - 9:00 PM Closing statements

Space is limited – Register Early
Invited Participants

Moderator:

Anthony Scialli, M.D.
Georgetown University, Washington, DC

Introductory Speakers:

Anthony Scialli, M.D.
Georgetown University, Washington, DC

Katherine Lyon Daniel, Ph.D.
Centers for Disease Control and Prevention, Atlanta, GA

Melissa Tassinari, Ph.D.
Pfizer, Inc., Groton, CT

Sandra Kweder, M.D.
CDER, U.S. FDA, Washington, DC

J. M. Friedman, M.D., Ph.D.
University of British Columbia, Vancouver, BC

Invited Panel Members:

Gerald Briggs, B. Pharm.
Women's Hospital
Long Beach, CA

Beth Conover, M.S.
University of Nebraska
Omaha, NE

Paul Doering, Pharm. D.
University of Florida
Gainesville, FL

Karen Filkins, M.D.
University of California Irvine
Irvine, CA

J. M. Friedman, M.D., Ph.D.
University of British Columbia
Vancouver, BC

Donald Mattison, M.D.
NICHHD
Bethesda, MD

Anne Pastuszak, M.S.
Fetal Medicine Centre
Mt. Sinai Hospital
Toronto, ON

William Rayburn, M.D.
University of New Mexico
Albuquerque, NM

Michael Schatz, M.D.
Kaiser Permanente Medical Center
San Diego, CA

Anthony Scialli, M.D.
Georgetown University
Washington, DC

Kathy Wisner, M.D.
West Psychiatric Institute, University of Pittsburgh, School of Medicine
Pittsburgh, PA

Workshop Organizing Committee

Christina Chambers, (Chair)

Judy Buelke-Sam
J.M. Friedman
Carole Kimmel

Janine Polifka
Anthony Scialli
Melissa Tassinari
Loews Philadelphia Hotel

June 23, 2003, 1:00 PM – 9:00 PM

The Workshop will be held at the Loews Philadelphia Hotel in the heart of downtown Philadelphia, PA, in conjunction with the Annual Scientific Meetings of:

• The Teratology Society (June 21st - 26th)
• Organization of Teratology Information Services (June 20th - 24th)
• The Neurobehavioral Teratology Society (June 21st - 26th)

The Teratology Society has secured discounted room rates for the week including the workshop. Reservations should be made prior to May 15, 2003, and can only be honored on a space and rate available basis. Register Early and ask for the Teratology Society discount when making your reservation. To make a reservation, please contact the Loews Philadelphia Hotel directly. A hotel registration request form may be found on the Teratology Society’s web site at www.teratology.org.

Loews Philadelphia Hotel

Reservations by phone: (215) 627-1200
Reservation FAX number: (215) 231-7310

Special Thanks to Workshop Co-Sponsors
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Centers for Disease Control and Prevention

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Neurobehavioral Teratology Society

Organization of Teratology Information Services

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Workshop Registration Form

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www.nbts.org/newframes.htm

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