Agenda

FDA's Communication of Drug Safety Information

National Transportation Safety Board Conference Center 429 L'Enfant Plaza Washington, D.C.

December 7, 2005, 8:00 a.m. – 3:30 p.m. December 8, 2005, 8:00 a.m. – 4:30 p.m.

FDA Moderator – Dr. Paul Seligman

FDA Expert Panel – Day 1: Scott Gottlieb, Sandra Kweder, Paul Seligman, Nancy Smith, Douglas Throckmorton, Theresa Toigo and Anne Trontell

FDA Expert Panel – Day 2: Susan Cummins, Sandra Kweder, Nancy Ostrove, Paul Seligman, Theresa Toigo and Anne Trontell

December 7, 2005

8:00 a.m. - FDA Welcome and Opening Remarks - Dr. Steven Galson

8:30 a.m. - Panel 1

- o Kevin Outterson, West Virginia University College of Law
- Ruth Day, Duke University
- o Michael S. Wolf, PhD, Feinburg School of Medicine, Northwestern University
- Elizabeth Andrews, RTI Health Solutions

9:30 a.m. - FDA Expert Panel Questions

10:00 a.m. - Break

10:15 a.m. - Panel 2

- o Sidney Wolfe, Public Citizen's Health Research Group
- o Diana Zuckerman, National Research Center for Women and Families
- Ray Bullman, NCPIE
- Rebecca Burkholder, National Consumers League
- Annetta Cheek, PLAIN

11:45 a.m. - FDA Expert Panel Questions

12:15 p.m. – Lunch

1:30 p.m. – <u>Panel 3</u>

- Ellen Liversidge
- Carol Rothkopf, Time Inc

2:00 p.m. - FDA Expert Panel Questions

2:30 p.m. – Break

2:45 p.m. - Additional comments/speakers

3:15 p.m. - Closing remarks

3:30 p.m. - Adjourn

December 8, 2005

8:00 a.m. – FDA Welcome – Dr. Paul Seligman

8:10 a.m. - FDA Opening Remarks - Dr. Scott Gottlieb

8:30 a.m. - Panel 5

- o Douglas McNair, Cerner Corporation
- Cherif Bennattia, APhaRC
- Alan Goldhammer, PhRMA
- o John Wolleben, Pfizer
- Stephen Goldman, MD, Stephen A Goldman Consulting Services

9:45 a.m. - FDA Expert Panel Questions

10:15 a.m. – Break

10:30 a.m. – <u>Panel 6</u>

- Janice Dunsavage, ISMP
- Joe Cranston, American Medical Association
- o Susan Winckler, American Pharmacists Association
- Tom Lawlor National Association of Chain Drug Stores

11: 30 a.m. - FDA Expert Panel Questions

12:00 p.m. – Lunch

1:00 p.m. – <u>Panel 7</u>

• Nicholas Ratto, First DataBank

- Wendy Jezarian, Time Inc.
- o John Kamp, Coalition for Healthcare Communication
- o Susan Kleimann, Center for Plain Language

2:00 p.m. – Break

- 2:15 p.m. Panel 7 (continued)
 - Peter Mayberry, Pharmaceutical Printed Literature Association
 - Harry Sweeny, Dorland Global Health
- 2:45 p.m. FDA Expert Panel Questions

3:15 p.m. – Additional Comments/Speakers

- o Vanessa Cullins, Planned Parenthood Federation of America
- o Joseph Poirier
- 3:45 p.m. FDA Expert Panel Questions
- 4:15 p.m. Closing Remarks
- 4:30 p.m. Adjourn