

**FDA Risk Communication Advisory Committee
+ Members of the Drug Safety and Risk Management Advisory Committee
NTSB Conference Center, 429 L'Enfant Plaza S. W. Washington, DC
February 26-27, 2009
AGENDA**

February 26, 2009

8:00 Call to Order

8:05 Conflict of Interest Statement – Designated Federal Officer

8:10 Introductions of Committee Members

8:30 Welcome

Deborah Henderson, Director, Office of Executive Programs, CDER

8:45 Background and Overview of the CMI, PPI, Medication Guides Programs

Nancy Ostrove, Ph.D., Director for Risk Communication,
Office of Policy and Planning, FDA

Jodi Duckhorn, M.A., Team Leader, Division of Risk Management
Office of Surveillance and Epidemiology, CDER

10:00 Questions and Answers

10:15 BREAK

**10:30 Expert and Consumer Evaluation of Consumer Medication Information –
2008 Final Report**

Carole L. Kimberlin, Ph.D.

Professor, Pharmaceutical Outcomes and Policy
University of Florida College of Pharmacy

Almut Winterstein, Ph.D.

Associate Professor, Pharmaceutical Outcomes and Policy, College of Pharmacy, and
Epidemiology and Biostatistics, College of Public Health and Health Professions
University of Florida

11:30 Questions and Answers

11:45 Lunch (on your own: there are several restaurants in the mall)

1:00 Open Public Hearing

3:00 Break

3:15 Committee Discussion

5:00 Adjourn for the day

February 27, 2009

8:00 Call to Order and Conflict of Interest Statement

8:05 Introductions of Committee Members

8:10 Welcome

Jeffrey Shuren, M.D., J.D., Associate Commissioner for Policy and Planning

8:20 Guest Speakers: Approaches to Improving Patient Information

8:20 The effectiveness of the drug facts box in communicating the benefits and side effects of prescription drugs

Lisa Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S.

Outcomes Group, VA Medical Center, White River Junction, VT

9:00 Consumer Medicines Information in Europe; learnings from research, policy and practice

Dr DK Theo Raynor

Professor of Pharmacy Practice, University of Leeds, UK

9:40 Communicating with patients about prescription drugs and health care: The role of diminished status and other systemic factors in addressing risk and vulnerability

David P. Moxley, M.S.W., Ph.D., D.P.A.

Oklahoma Healthcare Authority Medicaid Endowed Professor of Health and Public Health, and Professor of Social Work

University of Oklahoma

10:20 Break

10:30 Open Public Hearing

11:30 Lunch

12:30 Committee Discussion

2:00 Adjourn