

**AGENDA September 22, 2003**

*Rec'd 9/17/03 b*

**9:00 a.m.**

**Tom Abrams, RPh  
Janet Woodcock, MD**

**Welcome and FDA  
Opening Remarks**

**9:45 a.m.**

**Kathryn Aikin, PhD  
*Consumer Prescription Drug  
Advertising on the Physician-  
Patient Relationship***

***The Impact of Direct-to-***

**Questions**

**10:15-10:30 a.m. BREAK**

**10:30 a.m.**

**NATIONAL SURVEYS:  
Sharon Allison-Otley, MD  
Coshar Medical, Inc**

***DTC and the AA Physician  
& Patient***

**Linda Golodner  
National Consumers League**

***Effectiveness of & Attitudes  
Toward Medication Advertising***

**Carol Rothkopf  
Time Inc.**

***The DTC Information Process***

**Edwin Slaughter  
Rodale, Inc.  
1997-2002**

***Consumer Reaction to DTC  
Advertising of Rx Medicines***

**Joel S. Weissman, PhD  
Massachusetts General  
Hospital Institute for Health**

***Consumer & Physician  
Reports on the Health Effects  
of DTCA***

**Questions for Speakers**

**12: 15-1:30 p.m. LUNCH**

*2003N-0344*

*LST 1*

1:30 p.m.

**EFFECTS OF DTC ON PRESCRIBING:**

Julie M. Donohue  
Harvard Medical School  
*Treatment of Depression*

*Effects of DTC Advertising of  
Prescription Drugs on the*

Robert Dubois, MD, PhD  
Zynx Health Incorporated  
*Out with the Bathwater*

*Pharmaceutical Promotion:  
Perhaps Don't Throw the Baby*

Barbara Mintzes  
University of British Columbia  
*Primary care environments*

*How does DTC Affect  
Prescribing? A survey in*

Petra T. Schultz, PharmD  
Mayo Clinic  
*Consumers & Prescribers*

*Assessment of Impact of DTC  
Advertising of Rx Drugs on*

Questions for Speakers

3:00-3:15 pm

BREAK

3:15 pm

**ADVERTISING EFFECTIVENESS:**

Lynn Benzing  
Patient Marketing Group, Inc.  
*Information Needed to Enhance  
Public Health*

*The Role of Drug Marketers in  
Providing Consumer Tools and*

Ruth Day  
Duke University

*Cognitive Accessibility of Rx  
Drug Information*

Angela V. Hausman, PhD  
University of Texas

*DTC Advertising & Its Impact  
of Patient Healthcare Behaviors*

Henry N. Young, PhD  
University of California  
*Preliminary Study*

*Does DTC Promote Shared  
Decision Making? A*

Questions for Speakers

5:00 pm

End of Day 1

**FDA Panel Members:**

**Thomas Abrams, RPh, Director, DDMAC, CDER**

**Kathryn Aikin, PhD, DDMAC, CDER**

**Glenn Byrd, MBA, Center for Biologics Evaluation & Research**

**Martine Hartogensis, DVM, Center for Veterinary Medicine**

**Melissa Moncavage, MPH, DDMAC, CDER**

**Nancy Ostrove, PhD, FDA Office of Planning**

**Peter Pitts, FDA Office of External Relations**

**Robert Temple, MD, Director, Office of Medical Policy, CDER**

**Daniel Troy, JD, Director, FDA Office of Chief Counsel**

**Janet Woodcock, MD, Director, Center for Drug Evaluation & Research**

**Deborah Wolf, CDRH**

**CBER: Center for Biologics Evaluation and Research**

**CDER: Center for Drug Evaluation and Research**

**CDRH: Center for Devices & Radiological Health**

**CVM: Center for Veterinary Medicine**

**DDMAC: Division of Drug Marketing, Advertising and Communication**

AGENDA, September 23, 2003:

9:00 a.m.

Melissa Moncavage, MPH

Welcome

9:15 a.m.

**UTILIZATION AND DEMAND:**

John E. Calfee  
American Enterprise Institute

*DTC Effect on Statins*

Jon Hallberg, MD  
University of Minnesota

*"I Saw This Ad Last Night..."*

Frank R. Lichtenberg  
Columbia University

*DTC Advertising and  
Public Health*

Neal Masia  
Pfizer Inc.

*Economic impact of DTC  
Advertising*

Questions for Speakers

10:45-11:00 a.m. BREAK

11:00 a.m.

**BRIEF SUMMARY:**

Michael Roberts, RPh MBA  
Catalina Health Resource

*Alternatives to the "Brief  
Summary"*

Andrew Schirmer

*Comparative Advertising, Fair*

McCann Erickson

*Balance & Patient-Consumer*

Lisa Schwartz, MD, MS  
VA Medical Center

*Effect of a prescription drug  
benefit box on the public's  
assessment of drug efficacy*

Steven Woloshin, MD, MS  
VA Medical Center

*The public's valuation &  
comprehension of a proposed  
Prescription drug benefit box*

Questions for Speakers

12:30-1:45 p.m. LUNCH

1:45 p.m.

**PATIENT/PHYSICIAN INTERACTION - GLOBAL**

Mike Magee  
Pfizer inc.

*Physician-Patient Relationship  
Patient Empowerment & the  
Role of Information*

Dean G. Smith, PhD  
University of Michigan

*The Views of Healthcare  
Professionals and Consumers  
On DTC Promotion of  
Rx Drugs in New Zealand*

Clifford Thumma  
Pfizer Inc.

*DTC Advertising and  
Doctor-Patient Interactions*

Questions for Speakers

2:45-3:00 p.m. BREAK

3:00 p.m.

**INTERNET & COMPLIANCE**

Alan Goldhammer, PhD  
Pharm. Research &  
Manufacturers of America

*The Internet & Useful Patient  
Information*

Gay Kassan  
Parade Magazine

*Compliance, Caregivers, and  
The Consumer*

William J. Vigilante, Jr., PhD  
Robson Lapina

*DTC Advertising of Rx  
Medications on the WWW:  
Assessing the Communication  
Of Risks & Benefits*

## Questions for Speakers

4:15 p.m.

Robert Temple, MD

Clos

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Kathryn Aikin, PhD, DDMAC, CDER

Glenn Byrd, MBA, CBER

Jesse Goodman, MD, Director, CBER

Martine Hartogenesis, DVM, CVM

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