

**Adolescent Over-the-Counter (OTC) Drug Product Use:
A Public Workshop
December 6 and 7, 2007**

**NIH Natcher Conference Center
45 Center Drive
Bethesda, Maryland 20892**

Day One: December 6, 2007

8:30 Welcome

NIH Duane Alexander, MD, Director, National Institute of Child Health and Human Development

FDA Dianne Murphy, MD, Director, Office of Pediatric Therapeutics

CHPA Heinz Schneider, DrMed, Vice President, Regulatory and Scientific Affairs

8:45 Plenary Session

- Eric Brass, MD, PhD, Harbor-UCLA Medical Center
 - Using Clinical Research To Inform Regulatory Decisions For OTC Drugs: Understanding Consumer Behavior
- Lisa Mathis, MD, OND Associate Director, Pediatric and Maternal Health Staff, Office of New Drugs, Center for Drug Evaluation and Research, FDA
 - OTC Drug Development in Adolescent Patients
- Donald Mattison, MD, Senior Advisor to the Directors of NICHD and CRMC, Branch Chief, Obstetric and Pediatric Pharmacology Branch, Center for Research for Mothers and Children, National Institute of Child Health and Human Development, NIH
 - Research Opportunities and Challenges – NIH and Best Pharmaceuticals For Children Act (BPCA)

9:30 Question/Answer/Discussion Session

9:45 Panel I – Overview of Regulatory/Marketing of OTC Drug Product Use By Adolescents

Chair – Heinz Schneider, DrMed, Consumer Healthcare Products Association

- Michele Weissman, Senior Vice President, Panel Consulting
 - Household Survey Data on the Adolescent Use of OTC Medicines
- Leonard A. Wood, President, Pharmaceuticals & Healthcare Marketing, Multi-Sponsor Surveys, Inc.
 - Teen Surveys on Marketed OTC Products

10:30 Break

10:45 Panel I – (continued)

- Bindi Nikhar, MD, Medical Officer, Food and Drug Administration

- FDA Consumer Studies of Adolescents
- Richard Cleland, Assistant Director, Division of Advertising Practices, Federal Trade Commission
 - FTC Perspective of Marketing/Advertising OTC Drugs

11:30 **Question/Answer/Discussion Session**

12:30 **Lunch**

1:45 **Panel II – Adolescent Development, Behavior and Decision-Making**

Chair – Susan K. Cummins, MD, MPH, Food and Drug Administration

- Laurence Steinberg, PhD, Distinguished University Professor of Psychology, Temple University
 - Overview of Adolescent Brain and Behavioral Development
- Heather Huszti, PhD, Director of Training and Senior Psychologist, Children’s Hospital of Orange County
 - Adolescent Concepts of Health and Wellness

3:00 **Break**

3:15 **Panel II (continued)**

- Wandi Bruine de Bruin, PhD, Research Faculty, Carnegie Mellon University
 - Adolescent Decision-Making
- Robert W. Denniston, Director, National Youth Anti-Drug Media Campaign, Office of National Drug Control Policy
 - OTC-Relevant Lessons from the Anti-Drug Campaign

4:15 **Question/Answer/Discussion Session**

5:30 **Adjourn**

Day Two: December 7, 2007

8:30 **Welcome/Day 1 Review** – Eric Brass, MD, PhD

8:45 **Panel III – Factors Promoting Safe and Effective Use of OTC Drugs By Adolescents**

Chair – Lynn Bosco, MD, MPH, National Institutes of Health

- James Jaccard, PhD, Professor, Department of Psychology, SUNY Albany
 - Models for Communicating to Adolescents
- Lee Sanders, MD, MPH, Associate Professor of Pediatrics, University of Miami, Miller School of Medicine
 - Health Literacy Among Teens

9:35 **Break**

9:50 **Panel III (Continued)**

- Cornelia Pechmann, PhD, Professor of Marketing, The Paul Merage School of Business, University of California, Irvine
 - Teen Marketing Psychology Research
- Julie Aker, BS, MT (ASCP), President and CEO, Concentrics Research
 - Design of Consumer Studies in Adolescents

10:40 **Question/Answer/Discussion Session**

11:30 **Open Public Session**

12:00 **Lunch**

1:00 **ROUNDTABLE**

Moderator – Eric Brass, MD, PhD

Roundtable Participants

Julie Aker, BS, MT (ASCP)

Wandi Bruine de Bruin, PhD

Robert Denniston

Heather Huszti, PhD

James Jaccard, PhD

Patricia K. Kokotailo, MD, MPH, FAAP, FSAM

(representing the American Academy of Pediatrics)

Cornelia Pechmann, PhD

Lee Sanders, MD, MPH

Tomas J. Silber, MD, MASS, FAAP, FSAM

(representing the Society of Adolescent Medicine)

Federal Agency and Industry Representatives

NIH Lynn Bosco, MD, MPH, Medical Officer, Office of Behavioral and Social Sciences Research

FDA Sandra Kweder, MD, Deputy Director, Office of New Drugs, Center for Drug Evaluation and Research

FTC Richard Cleland, Assistant Director, Division of Advertising Practices

CHPA David Spangler, Senior Vice President, Policy & International Affairs

Opportunities and Challenges - Roundtable Participants

Regulators

1. What are the opportunities for regulators (i.e., FDA, FTC) for enhancing safe and effective use of OTC drugs by adolescents?
2. What are the challenges for regulators?

Researchers

1. What are the opportunities for researchers and the NIH for enhancing safe and effective use of OTC drugs by adolescents?
2. What are the challenges for researchers and the NIH?

Clinicians and Advocacy Groups

1. What are the opportunities for clinicians and advocacy groups for enhancing safe and effective use of OTC drugs by adolescents?
2. What are the challenges for clinicians and advocacy groups?

Industry

1. What are the opportunities for industry for enhancing safe and effective use of OTC drugs by adolescents?
2. What are the challenges for industry?

Next Steps - Roundtable Participants and Audience

1. What next steps would you recommend for regulators, researchers, clinicians, advocacy groups, and/or industry?
2. How would you prioritize recommended next steps?

3:25 **Concluding Thoughts** - Eric Brass, MD, PhD

3:30 **Adjourn**

NOTE

TRANSCRIPT (APPROXIMATELY 30 DAYS) AND SPEAKER PRESENTATIONS (WITHIN ONE WEEK) WILL BE POSTED TO:
http://www.fda.gov/cder/meeting/adolescent_OTC.htm.