



Opioid Abuse Resistance

October 27-28, 2005

The Colonnade Hotel
120 Huntington Avenue
Boston, Mass.



Agenda

Meeting Chair: Nathaniel Katz, MD, MS

Thursday, October 27

Boston Ballroom, Second Floor

7:00 a.m. **Breakfast and Registration**

Background

8:00 a.m. **The Phenomenology of Prescription Opioid Abuse:
What Types of Abuse Do Products Need to Resist?**

Sidney H. Schnoll, MD, PhD
Medical College of Virginia
Columbia University

8:30 a.m. **Discussion**

Roger Weiss, MD
Professor of Psychiatry, Harvard Medical School
Clinical Director of the Alcohol and Drug Abuse Treatment Program
McLean Hospital

8:50 a.m. **Survey**

Nathaniel Katz, MD, MS
Adjunct Assistant Professor
Adjunct Professor of Anesthesiology
Tufts University School of Medicine

9:00 a.m. **The Quest for Non-Abusable Opioid Analgesics**

Charles Grudzinkas, PhD
Co-Founder and Principal, NDA Partners LLC
Center for Drug Development Science (CDDS), Department of Pharmacology
UCSF



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- 9:15 a.m. **Discussion**
Donald Jasinski, MD
Professor of Medicine
Chief Center for Chemical Dependence
Johns Hopkins Bayview Medical Center
- 9:35 a.m. **FDA Concerns Regarding the Development of Abuse-Resistant Products**
Bob Rappaport, MD
Director, Division of Anesthetic, Critical Care, and
Addiction Drug Products, Food and Drug Administration
- 9:50 a.m. **Discussion**
- 10:10 a.m. **Break**
- 10:30 a.m. **Industry Incentives, Industry Risks**
Debra Travers, MT (ASCP)
Marketing Director
Endo Pharmaceuticals
- 10:45 a.m. **Discussion**
- 11:05 a.m. **Labeling Considerations**
William Pierce, PharmD
FDA/CDER/Office of New Drugs
Study Endpoints and Label Development (SEALD)
- 11:35 a.m. **Discussion**
- 12:00 p.m. **Lunch**



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Agenda, continued

12:30 p.m. **Regulation of Prescription Drug Promotion**
Elaine J. Hu, RPh
LCDR, United States Public Health Service Group Leader
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration

12:45 p.m. **Discussion**

Measurement

1:00 p.m. **Benchtop Evaluations of Tampering with Pharmaceutical Dosage Forms**
Philip Goliber, PhD
President
Andrew's Enterprise, LLC

1:30 p.m. **Discussion**
Nathaniel Katz, MD, MS

2:00 p.m. **Human Abuse Liability Studies: What Do They Measure?**
Edward Sellers, MD, PhD, FRCPC
President and CEO
Ventana Clinical Research Corporation

2:30 p.m. **Discussion**
Sandra D. Comer, PhD
Associate Professor of Clinical Neuroscience
Department of Psychiatry
College of Physicians & Surgeons of Columbia University
Research Scientist V
New York State Psychiatric Institute

2:45 p.m. **Substance Abuse Issues in Pain Management**
Steven D. Passik, PhD
Associate Attending Psychologist
Associate Professor of Psychiatry
Memorial Sloan Kettering Cancer Center

3:15 p.m. **Discussion**
Robert D. Colucci, PharmD
Colucci & Associates, LLC



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Agenda, continued

3:30 p.m. **Break**

4:00 p.m. **Can Epidemiologic Studies Be Used to Measure Abuse Resistance?**

Howard Chilcoat, ScD
Associate Professor
Bloomberg School of Public Health

4:30 p.m. **Discussion**

Edgar H. Adams, ScD
Executive Director, Epidemiology
Late Stage Development Services
Covance

5:00 p.m. **Adjourn for Reception and Dinner**

6:00 p.m. **Reception and Dinner**

Braemore/Kenmore and Huntington Suite III, Lobby Level



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Agenda, continued



Friday, October 28, 2005

- 7:00 a.m. **Breakfast and Registration**
Boston Ballroom, Second Floor
- 8:00 a.m. **Summary of Day 1 and Overview of Day 2**
Nathaniel Katz, MD, MS
- 8:30 a.m. **Concurrent Breakout Sessions**
- Session 1 – Braemore Room, Lobby Level**
Classification and Definitions of Abuse in Relation to Abuse-Resistant Formulations
Facilitator: Sidney Schnoll, MD, PhD
- Session 2 – Kenmore Room, Lobby Level**
Extractability Standards
Facilitator: Philip Goliber, PhD
- Session 3 - Boston Ballroom, 2nd floor (stage area)**
Role of Human Abuse Liability Studies in Supporting Abuse Resistance Labeling
Facilitator: Edward Sellers, MD
- Session 4 – Colonnade West, 5th floor**
Role of Outcome Measurement in Clinical Trials in Supporting Abuse Resistance Labeling
Facilitator: Steven Passik, PhD
- Session 5 – Colonnade East, 5th floor**
Role of Epidemiology in Supporting Abuse Resistance Labeling
Facilitator: Howard Chilcoat, ScD
- Session 6 – Boston Ballroom, 2nd floor**
Clinical Role of Abuse-Resistant Opioids
Facilitator: Nathaniel Katz, MD
- 10:00 a.m. **Break**
- 10:15 a.m. **Presentations from Concurrent Breakout Sessions**
- 12:00 noon **Lunch**
Braemore/Kenmore, Lobby Level
- 12:30 p.m. **Meeting Adjourns**
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