

Science of Abuse Liability Assessment

FDA NIDA NATIONAL INSTITUTE ON DRUG ABUSE CPDD

November 10, 2011 • 8:30 a.m. – 5:00 p.m.
The Legacy Hotel & Meeting Centre, Rockville, MD

AGENDA

7:30 a.m. **Registration and Continental Breakfast**

8:30 a.m. **Welcome from the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA)**

Phil Skolnick, Ph.D., D.Sc. (hon.), Director, Division of Pharmacotherapies and Medical Consequences of Drug Abuse, NIDA

Douglas Throckmorton, M.D., Deputy Director, Center for Drug Evaluation and Research (CDER), FDA

8:45 a.m. **Introduction, Overview, Goals, and Process**

Co-chairs:

*Michael Klein, Ph.D., Director, Controlled Substance Staff
Office of the Center Director, Center for Drug Evaluation and Research (CDER), FDA*

Phil Skolnick, Ph.D., D.Sc. (hon.), Director, Division of Pharmacotherapies and Medical Consequences of Drug Abuse, NIDA

Patrick M. Beardsley, Ph.D., Chair, Committee on the Abuse Liability of Drugs, College on Problems of Drug Dependence (CPDD)

8:50 a.m. **FDA Guidance for Industry: Assessment of Abuse Potential of Drugs Overview, Issues, Decision Tree (Working Draft): Michael Klein, Ph.D.**

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9:15 a.m. **Preclinical Challenges for Assessing Abuse Potential of Nontraditional Drugs and Drug Formulations** – Moderator, *Patrick Beardsley, Ph.D.*

Presenter: ***Nancy A. Ator, Ph.D.***
Professor of Behavioral Biology
Johns Hopkins University School of Medicine

Comment: ***Does Reinforcement Mean Abuse Liability?***
Michael Nader, Ph.D.
Professor of Physiology and Pharmacology
Wake Forest University School of Medicine

Comment: ***Discontinuation Phenomena***
Patrick M. Beardsley, Ph.D.
Professor of Pharmacology & Toxicology
Virginia Commonwealth University

10:15 a.m. **Break (Posters are available for viewing during breaks)**

10:45 a.m. **Assessing Abuse Potential in Human Studies** – Moderator, *Silvia Calderon, Ph.D.*,
Team Leader, Controlled Substance Staff, Office of the Center Director, CDER, FDA

–Human Subject Abuse Potential Studies

a. Human Subject Abuse Potential Studies: Subject Selection and Study Design
Roland Griffiths, Ph.D.
Professor, Departments of Psychiatry and Neuroscience
Johns Hopkins University School of Medicine

11:15 a.m. **b. Human Subject Abuse Potential Studies: Validated Scales and Statistical and Clinical Assessments**
Kerri Schoedel, Ph.D.
Scientific Director, Clinical Pharmacology
INC Research

c. Human Subject Abuse Potential Studies: Evaluation of Complex Drug Formulations and its Special Challenges
Jack E. Henningfield, Ph.D.
Vice President, Research & Health Policy, Pinney Associates and
Professor, Adjunct, Behavioral Biology, The Johns Hopkins University School of
Medicine

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d. Human Subject Abuse Potential Studies: Discussion of Various Applications and Limitations During Testing

Marta Sokolowska, Ph.D.

*Director, Center for Excellence in Abuse Liability
Grunenthal USA*

12:15 p.m. **Lunch** (On your own)

1:45 p.m. **Assessing Abuse Potential in Human Studies** – Moderator, *Jane Acri, Ph.D., Chief, Medications Discovery and Toxicology Branch, NIDA*

–Adverse Events in Human Trials

e. Adverse Events as an Abuse Signal

A.J. Allen, M.D., Ph.D.

Eli Lilly and Company

f. Adverse Events in Drug Abuse – Review and Guidance

Myroslava K. Romach, M.D., M.Sc.

Principal

DL Global Partners Inc.

g. Adverse Events Following Drug Discontinuation

Sian Ratcliffe, Ph.D.

Senior Director, Clinical Lead

Clinical Affairs, Specialty Care Business Unit

Pfizer, Inc. – UK

3:00 p.m. **Break** (*posters are available for viewing*)

3:30 p.m. **Discussants: Challenges in Assessing Abuse Potential in Human Studies / Future Research Needs** – Moderator, *Michael Klein, Ph.D.*

Rob Mansbach, Ph.D., Consultant, Mansbach Consulting

Beatriz A. Rocha, M.D., Ph.D., Director Worldwide Regulatory Affairs, Merck Sharp & Dohme Corp.

Science of Abuse Liability Assessment: Perspective of Cross Company Abuse Liability Consortium (CCALC) - Applications and Future Research Needs

Mark A. Ammann, Pharm.D.

President

Catalyst Regulatory Services, LLC

4:45 p.m. **Closing Remarks**

5:00 p.m. **Adjournment**

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Poster Viewing During Breaks:

Decision Tree (Working Draft)

Stephen Sun, M.D., Medical Officer and Katherine Bonson, Ph.D., Pharmacologist, Controlled Substance Staff, CDER, FDA

Identifying Items and Scales for a Shorter Questionnaire in Human Abuse Potential Trials: A Proposed Study of Adverse Events and Clusters That Simultaneously Predict a Psychometric Scale and Unique Variation in Scale Items

Richard Francoeur, Ph.D., Associate Professor, Adelphi University School of Social Work

Analysis of Data from Human Abuse Potential Studies

Ling Chen, Ph.D., Office of Translational Sciences, Office of Biostatistics, Division of Division of Biometrics VI, Special Projects Team, CDER, FDA

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