

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
FDA White Oak Campus, 10903 New Hampshire Ave.,
Bldg. 31, Conference Center, Silver Spring, M.D.

Clinical Development Programs for Sedation Products: Public Workshop
AGENDA
May 3, 2012

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is conducting a scientific workshop to solicit information on the clinical development of sedation products.

Workshop Moderators:

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) CDER/FDA

Robert Dworkin, Ph.D.
University of Rochester School of Medicine and Dentistry

8:30 A.M. Opening Remarks – Welcome and overview of the workshop
Bob Rappaport, M.D., Director, DAAAP, CDER/FDA

8:35 **Drug Trials for the Indication of Sedation: Designs, Endpoints,
and Methodological Concerns**
Bradford Harris, M.D., Medical Officer, DAAAP, CDER/FDA

8:50 **Study Designs for Use in Sedation Trials**
Dionne L. Price, Ph.D., Team Leader, Division of Biometrics II,
Office of Biostatistics, Office of Translational Sciences, CDER/FDA

9:05 Questions & Answers

Panel #1: Procedural and OR Sedation
Panel Moderator: Christopher Breder, M.D., Ph.D.
Clinical Team Leader for Anesthetic Products
DAAAP, CDER/FDA

9:10 **Procedural and OR Sedation Literature Review**
Douglas Carlson, M.D., Washington University School of Medicine

9:40 **Discussion of the Procedural and OR Sedation Literature**
John Vargo, M.D., M.P.H., Cleveland Clinic

10:00 **Discussion of the Procedural and OR Sedation Literature**
Rebecca Twersky, M.D., M.P.H.
State University of New York, Downstate Medical Center

- 10:20 Break
- 10:40 Panel discussion of Procedural and OR Sedation issues (1 hr)
Further panel discussion of Procedural and OR Sedation pediatric-specific issues (40 min)

Panel Members:

Douglas Carlson, M.D., Washington University School of Medicine

John Vargo, M.D., M.P.H., Cleveland Clinic

Rebecca Twersky, M.D., M.P.H., State University of New York,
Downstate Medical Center

Keira Mason, M.D., Children's Hospital Boston, Harvard Medical School

Charles Cote, M.D., Massachusetts General Hospital

James Miner, M.D., Hennepin County Medical Center

Baruch Krauss, M.D., Ed.M., Children's Hospital Boston, Harvard Medical School

Stephen Wilson, D.M.D., M.A., Ph.D., Cincinnati Children's Hospital Medical Center

James Ware, Ph.D., Harvard University School of Public Health

- 12:20 P.M. Questions & Answers

- 12:30 Lunch

1:30 **Open Public Hearing**

1. David Goodale, M.D.
Executive Clinical Director
DBG Pharma LLC
2. Walter Maurer, M.D.
Section Chief, Ambulatory Anesthesia, Department of General Anesthesia
Division of Anesthesiology and Critical Care, Cleveland Clinic
3. Hannah Wunsch, M.D., M.Sc.
Herbert Irving Assistant Professor of Anesthesiology & Epidemiology
Columbia University
4. Robert O'Connor, M.D., M.P.H.
Professor and Chair, Department of Emergency Medicine
University of Virginia School of Medicine

2:00 **Lorazepam Trial: Challenges of Pediatric Sedation Scores**

Janice Sullivan, M.D.

Professor, Department of Pediatrics, University of Louisville
Chief & Medical Director, KCPCRU

- 2:15 Questions & Answers

Panel #2: ICU Sedation

Panel Moderator: Anne Zajicek, M.D., Pharm.D.
National Institutes of Health

- 2:20 **Adult ICU Sedation Literature Review**
John Kress, M.D., Department of Medicine, University of Chicago
- 2:45 **Pediatric ICU Sedation Literature review**
Joseph Cravero, M.D., Dartmouth-Hitchcock Medical Center
- 3:05 **Discussion of the ICU Sedation Literature**
Pratik Pandharipande, M.D., Vanderbilt University School of Medicine
- 3:25 Break (15 min)
- 3:40 Panel discussion of ICU Sedation issues (45 min)
Panel discussion of ICU Sedation pediatric-specific issues (25 min)

Panel Members:

John Kress, M.D., Department of Medicine, University of Chicago
Joseph Cravero, M.D., Dartmouth-Hitchcock Medical Center
Pratik Pandharipande, M.D., Vanderbilt University School of Medicine
Martha A.Q. Curley, R.N., Ph.D., University of Pennsylvania School of Nursing
Marek Mirski, M.D., Ph.D., Johns Hopkins University School of Medicine
Joseph Tobin, M.D., The Wake Forest University School of Medicine
Richard Riker, M.D., Maine Medical Center; Tufts University School of Medicine
James Ware, Ph.D., Harvard University School of Public Health

- 4:50 Questions & Answers
- 4:55 Closing comments and adjournment
Bob Rappaport, M.D.
Director, DAAAP/CDER/FDA
- 5:00 ADJOURN

Corrected link to the Clinical Development Programs for Sedation Products Public Workshop
Web page: <http://www.fda.gov/Drugs/NewsEvents/ucm301022.htm>