

AGENDA FOR SEPTEMBER 13TH AND 14TH ALSDAC

September 13, 2001

Morning Session

- 8:00 Introductions
- 8:15 COI Statements
- 8:30 Opening Remarks and Charge to the Committee (McCormick)
- 8:45 Open Public Hearing
- 9:45 Industry Presentation
- 10:05 Introduction to Session I on Opiate Analgesic Development and Use (Rappaport)
- 10:15 Pain Treatment Guidelines (Levy)
- 10:45 Treatment of the Patient with Chronic Pain (Portenoy)
- 11:15 Break
- 11:30 Opiate Analgesic Trials and Drug Development Plans (DalPan)
- 11:45 Questions and Discussion

- 1:00 Lunch

Afternoon Session

- 2:00 Introduction to Session II on Opiate Analgesic Use in Pediatric Patients
(Rappaport)
- 2:10 Pediatric Analgesic Use (Friedman)
- 2:40 Pediatric Exclusivity and the Pediatric Rule (Roberts)
- 3:00 Pediatric Opiate Analgesic Trials and Development Plans: Case studies (Chang)
- 3:15 Questions and Discussion

September 14, 2001

- 8:00 Welcome to Second Day and Introductory Comments (McCormick)
- 8:15 Open Public Comments
- 9:15 Industry Presentation
- 10:05 Introduction to Session III on Prescription Drug Abuse (Rappaport)
- 10:15 Current Data on Abuse and Diversion (Judy Ball)
- 10:35 Break
- 10:50 Criminal Activity Associated with Opiate Analgesics (DEA Staff)
- 11:10 FDA Assessment of Abuse Liability (Leiderman)
- 11:30 Discussion
- 11:45 Epidemiology of Prescription Drug Abuse: Implications for the Clinical Setting
(Chilcoat)
- 12:15 Prescription Drug Abuse in Pain Patients (Passik)
- 12:45 Discussion

- 1:00 Lunch

- 2:00 Regulatory Approaches to Risk Management of Prescription Opioid Drug Abuse
(Hertz)
- 2:15 Questions and Discussion