

# Tufts Health Care Institute Program on Opioid Risk Management

Guidelines for the Development of  
Abuse-Deterrent Opioid Formulations  
November 9 – 10, 2006



THCI Program on  
Opioid Risk Management



# Epidemiological Studies

- Edgar H. Adams, ScD - facilitator
- Theodore J. Cicero, PhD
- J. David Haddox, DDS, MD
- Sidney H. Schnoll, MD, PhD

# Who Cares?

- Public Health Concerns
  - Maintaining benefit (analgesia/access)
  - Reducing adverse consequences
    - Patients
    - Non-patients
      - Abusing population
      - Inadvertent exposure (e.g., children-accidental use)
    - Health care costs
      - Direct (e.g., cost of addiction treatment)
      - Indirect (e.g., cost of abuse-related diseases)

# Who Cares?

- Commercial
  - Differential Scheduling
  - RMPs tailored to actual risk
  - Product differentiation

# Desired Label Language

- Epidemiological studies
  - Pre-market studies are unlikely to influence the initially approved label language.
  - Pre-market studies may be useful in establishing baselines against which post-marketing studies can be compared.

# Desired Post-approval Label

- "<Trade Name> has been shown to be associated with lower prevalence of abuse than other formulations containing the same active ingredient(s)"
- "<Trade Name> has been shown to be associated with lower prevalence of <route of administration> abuse than other formulations containing the same active ingredient(s)"

# Post-approval Patient Studies

- Appropriate active comparators
- Indicators of abuse / addiction
- Indicators of diversion
- Active safety surveillance
  - Adverse events
  - Diminished efficacy
- Active effectiveness surveillance

# Post-approval Patient Studies

- Stratification
  - Known risk factors for abuse
  - Co-morbidities
  - Pharmacogenomics
- Registry Studies
  - Condition-based, as opposed to only product-based
- Consistent with existing FDA Guidances



# Post-approval Abuser Studies

- Prospective studies desirable, but may not be practical, due to
  - Recruitment
  - Retention
- Retrospective and Sentinel Populations
  - Ethnographic studies
  - Physicians could be both
    - Sentinel population (impaired)
    - Source of information about abusers (SUD treatment)

# Post-approval Abuser Studies

- Diversion studies
  - Prevalence
  - Street prices
- Existing data collection systems
  - DAWN, NSDUH, TESS, NFLIS, etc.
  - A key finding would be concordance amongst multiple systems