ENDO®

PHARMACEUTICALS

Industry Perspective on Risk Management

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Industry Perspective on Risk Management

- Pharma is committed to improve the care of pain patients while at the same time minimizing the risks that may be associated with the use of opioids, e.g., potential abuse, misuse, and diversion.
- Pharma should be proactive in managing risk, not reactive.
- Pharma wants to do the RIGHT THINGS.
  - Protect pain patients rights to obtain needed treatments.
  - Protect society from risks of opioid abuse/diversion.

Risk Management Plans

In general the FDA believes that a RMP should address 3 elements:

- Risk of accidental exposure - especially in Modified Release (MR) products with large amounts of opioid.
  - Packaging (e.g., Actiq)
- Improper patient selection – ensure physician's are selecting appropriate patients
  - Educational Initiatives
  - Promotional Materials
  - Package Insert
  - Sales Force Training
- Risk for abuse and misuse – reduce risk for patients and community.
  - Websites for patients
  - Patient educational material

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- Who is responsible for the assessment of prevalence of abuse/diversion?
  - And how is it assessed

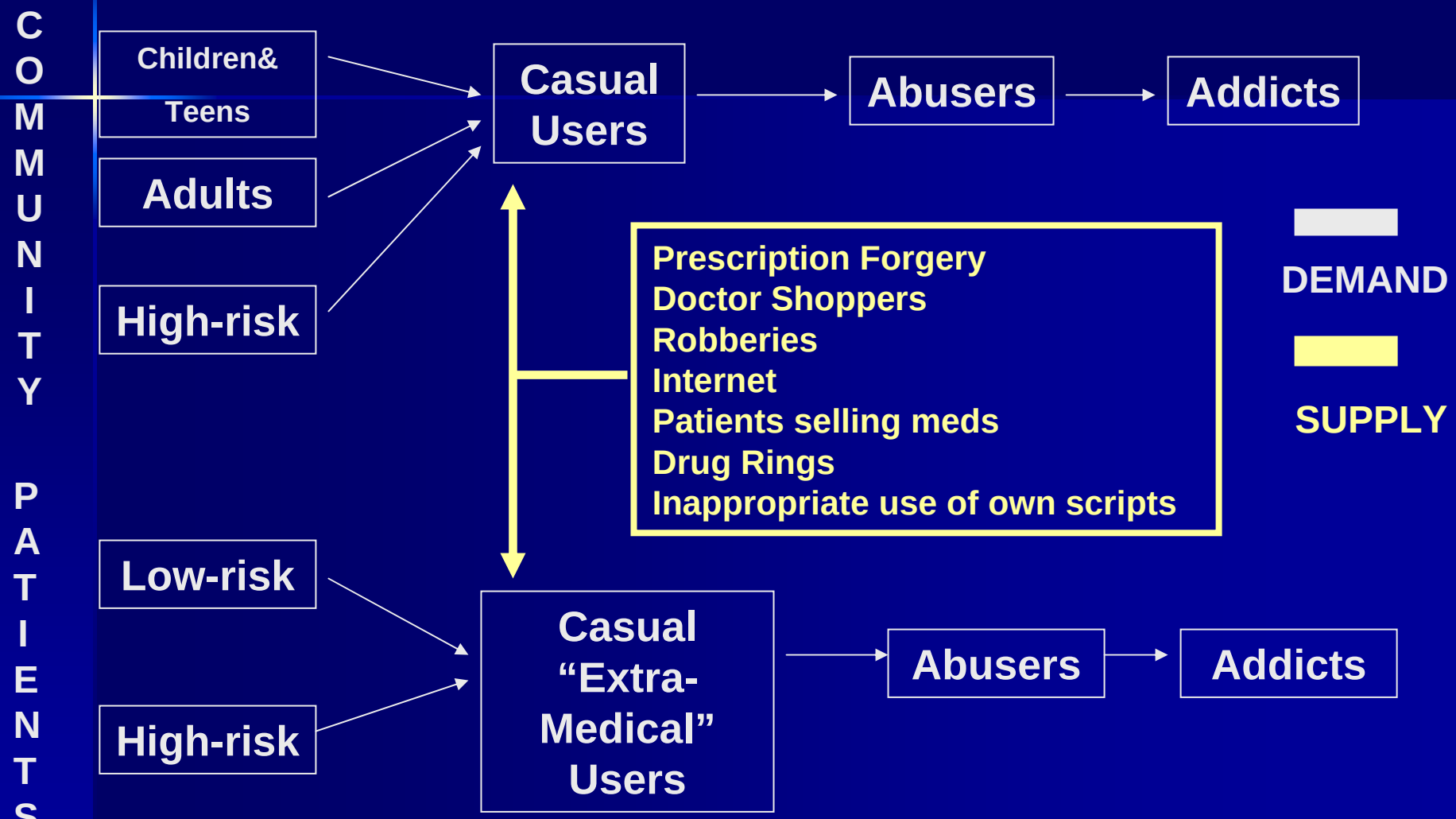
  DAWN

  NHSUH

  TEDS

  etc

Pathways to Prescription Opioid Abuse



Industry Perspective on Risk Management- Risk Intervention

- Risk Intervention
  - Who intervenes?
    - Pharma definitely has a responsibility
  - Intervention to targeted areas
    - Increased education
    - Notification of local law enforcement agencies
    - Notification of state medical board
    - Work closely with FDA and DEA
    - Maintain tight control of supply chain
  - BUT- what works?

Industry Perspective on Risk Management – Open Issues

- How much involvement should Pharma have with regards to:
  - Prescription Forgery
  - Doctor Shoppers
  - Robberies
  - Internet
  - Patients selling own meds
  - Drug Rings
- Who is responsible for the practice of medicine? (board of medical practice)
- Who is responsible for street addicts?
- What are the ethical and legal issues?

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- What roles do the following “players” have in RM?
  - FDA
  - DEA
  - NIDA
  - SAMSHA
  - Pharma
- No pre-defined roles

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- Proactive steps
- Minimize improper patient selection
  - Emphasize Education
  - Endo and other companies have taken initiative to help deliver tools to aid HCP in appropriate patient selection (Opioid Handbook)
  - RADARS
  - SOAPP
    - Screener and Opioid Assessment for Patients with Pain
    - Screening tool to assist in the identification of patients who may have difficulty with opioids

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- The ultimate goal for all parties involved is to work cooperatively to:
  - **PROTECT PUBLIC HEALTH**

Industry Perspective on Risk Management -Where do we go from here

- Should we establish principles of how to monitor data?
- Who should monitor data?
  - Should a third party be involved to review data from national databases?
  - What constitutes a signal?
- What type of interventions are warranted?
  - Education
  - Notification of local law enforcement agencies

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- When an area of increased abuse is identified and intervention has occurred, how do we measure success?
  - What metrics can be used?
- Potential forums to answer these questions
  - Symposia (like today)
  - Multi-disciplinary task force (FDA, Pharma, DEA, SAMSHA, etc.,)
  - BUT need working group with “teeth”

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Time for stimulating discussion!!!