

Opioid Risk Management

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Risk Minimization: Broader Issues

--Promotion & marketing of controlled drugs

--Industry

--DEA

--FDA

--PMP

“Recovery of morphine from a
controlled-release preparation: a
source of opioid abuse”

Crews JC; Denson DD
CANCER Dec. 15, 1990

“...over the past 18 months, MS-Contin has
surpassed hydromorphone...as the most
desirable and abused prescription opioid
in this area...”

Promotion & Marketing of OxyContin

- Most extensive ever opioid marketing
- Trivializing the risk, over-selling benefits
- Sponsorship of pain meetings/education
- Targeting high prescribing physicians & lucrative incentives
- Promotion to primary care doctors
- Promotion for chronic non-cancer pain

Purdue Pharma's aggressive marketing & promotion of Oxycontin

- Took a drug that evidence based medicine would show is comparable in efficacy & safety to IR oxycodone and other SR opioids—and made it a blockbuster drug, the most heavily prescribed brand name opioid
- High availability of a highly abusable drug was associated with increasing diversion, abuse, and addiction that spread throughout the country

Risk Minimization: The Industry

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 minimization: Suggestions to consider for Industry—Marketing & Promotion

- Get the message right: an evidence based risk analysis weighing risks vs. benefits
- Limitation on industry sponsored CME for controlled/abusable drugs
- IMS physician profiling, targeting physicians & lucrative incentives---alternatives
- Careful selection of physician audience to target for influencing prescribing patterns

Risk minimization:
Suggestions to consider for
Industry
Other possibilities

- patient point of care technology to decrease diversion
- ONLY opioid products that minimize abuse brought to the market-place
- support of prescription monitoring programs
 - industry supported
 - industry/government partnership

Suggestions for Industry to consider:

- Industry sponsored fund for prescription drug abuse prevention & treatment

Purdue Pharma Legal Nightmare

- 1400 lawsuits over OxyContin
- Hired 40 law firms in 32 states
- 322 partners, 849 associates, 1,023 para
- Billed 1.2 million hours of legal work

Purdue Pharma & its Insurer

- Steadfast Insurance of Zurich Insurance Co. declined to pay more than \$400 million of the legal costs related to the defense of the painkiller
- as part of the settlement, Steadfast will pay something more than \$200 million

Wall Street Journal Online June, 2006

Risk minimization: Suggestions for The DEA to consider

- Schedule II & III prescribing contingent on 8-16 hours CME on pain & addiction
- Schedule II methadone prescribing contingent on additional 4 hours CME

Risk minimization: Suggestions for FDA to consider

- The need for a much empowered FDA with sufficient staff to review, monitor marketing of controlled drugs
- Limitation on marketing/promotional monies for controlled drugs
- Review of promotional materials & CME materials before dissemination

Risk minimization:

Suggestions to consider for FDA (cont.)

- Do we need new opioid preparations brought to the market-place now with same broad indications for chronic non-malignant pain if they offer no advantage over available drugs?

Risk minimization: FDA (cont)

- Do we need to re-examine the at present very broad indications given SR opioids for chronic non-malignant pain now that it is apparent the risks of SR opioids can be higher (higher addiction potential when abused, & higher OD/death risk) than IR opioids?

Risk minimization: FDA (cont)

- Is it time to require any new opioid preparation brought to market-place to be an abuse resistant preparation?

Risk Minimization: Possible suggestions for Industry, DEA, FDA, SAMHSA all of us at the table

- Risk management enormously enhanced if we can much better define the questions and problems associated with the use of opioids for treatment for chronic non-malignant pain.
- Long term studies (Institute of Medicine?) to define efficacy over time, risks and benefits over long periods of time, addiction risk, functional out-comes, etc