

What are the legal and ethical responsibilities of a pharmaceutical company to intervene in response to prescription drug abuse?

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***“If we lose control of pain medications,
we can lose control of pain.”***

***Some patients are not getting the
medications they need anymore
because of these concerns about
diversion.”***

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Pain & Policy Studies Group, World Health Organization Collaborating Center

Today's example of "lost control" ...

- Fentanyl 50 mcg - 1 patch every 3 days – 10
- OxyContin 40mg - BID - 80 per month
- Methadone 10mg - 270 per month
- Hydrocodone 7.5 – 90 per month PRN

Which stakeholder should be looked to first?

Recent example

- Patient X has an insurance company that sets a maximum dosage limit on a Schedule II pain medication.
- The medication is effective for the patient but not with this limitation.
- Would it be legally or ethically proper for a pharmaceutical representative to encourage the doctor to prescribe the limit of medication A and then prescribe the same patient the limit of medication B and so on, until the doctor achieves pain relief with the patient?

Taking back turf



Responsibilities



- **Information possessed by pharmaceutical company**

- **Corresponding responsibilities**

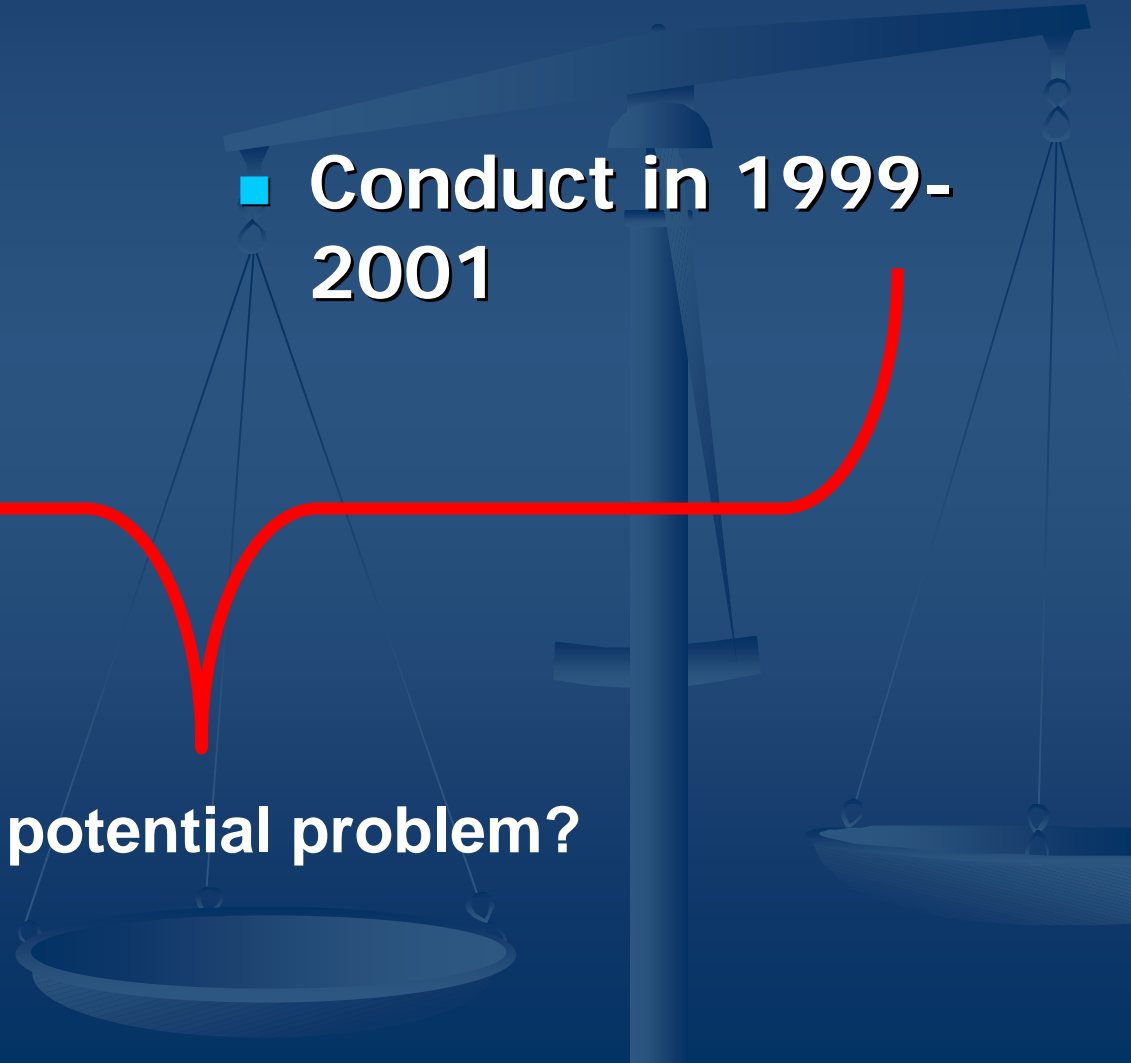
- **Consequences of "doing" or "not doing"**

A Litigator's Mindset

- Complaint in 2006

- Conduct in 1999-2001

See a potential problem?



Legal Responsibilities



Legal Responsibilities

- Promotional Regulation – Responsible Labeling
 - Black box issues
 - Monitoring and enforcement issues
 - Enforcement levels and Penalties
- Risk Monitoring, Reporting, and Responsiveness
 - Risk management plans
 - Proactive efforts*

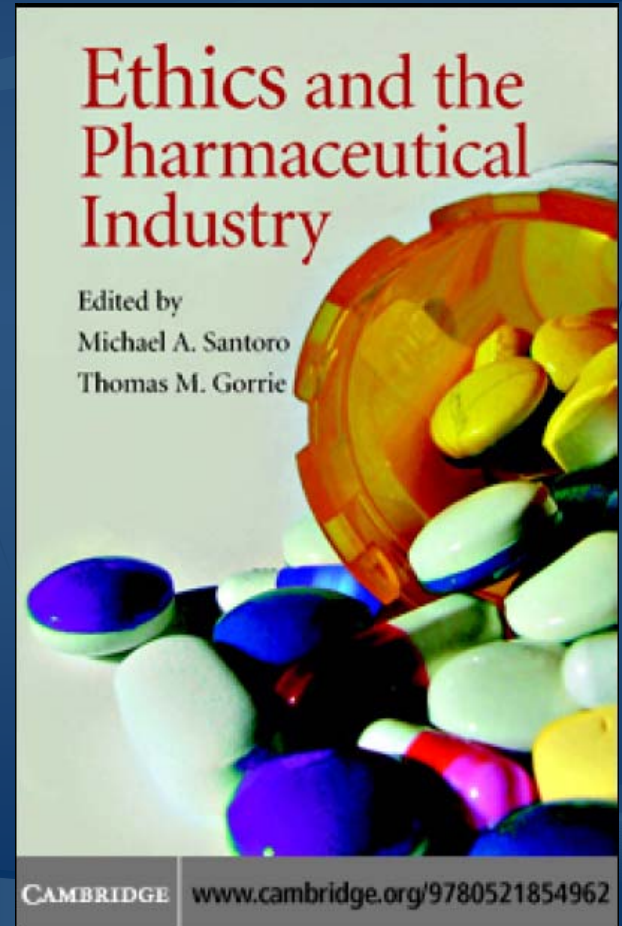
Federal Law & Regulations (and *encouraged behaviors)




Ethical Responsibilities



Ethics and Intervention in the Abuse and Diversion



Ethical Responsibilities

- Promotion*
 - Prescribing
 - Off-label Communications
 - Access to Drugs/Pharmacy Benefits
(Rebates; Formulary Issues)
- 

Physician Dilemmas



- Are there data to support the prescribing decision?
- Have non-pharmacologic strategies been explored sufficiently?
- Which medication? What about medication combinations?
- Informed consent issues? <key role point for pharmaceutical companies>
- Is my practice consistent with accepted standards of care and regulatory expectations?
- What formulary considerations do I need to worry about
- How much time will I have to spend following or monitoring the patient if I choose Drug A versus Drug B or drugs versus no drugs?

Recent example

Can methadone be used for pain control?

Methadone, a schedule II controlled substance, has been approved by the FDA as an analgesic. While a physician must have a separate DEA registration to dispense methadone for maintenance or detoxification, no separate registration is required to prescribe methadone for pain. However, in a document entitled ``Methadone-Associated Mortality: Report of a National Assessment,' SAMHSA recently recommended that ``physicians need to understand methadone's pharmacology and appropriate use, as well as specific indications and cautions to consider when deciding whether to use this medication in the treatment of pain.''

\35\ This recommendation was made in light of mortality rates associated with methadone.

Voices from Across the U.S.

(an informal survey of desired “best practices”)

- AL
- GA
- OK
- TX
- UT
- WI

- Total surveyed
- 100 MDs
- 35 RNs
- 20 Others
- August 2006

Overwhelmingly, the number one (and often the only) response was “tell us the ‘good, bad, and ugly’ about your drug.”

Other responses:

Tell us how your drug can be abused – what you know about how people might compromise the delivery system.

Help us with entrance and exit strategies for the use of your drug – these are our realities and yours too!

