The Legal Implications of Prescribing & Dispensing Opiates for Non-cancer Pain

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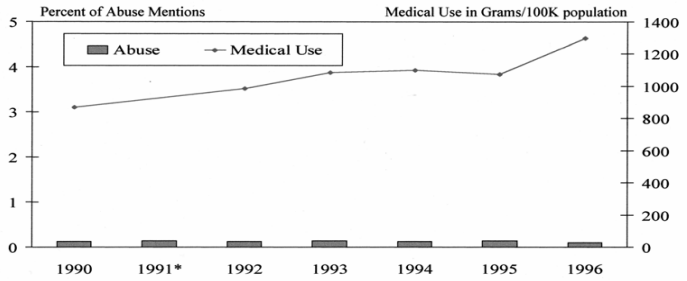
Objectives

- To discuss the 4 “A’s” of pain management
- To advise on how to avoid regulatory problems
- To review pain management guidelines
- To describe common drug scams

Medical Use and Abuse of Morphine in the US



- Source:
  - DAWN - overdose data
  - ARCOS - Purchase data per 100 K population
    - (interpolated for 1991)

How to Avoid Trouble

- Know the federal and state drug laws & State pain guidelines

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Pain Management Guidelines

- **Washington Dept. of Health**
- **American Geriatrics Society**
- **Joint Commission on Accreditation of Health Care Organizations (JCAHO)**
- **Federation of State Medical Boards**

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Pain Management Guidelines - Washington

- Treatment of intractable pain OK 1993
- Pain guidelines adopted 1996
- Follow guidelines to protect license
- Don't turn away legitimate pain patients
- If MD, RPh, etc. decide not to treat a pain patient please don't blame the Boards, DEA, etc.!

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Pain Management Guidelines, Continued

- Intractable pain
- 69.50.308(g) RCW
  - "Medical treatment includes dispensing or administering a narcotic drug for pain, **including intractable pain**."
  - (Adopted 1993)

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WA Department of Health Pain Management Guidelines

- "It is the position of DOH that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline."

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Pain Management Guidelines Continued

- Outline:
  - Background, introduction, purpose
  - Policy
  - Guidelines
  - Definitions
  - Assessment & documentation in non-cancer pain
  - Patient responsibilities

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Pain Management Guidelines, Continued

- Guidelines assessment & documentation
  - History & physical
  - Diagnosis & medical indication
  - Treatment plan with measurable objectives
  - Informed consent
  - Periodic reviews & modifications indicated
  - Consultation
  - Records, assessment & monitoring

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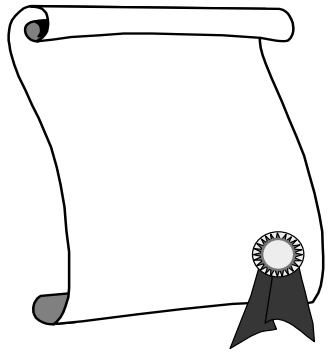
Reinforcement of Guidelines

- October 9, 1999 Washington State Medical Quality Assurance Commission adopted pain guidelines into rule. This formalizes the status of the guidelines!



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MQAC Rules 10/99

- WAC 246-919-810 how will Commission evaluate prescribing for pain?
- Clinically sound
- In accordance with currently accepted medical practice
- NO disciplinary action will be taken RE
  - Quantity or frequency of Rx

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Joint Commission on Accreditation of Health Care Organizations

- JCAHO Pain Standards
- Effective 2000
- Measured 2001
- Apply to ALL accredited organizations (hosp., hospice, LTC, etc.)

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Federation of State Medical Boards Guidelines

- Model guidelines
- Available for state use
- Quite similar to Washington's
  - Except no patient responsibilities

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Pharmacist Issues

- We know the drugs
- We know less about pain management
- We should know the laws & rules
- We play a pivotal role in ensuring patient access to pain medications.
- We need to err on the side of patient care not law enforcement
- See JAPhA Mar-Apr 2001, Joranson & Gilson

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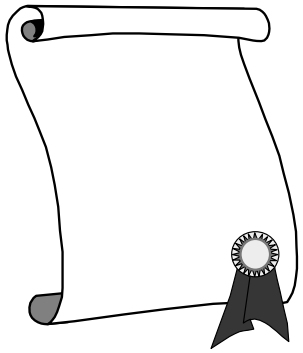
How to Avoid Trouble, Continued

- Prescribers should consider using patient pain contracts or agreements.



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Patient Contracts

- Informed consent
- Use a single prescriber & pharmacy
- Follow directions for use
- No extra meds
- Authorize the release of their medical information (to MD,PD,BD of Phcy, etc.)
- UA's (Where are the drugs going?)

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Reluctance to Adequately Treat Pain

- Inadequate training in pain management
- Fear of regulators
- Patient concerns about the drugs
- Confusing Addiction, Physical Dependence, and Tolerance

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Patient Concerns

- **60% of patients reluctant to take opioids due to fear of addiction**
- **B. Cryer, MD, U of TX Southwest**

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Addiction

- Psychological problem
- Loss of control over use of drugs
- Take drugs to get high rather than for pain
- Continued taking of drugs in spite of adverse consequences

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Physical Dependence

- Physical manifestation
- Opiates cause physical dependence
- Stopping opiate or administering an antagonist will cause withdrawal symptoms

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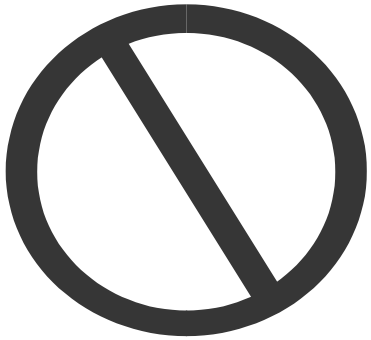
- Physical dependence is NOT addiction



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Tolerance

- Physical manifestation
- Over time increases in dosage may be needed to achieve same pain relief

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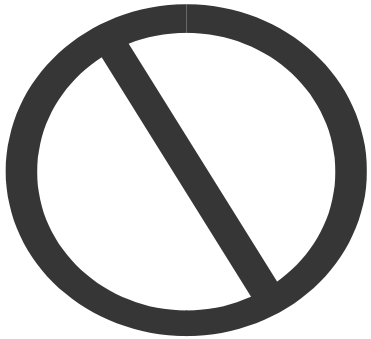
- Tolerance is NOT addiction



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Try to differentiate

- Is it
- Drug Seeking?
- Or
- Pseudoaddiction?

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Deciding to prescribe chronic controlled drugs

- The 5 questions
- Per:
- Ted Parran, MD
- Case Western Reserve University School of Medicine
- Cleveland OH

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Deciding to prescribe, cont.

- Five Questions Prescribers should ask themselves
  - 1. Is there a clear diagnosis?
  - 2. Have you documented an adequate work-up? (e.g., old records, previous studies, consultations, H&P, assessment and plan)
  - 3. Is there impairment of function? (get corroboration from significant others.)
  - 4. As non-controlled Rx plan failed?
  - 5. Have contraindications to opoids been ruled out?
  - Answers to each question must be YES!

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Thank you to Steven D. Passik PhD for the following information on the Four "A's" of treatment

Steven D. Passik, PhD

Director, Symptom Management and Palliative Care, Markey Cancer Center

Associate Professor of Medicine and Behavioral Sciences – University of Kentucky

Lexington, KY

Covington, KY, 03/25/03

The Four "A's" of Pain Treatment Outcomes

- Analgesia (pain relief)
- Activities of Daily Living (psychosocial functioning)
- Adverse effects (side effects)
- Aberrant drug taking (addiction-related outcomes)

Passik & Weinreb, 1998

The 4 A's: Analgesia

Selected Questions

Using a scale of 0 to 10, in which 0 means no pain and 10 means the worst pain imaginable, please rank the following:

What was your pain level on average during the past week?

What was your pain level at its worst during the past week?

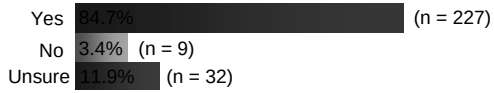
Compare your average pain during the past week with the average pain you had before you were treated with your current pain relievers. What percentage of your pain has been relieved?

The 4 A's: Analgesia

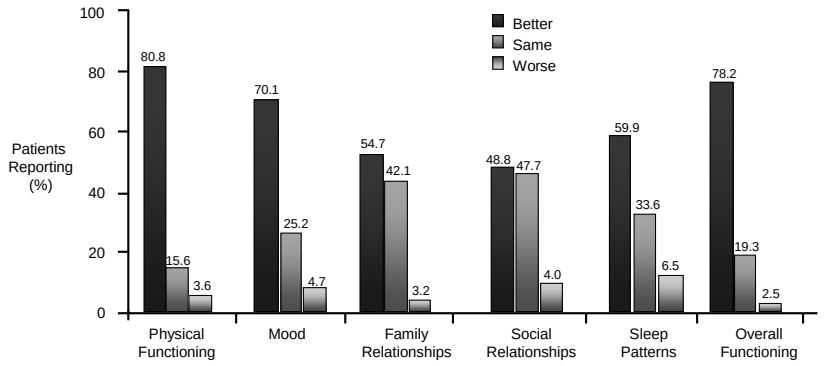
Selected Questions

Is the amount of pain relief you are now obtaining from your current pain relievers enough to make a real difference in your life?

(To doctor) Is the pain relief clinically significant?



The 4 A's: Activities of Daily Living



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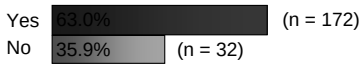
The 4 A's: Adverse Side Effects

Selected Questions

Are you able to tolerate your current pain relievers?

Are you experiencing any side effects from your current pain relievers?



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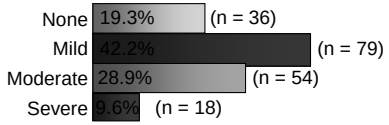
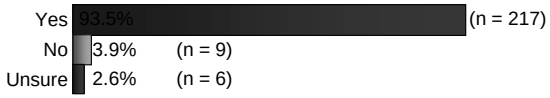
The 4 A's: Adverse Side Effects

Severity of the constipation you are experiencing:



(To doctor) Are the side effects tolerable for the patient?



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Aberrant Drug-taking Behaviors: The Model

- Probably more predictive
  - Selling prescription drugs
  - Prescription forgery
  - Stealing or borrowing another patient's drugs
  - Injecting oral formulation
  - Obtaining prescription drugs from non-medical sources
  - Concurrent abuse of related illicit drugs
  - Multiple unsanctioned dose escalations
  - Recurrent prescription losses
- Probably less predictive
  - Aggressive complaining about need for higher doses
  - Drug hoarding during periods of reduced symptoms
  - Requesting specific drugs
  - Acquisition of similar drugs from other medical sources
  - Unsanctioned dose escalation 1 – 2 times
  - Unapproved use of the drug to treat another symptom
  - Reporting psychic effects not intended by the clinician

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Passik and Portenoy, 1998

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. What was your pain level on average during the past week? (Please circle the appropriate number)

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

2. What was your pain level at its worst during the past week?

No Pain 0 1 2 3 4 5 6 7 8 9 10 **Pain as bad as it can be**

3. What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100%.) _____

4. Is the amount of pain relief you are now obtaining from your current pain relievers enough to make a real difference in your life?
❑ Yes ❑ No

5. **Query to clinician**: Is the patient's pain relief clinically significant?
❑ Yes ❑ No ❑ Unsure

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Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with the PADT.* (Please check the box for Better, Same, or Worse for each item below.)

	Better	Same	Worse
1. Physical functioning	❑	❑	❑
2. Family relationships	❑	❑	❑
3. Social relationships	❑	❑	❑
4. Mood	❑	❑	❑
5. Sleep patterns	❑	❑	❑
6. Overall functioning	❑	❑	❑

* If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.

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Adverse Events

1. Is patient experiencing any side effects from current pain relievers? ❑ Yes ❑ No

Ask patient about potential side effects:

	None	Mild	Moderate	Severe
a. Nausea	❑	❑	❑	❑
b. Vomiting	❑	❑	❑	❑
c. Constipation	❑	❑	❑	❑
d. Itching	❑	❑	❑	❑
e. Mental cloudiness	❑	❑	❑	❑
f. Sweating	❑	❑	❑	❑
g. Fatigue	❑	❑	❑	❑
h. Drowsiness	❑	❑	❑	❑
i. Other _____	❑	❑	❑	❑
j. Other _____	❑	❑	❑	❑

2. Patient's overall severity of side effects?
❑ None ❑ Mild ❑ Moderate ❑ Severe

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Potential Aberrant Drug-Related Behavior

*Please **check** any of the following items that you discovered during your interactions with the patient.* Please note that some of these are directly observable (eg, appears intoxicated), while others may require more active listening and/or probing. Use the "Assessment" section below to note additional details.

- ❑ Purposeful over-sedation
- ❑ Negative mood change
- ❑ Appears intoxicated
- ❑ Increasingly unkempt or impaired
- ❑ Involvement in car or other accident
- ❑ Requests frequent early renewals
- ❑ Increased dose without authorization
- ❑ Reports lost or stolen prescriptions
- ❑ Attempts to obtain prescriptions from other doctors
- ❑ Changes route of administration
- ❑ Uses pain medication in response to situational stressor
- ❑ Insists on certain medications by name
- ❑ Contact with street drug culture
- ❑ Abusing alcohol or illicit drugs
- ❑ Hoarding (ie, stockpiling) of medication
- ❑ Arrested by police
- ❑ Victim of abuse

Other: _____
_____
_____

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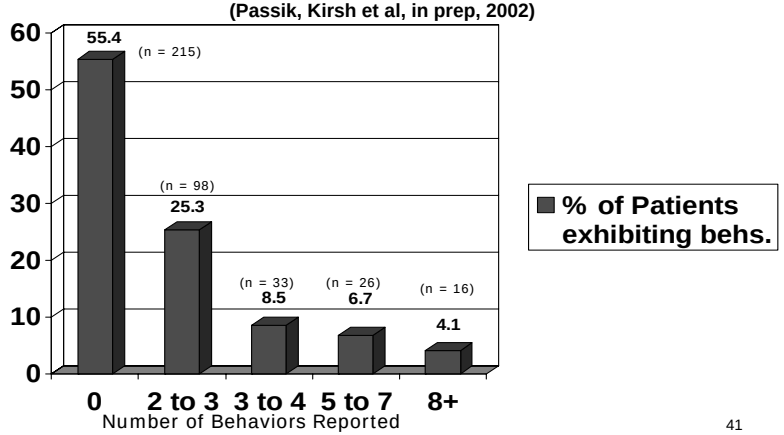
Aberrant Behaviors (n = 388)

(Passik, Kirsh et al, in prep, 2002)



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4th "A" - Aberrant Drug-related Behavior

Adverse consequences possibly resulting from drug use

Frequency of behavior=0

	n(%)
Purposeful over sedation	241 (89.6)
Negative mood Change	252 (92.6)
Decline in psychological function	255 (94.1)
Decline in social function	259 (94.9)
Appearing intoxicated	260 (95.6)
Decline in physical function	262 (96.0)
Increasingly unkempt or impaired	266 (97.8)
Worrisome drug effects ("Getting High")	267 (98.2)
Involvement in MVA	267 (98.5)
Engages in sale of sex to obtain drugs	229 (100*)

* No answer: 53

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4th "A" - Aberrant Drug-related Behavior

Possible loss of control or diversion of medications

Frequency of behavior=0

	n(%)
Requests frequent early renewals	220 (81.8)
Increases dose without authorization	235 (86.7)
Reports lost or stolen prescriptions	246 (90.8)
Requests higher doses in worrisome manner	248 (91.2)
Attempts to obtain prescriptions from other doctors	255 (94.4)
Uses medication for purpose other than described (to help sleep)	255 (95.2)
Engages in staff splitting	223 (97.8)
Changes route of administration	269 (98.5)

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4th "A" - Aberrant Drug-related Behavior

Preoccupation with opioids or other drugs

Frequency of behavior=0

	n (%)
Asks for medication by name	238 (89.8)
Does not comply with other recommended treatments	253 (93.0)
Reports no effects of other medications	255 (94.4)
Misses appointments except for medication renewal	256 (94.5)
Contact with street culture	258 (97.0)
Abusing alcohol and street drugs	265 (98.1)
Hording of medication	267 (98.9)

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Differential Diagnosis of Aberrant Drug-Taking Attitudes and Behavior

- Addiction
- Pseudo-addiction (inadequate analgesia)
- Other psychiatric diagnosis
  - Encephalopathy
  - Borderline personality disorder
  - Depression
  - Anxiety
- Criminal Intent

(Passik & Portenoy 1996) 45

What is the Risk of Addiction and Aberrant Behavior?

- Boston Collaborative Drug Surveillance Project: Porter and Jick, 1980. *NEJM.*
  - 4 cases of addiction in 11,882 patients with no prior history of abuse who received opioids during inpatient hospitalization
  - NOTE: Many pain docs challenge this study dhw
- Dunbar and Katz, 1996. *JPSM*.
  - 20 patients with ***both*** chronic pain and substance abuse problems on chronic opioid therapy
  - Nine out of 20 abused medication
  - Of the 11 who did not abuse the medications, all were active in recovery programs with good family support

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Spectrum of Risk of Addiction or Aberrant Behavior

LOW
Short-term exposure to opioids in non-addicts
Porter and Jick

HIGH
Long-term exposure to opioids in addicts,
Dunbar and Katz

Where is your patient?

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- Addiction or aberrant behavior results from a combination of
  - Chemical
  - Psychiatric
  - Social/Familial
  - Genetic
  - Spiritual

Influences

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Tailoring The Approach

- The uncomplicated patient: The Nice Little Old Lady
- The patient with co-morbid psychiatric and coping difficulties: “Chemical Copers”
- Addicted patients:
  - The actively abusing
  - The patient in drug free recovery
  - The patient on methadone maintenance

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The Nice Little Old Lady

- Minimal structure required due to lack of co-morbid psychiatric or substance abuse problems, and lack of contact with addiction subculture
- Managed via optimization of opioids and side effect management – ie, routine medical management
- 30 day supplies of meds with liberal rescues, monthly follow-up

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The “Chemical Coper”

- Bears resemblance to addiction with regard to the “centrality” of the drug and drug procurement to the patient
  - Overly drug focused
  - Always on the fringes of appropriate drug taking
  - Not progressing towards goals
- CCs need structure, psych input, and drug treatments that ***decentralize*** the pain medicine to their coping
- Decentralize pain medication: reduce its meaning, undo conditioning, undo socialization – accomplished through pain-related psychotherapy and prudent drug selection

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Outpatient Management of the Chemically Dependent Pain Patient

- Maximally structured approach includes:
  - Frequent visits
  - Limited supply of meds
  - Managed primarily with long-acting opioids with low street value – judicious use of rescues
  - Urine Toxicology
  - Recovery program/psychotherapy

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Chemically Dependent Patient

- "You can't just vote them off the island!"
  - Greg Holmquist, PharmD, Palliative Care Pharmacist

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Summary of 4 A's

- There is a difference between addiction and the complex issues of noncompliance and aberrant behavior during pain management that has been poorly articulated
- The pain population is diverse – the application of opioid therapy to this diverse population requires careful assessment and tailored approaches that recognizes this diversity

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Patient Scams

- Gertrude
- BK right leg amputation
- Just travelling thru
- Needs Dilaudid
- Has her records
- Motel theft scam

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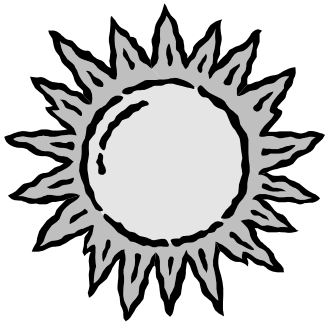
Patient Scams Continued

- "Boy, this burn really smarts!"
- Instant burn maker
  - Dilute liquefied phenol
  - Oven-off!



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The Drywall Hanger

- Gee Doc that Tussionex seems to work great!

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Patient Scams

- I lost my prescription form
- I lost my pills

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Patient Scams, Continued

- The dog ate my pills

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- My cat ate my pills!!!

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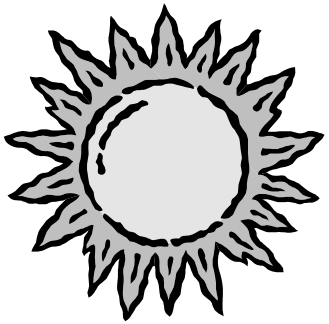
Patient Scams Continued

- "Boy, this burn really smarts!"
- Instant burn maker
  - Dilute liquefied phenol
  - Oven-off!



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Summary

- Discussed concerns of health patients and professionals and system problems
- Discussed the 4 "A's" of pain management
- Discussed various pain mgt.Guidelines
- Discussed how physicians & pharmacists can avoid problems in prescribing & dispensing
- Discussed "patient" drug scams

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What is the question most frequently asked of pharmacists?

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Summary, cont.

- Watch for scams
- Document, document, document
- Keep track of trends in pain management-follow guidelines
- Know the laws & rules
- Don't be afraid to treat the patients who need treatment

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The End

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