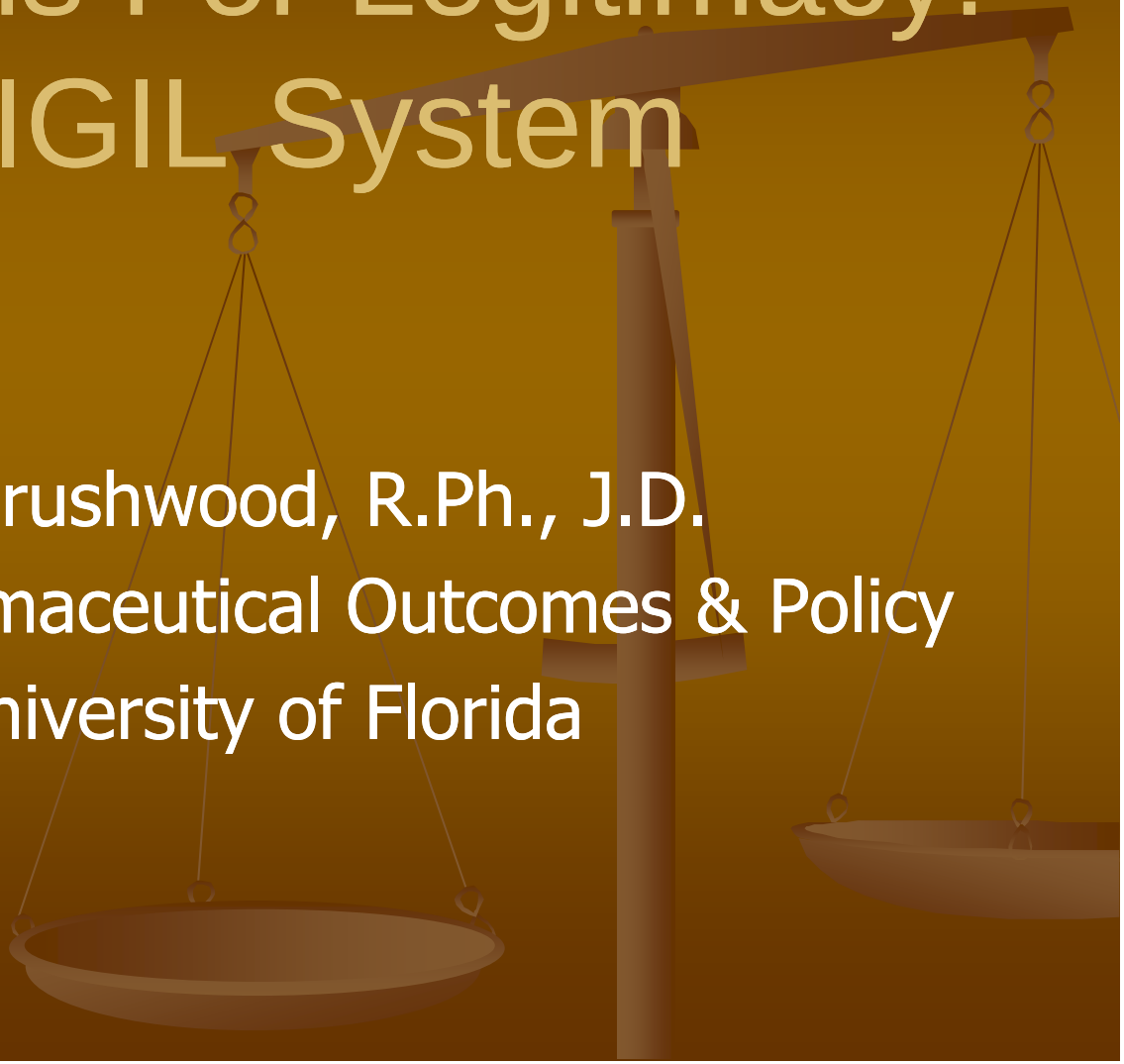
Screening Controlled Substance Prescriptions For Legitimacy: The VIGIL System



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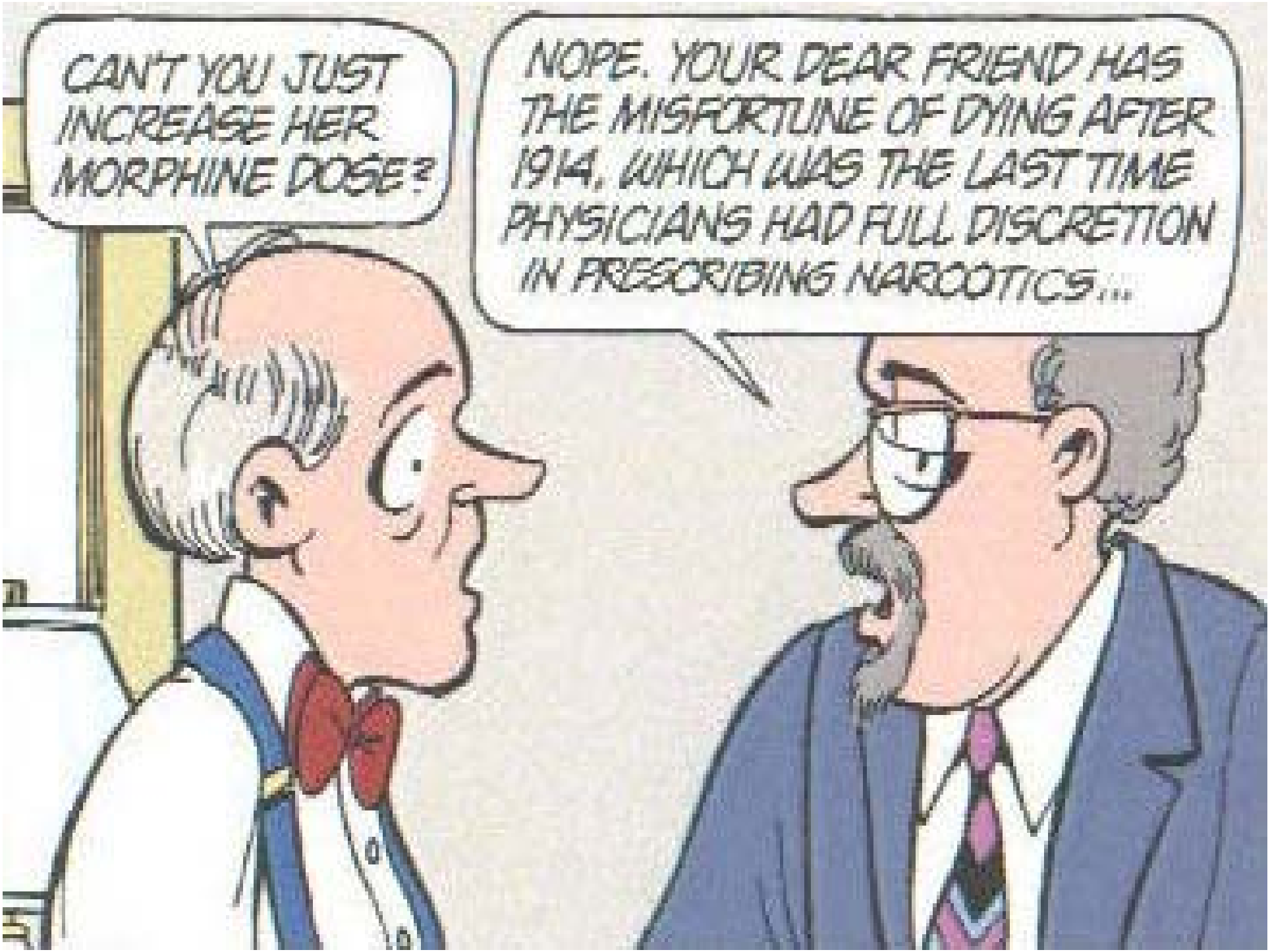
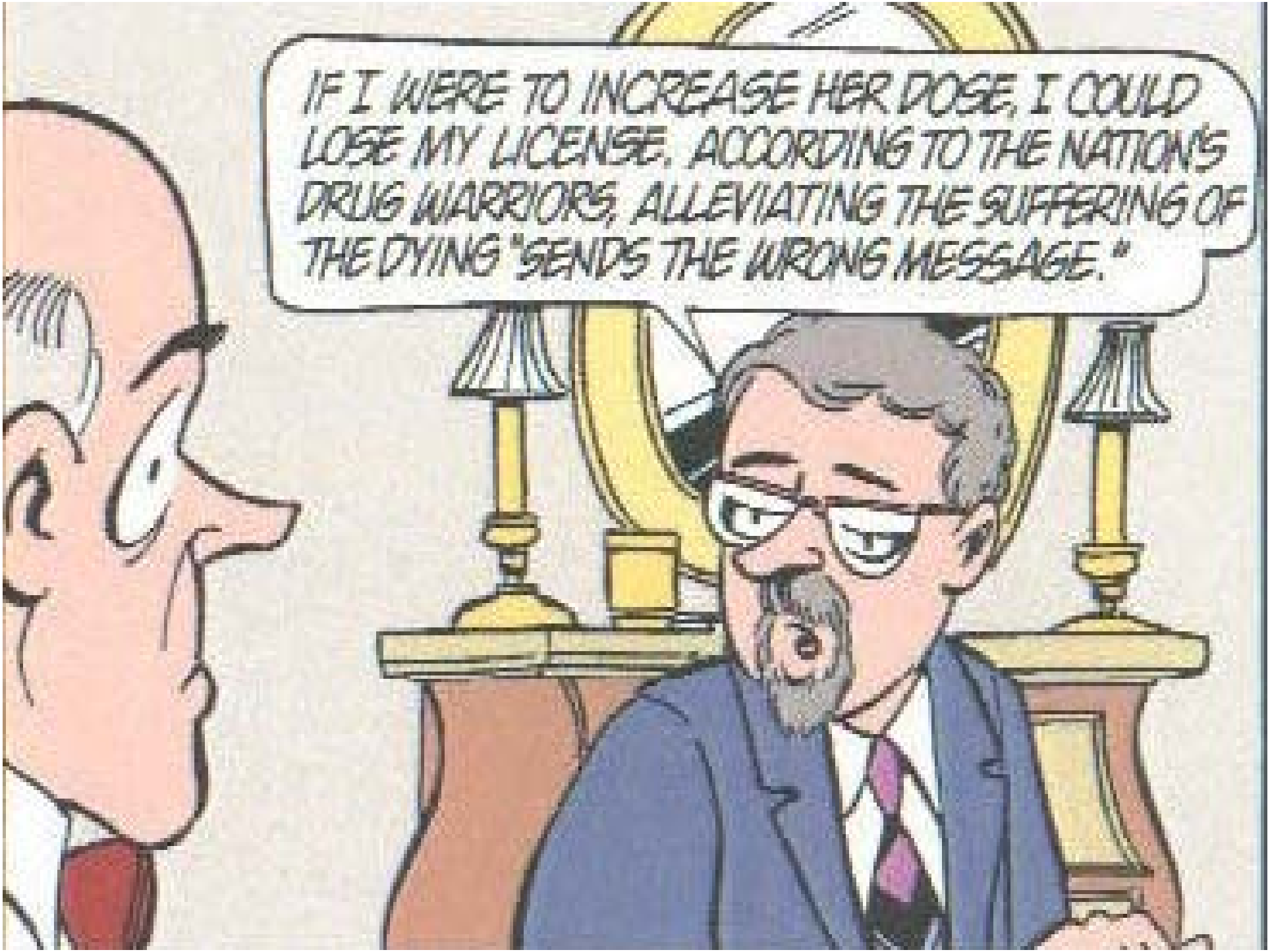
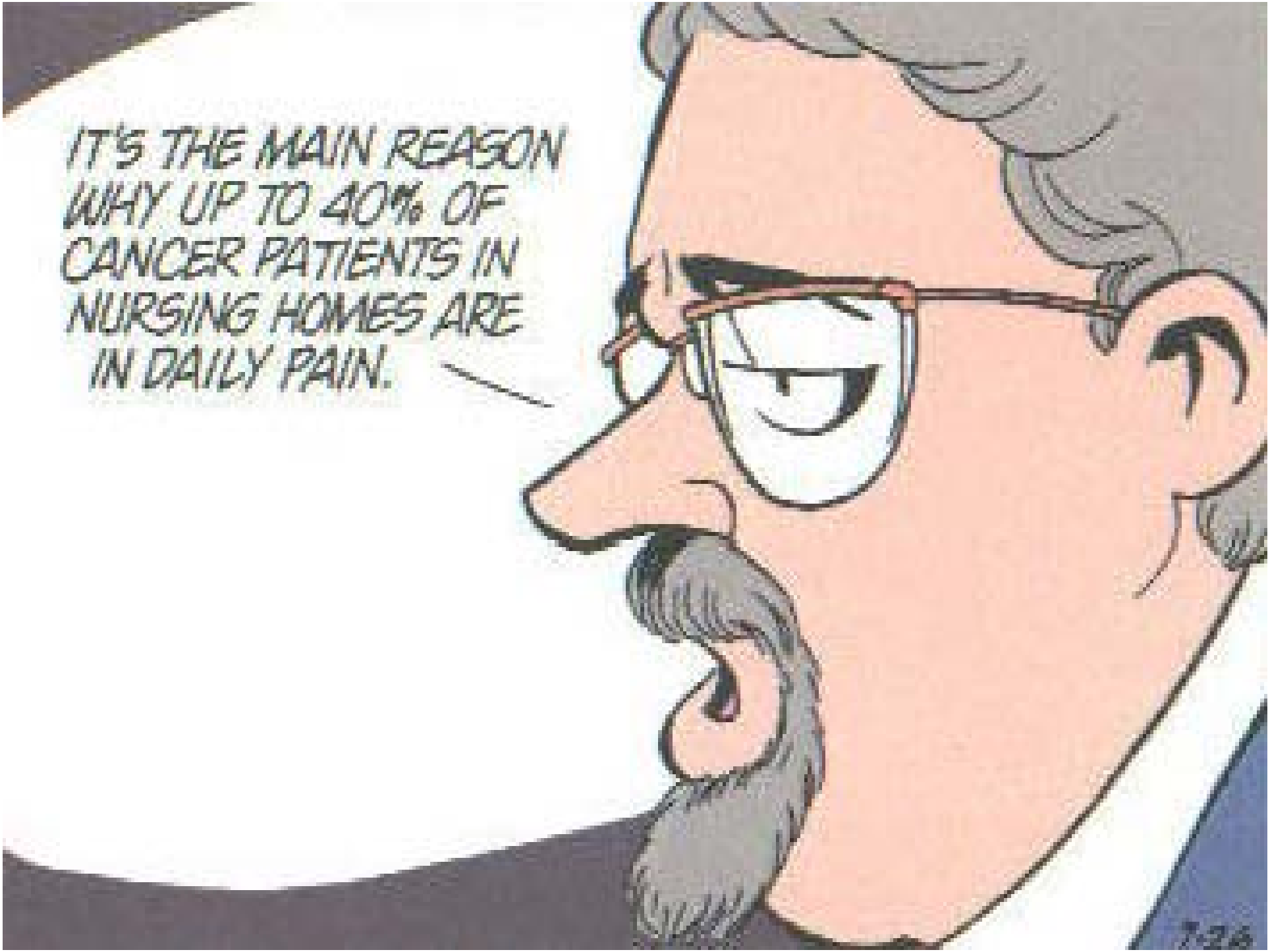
BY

G.B. TRUDEAU


YOU KNOW, DOCTOR, I THINK MRS. DAVENPORT IS STILL IN A LOT OF PAIN...
I KNOW. I WISH THERE WAS MORE I COULD DO...


CAN'T YOU JUST INCREASE HER MORPHINE DOSE?
NOPE. YOUR DEAR FRIEND HAS THE MISFORTUNE OF DYING AFTER 1914, WHICH WAS THE LAST TIME PHYSICIANS HAD FULL DISCRETION IN PRESCRIBING NARCOTICS...


IF I WERE TO INCREASE HER DOSE, I COULD LOSE MY LICENSE. ACCORDING TO THE NATION'S DRUG WARRIORS, ALLEVIATING THE SUFFERING OF THE DYING "SENDS THE WRONG MESSAGE."


IT'S THE MAIN REASON WHY UP TO 40% OF CANCER PATIENTS IN NURSING HOMES ARE IN DAILY PAIN.


OH.

There Is A Storm Brewing

- Patients in pain need their medications and they don't deserve pointless hassles.
- Abuse of Prescription Medications is Increasing.
- Drug Diverters Target Pharmacies.
- The Failure to Prevent Diversion is Costly in Economic and Social terms.
- It is Easy to Confuse Successful Practice With Diversion.
- All Parties Share This Concern.

Definitions
(Federation of State Medical Boards)

- Pain: "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage."
- Chronic Pain: "Chronic pain is a state in which pain persists beyond the usual course of disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years."

The Pharmacist's Dilemma

- The Therapeutic Imperative:

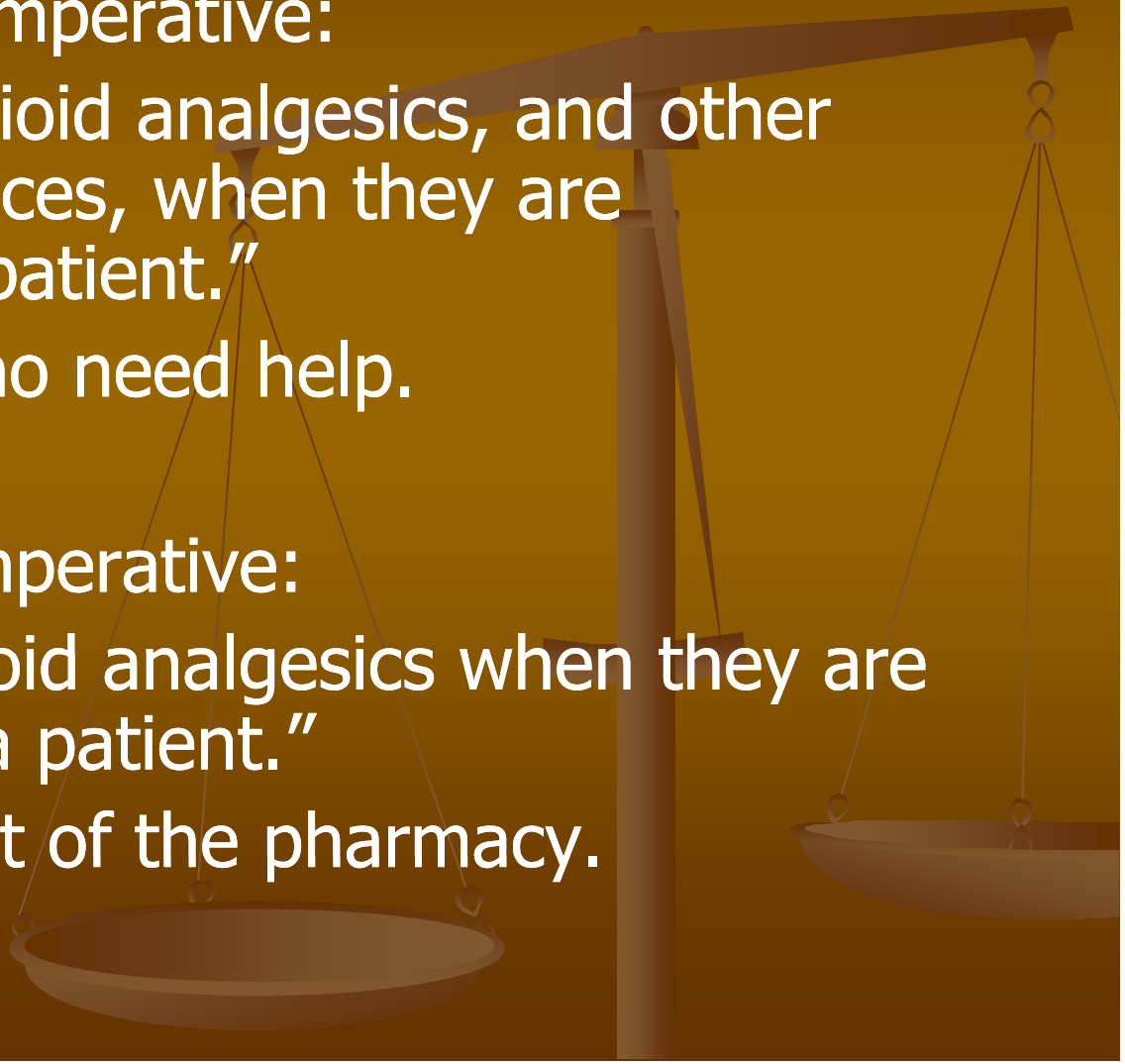
"Always dispense opioid analgesics, and other controlled substances, when they are appropriate for a patient."

Help the patients who need help.

- The Regulatory Imperative:

"Never dispense opioid analgesics when they are inappropriate for a patient."

Push the pushers out of the pharmacy.



Federal Law: Corresponding Responsibility

21 CFR § 1306.04 Purpose of Issue of Prescription

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the law.

The Key To Compliance: VIGIL

- How can pharmacists meet the needs of chronic pain patients and avoid "knowingly" filling purported prescriptions?
- Suggestion: VIGIL
  - Verification
  - Identification
  - Generalization
  - Interpretation
  - Legalization

Good and Bad Decisions

What is our *Dirty Little Secret*?

HCP Activity \ State of the World	Patient Is Legitimate Pain Patient*	Patient NOT Legitimate Pain Patient
Opioids are Prescribed/ Dispensed	Good Decision	Bad Decision
Opioids NOT Prescribed/ Dispensed	Bad Decision	Good Decision

*Assume that opioids are appropriate therapy for the patient.

Bad Decisions Cannot Be Eliminated

HCP Activity \ State of the World	Patient Is Legitimate Pain Patient*	Patient NOT Legitimate Pain Patient
Opioids are Prescribed/ Dispensed	Good Decision	Bad Decision
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Using Balance to Reduce Bad Decisions

HCP Activity \ State of the World	Patient Is Legitimate Pain Patient*	Patient NOT Legitimate Pain Patient
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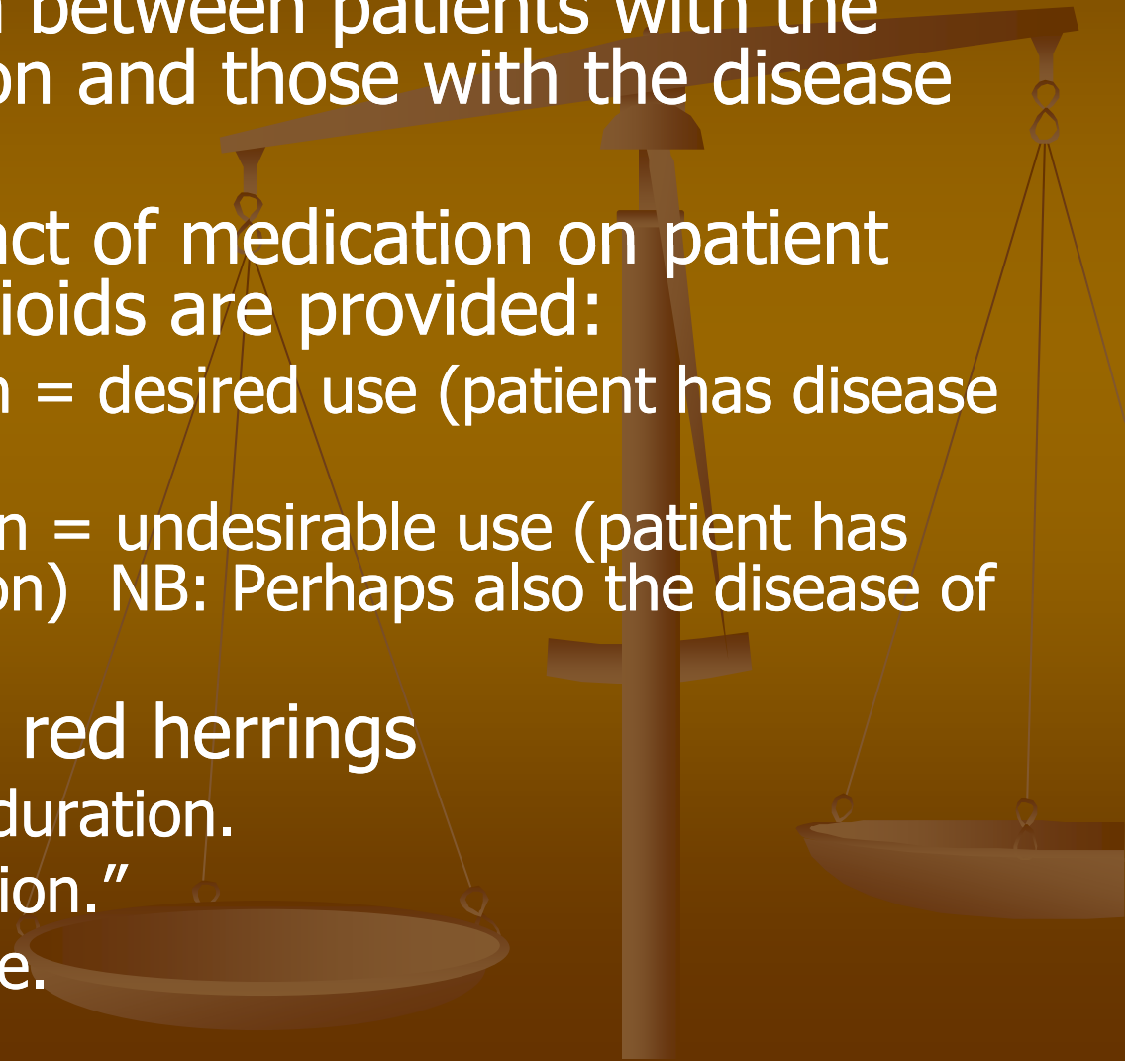
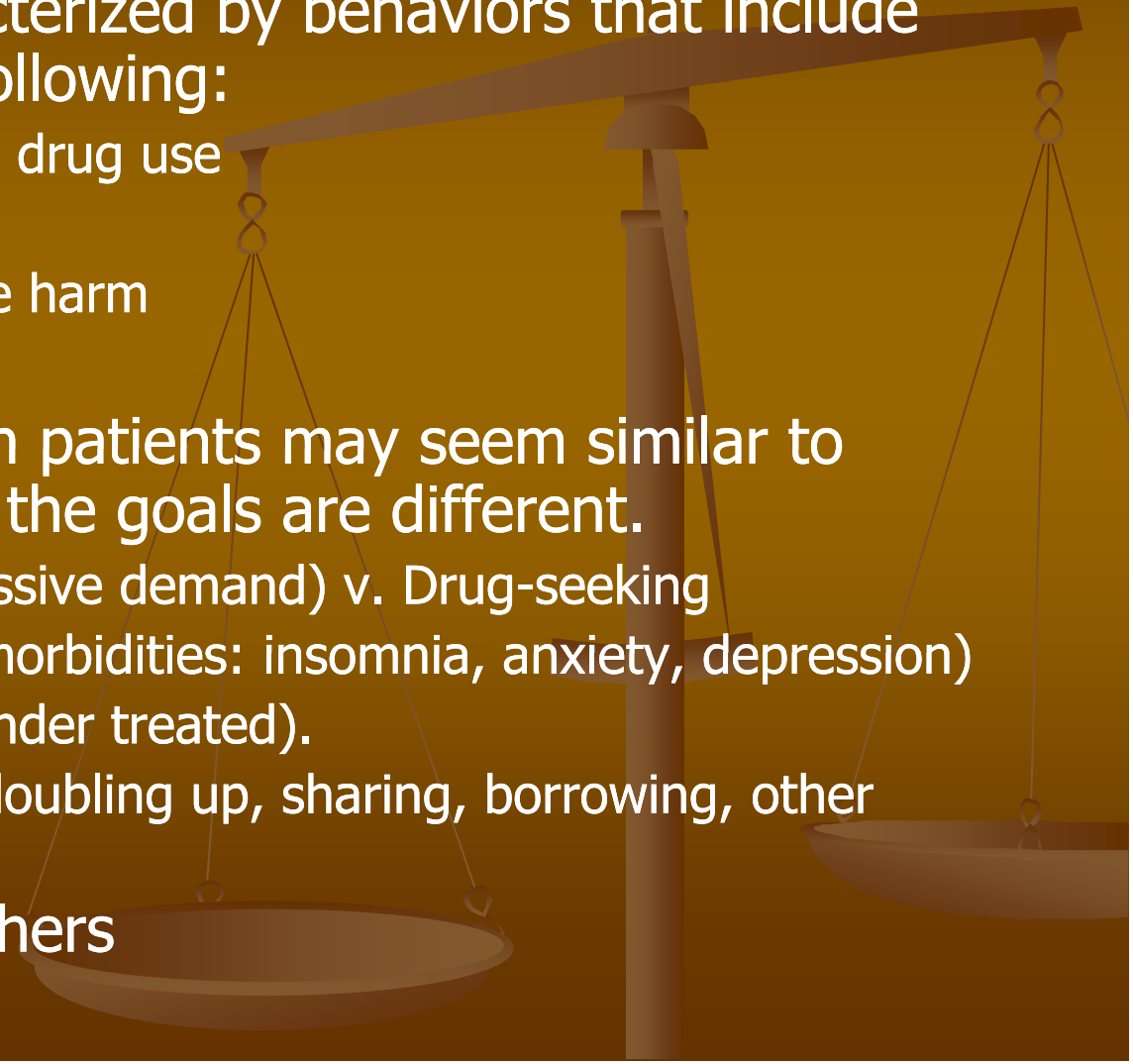
Distinguishing Pain Behaviors From Suspect Behaviors

- There is confusion between patients with the disease of addiction and those with the disease of pain.
- Focus on the impact of medication on patient function, when opioids are provided:
  - Increased function = desired use (patient has disease of pain)
  - Decreased function = undesirable use (patient has disease of addiction) NB: Perhaps also the disease of pain
- We must filter out red herrings
  - Dose, frequency, duration.
  - Physician "reputation."
  - Patient appearance.



Is It Addiction?

- Addiction is … characterized by behaviors that include one or more of the following:
  - Impaired control over drug use
  - Compulsive use
  - Continued use despite harm
  - Craving
- The behaviors of pain patients may seem similar to those of addicts, but the goals are different.
  - Relief-seeking (aggressive demand) v. Drug-seeking
  - "Polypharmacy" (co-morbidities: insomnia, anxiety, depression)
  - Doctor shopping (if under treated).
  - Aberrant behaviors (doubling up, sharing, borrowing, other indication, hoarding).
- Non-Addict Drug Pushers



FSMB Pain Mgt. Policy

- "Addiction" - "a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm." "Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction."

FSMB Pain Mgt. Policy

- "Tolerance" - "the need to increase the dose of opioid to achieve the same level of analgesia." "does not equate with addiction"
- "Physical Dependence" - "physiologic state of neuro-adaptation characterized by emergence of withdrawal syndrome if drug use is stopped or decreased abruptly." "does not equate with addiction."
- "Pseudoaddiction" - "pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management and can be mistaken for addiction"

FSMB Pain Mgt. Policy

- Evaluation
  - complete history and physical exam documented
- Treatment Plan
  - therapeutic goals, further evaluations
- Informed Consent
- Periodic Review
  - reasonable intervals
- Consultation
  - refer if necessary
- Medical Records
  - complete and accurate
- Compliance with Controlled Substance Laws

The Ambiguity of "Red Flags"

"Flag"	Regulators	Pharmacist
Pts. Come from miles away	Pill Shop	Specialty practice
Multiple symptoms treated	Polypharmacy	Holistic care
High Doses	No medical need Lethal	Individualized care
Pt. Asks for drugs by name	Addiction	Pt. accepting responsibility
Returns too early	Dealing	Crisis

DEA Pharmacist's Manual
Pharmacist's Guide to Prescription Fraud

"Characteristics of Forged Prescriptions"

"1. Prescription looks "too good"; the prescriber's handwriting is too legible."

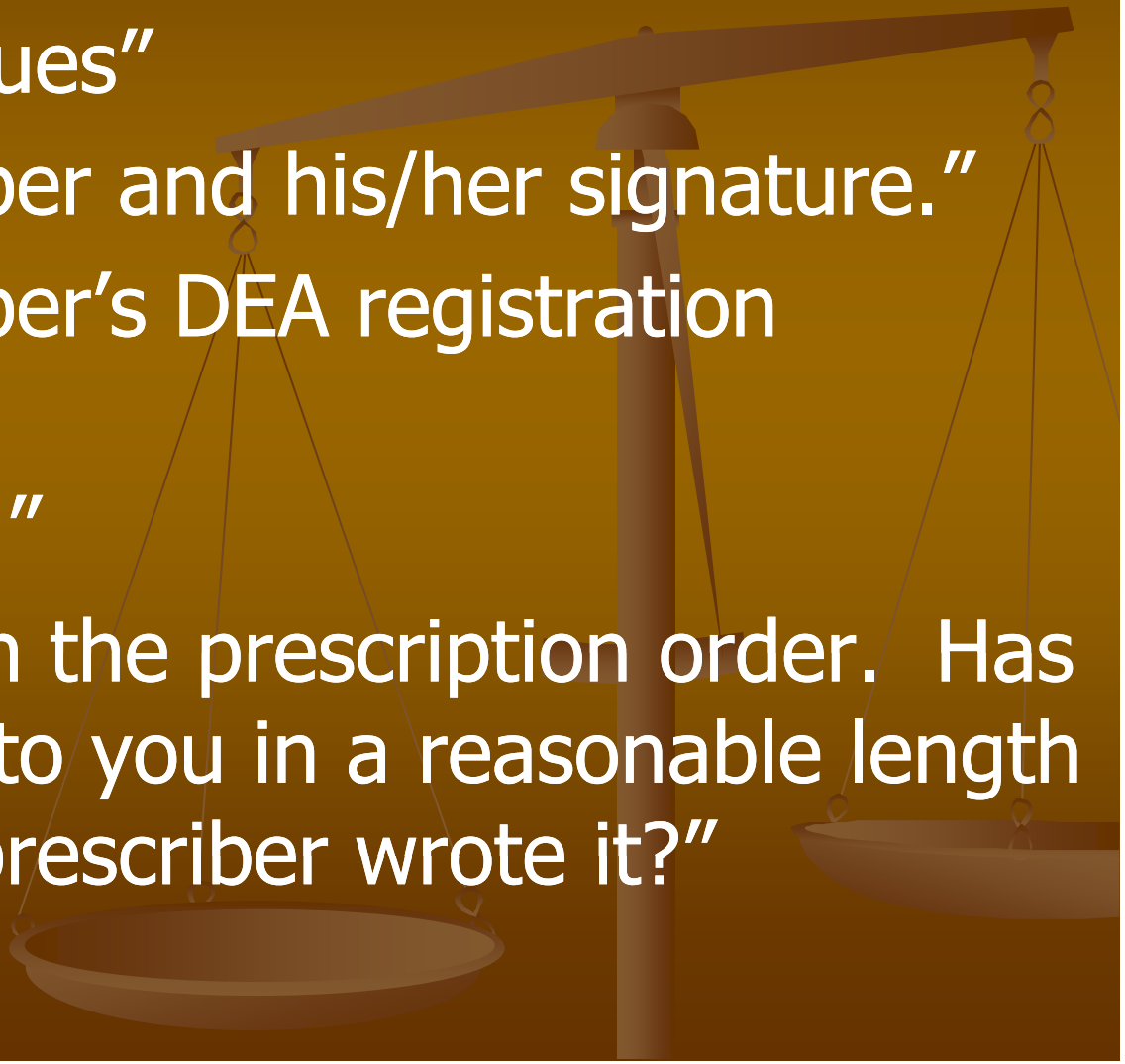
"2. Quantities, directions or dosages differ from usual medical usage."

"3. Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations."

"4. Prescription appears to be photocopied."

"5. Directions written in full with no abbreviations."

DEA Pharmacist's Manual
Pharmacist's Guide to Prescription Fraud



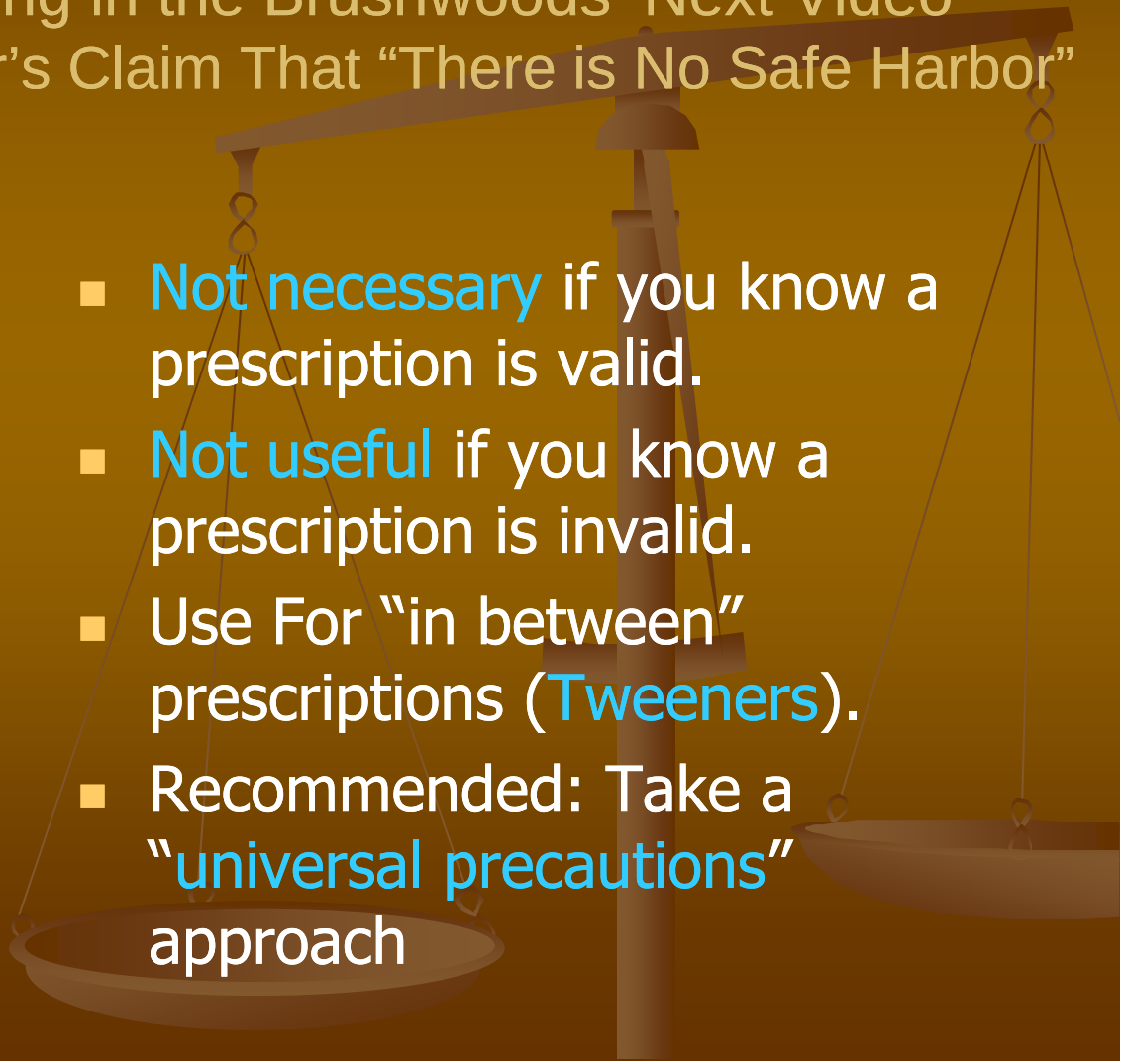
"Prevention Techniques"

- "Know the prescriber and his/her signature."
- "Know the prescriber's DEA registration number."
- "Know the patient."
- "Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?"

The VIGIL Process
Preventing the "Battle of Your Town"

or "How to Avoid Starring in the Brushwoods' Next Video"
or Responding to Dr. Fisher's Claim That "There is No Safe Harbor"

Verification
Identification
Generalization
Interpretation
Legalization



- Not necessary if you know a prescription is valid.
- Not useful if you know a prescription is invalid.
- Use For "in between" prescriptions (Tweeners).
- Recommended: Take a "universal precautions" approach

Verification

- Answers the question: "Is this a responsible opioid user?"
- Talk with the patient.
- Do not fill C-II opioid or hydrocodone/acetaminophen for the first time without verifying with the prescriber.
- Find out the purpose ("legitimate medical purpose") of the medication (not the diagnosis), *if you can*.
- Alternative to calling prescriber is a trusted colleague who may vouch for the patient.
- May provide partial supply if "unable to supply" full quantity due to inability to verify. 72 hours for balance.
- Responsibility continues over time. Call for verification if questions arise. Fax back thanks, and keep fax.

Identification

- Answers the question: "Do I know for sure who this person is?"
- Require government issued photo ID of anyone picking up Rx for C-II opioids or hydrocodone/acetaminophen.
- This includes patient or family member.
- Photocopy ID or write down information.
- Reasonable substitute is ok if circumstances warrant.

Generalization

- Answers the question: "Do we agree on mutual responsibilities and expectations?"
- I am your pharmacist and I agree to promptly and respectfully provide medications and services if rules are met.
- Possible rules (but you decide what fits):
  - Keep all controlled substances under lock & key.
  - No sharing drugs with anyone.
  - If more than 20% too early, call prescriber.
  - Rxs for new drugs during prescriber business hours.
  - No emergency "refills" when there is no emergency.
  - It is your responsibility to know when you will run out.
  - Your choice, but use only one pharmacy for CS drugs.
- Put this in writing if necessary.

Interpretation

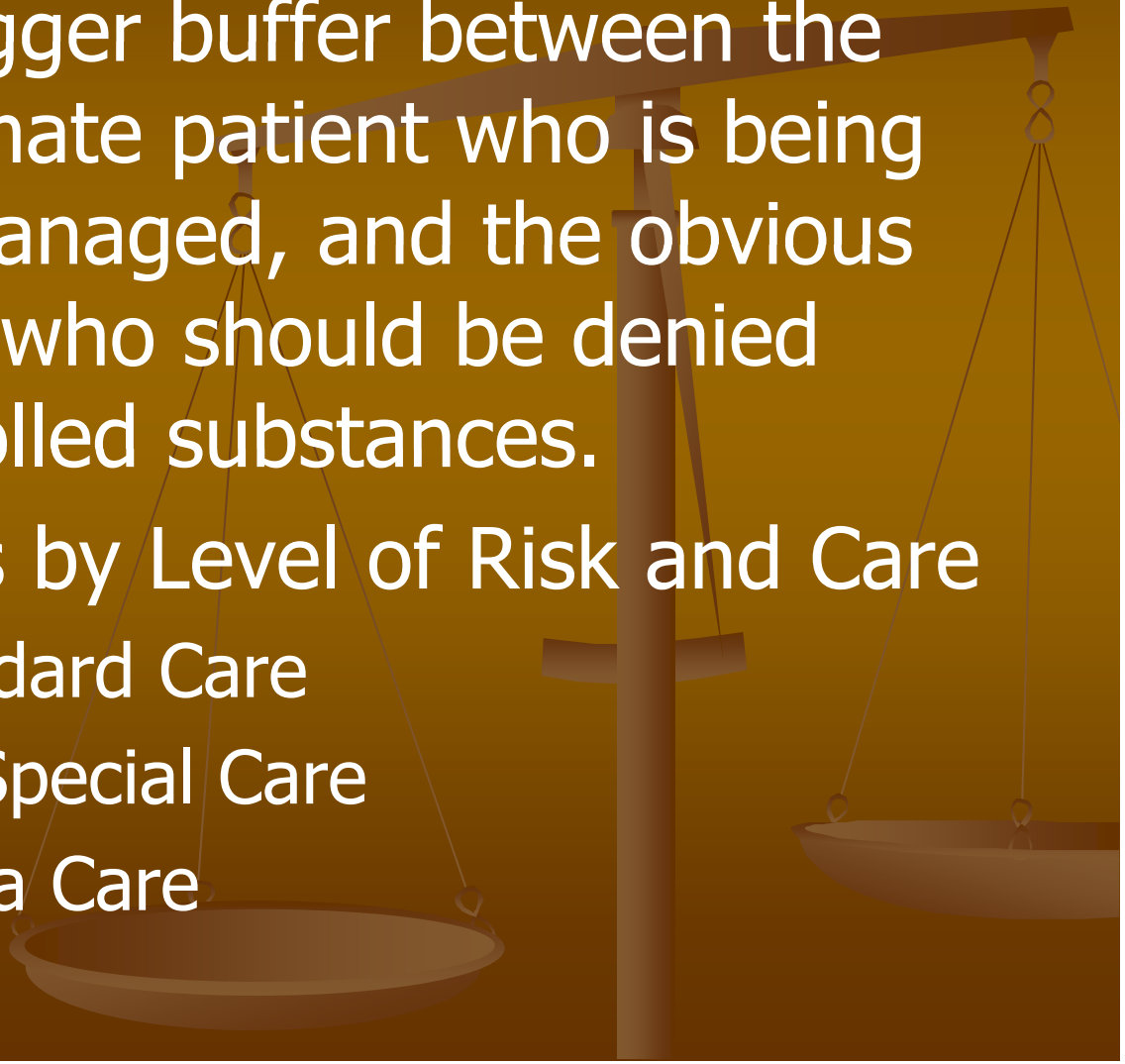
- Answers the question: "Do I now feel comfortable allowing this person to have controlled substances?"
- Contact another pharmacist for support with "hypothetical question." No names of anyone.
- Use brief questionnaire to predict misuse or abuse by patient (on Internet).
  - Opioid Risk Tool (ORT)
  - Screener and Opioid Assessment for Patients in Pain (SOAPP)
- Obtain family or friend participation and feedback regarding success of therapy based on patient functioning.

Legalization

- Answers the question: "How can I stay squeaky clean in meeting my legal requirements?"
- Follow state and federal laws for CS, with NO exceptions.
- Conduct a medication history for all chronic pain patients.
- Perform Drug Use Review for all opioid analgesic prescriptions.
- Provide patient education to all chronic pain patients.
- Document what you have done—but with care.

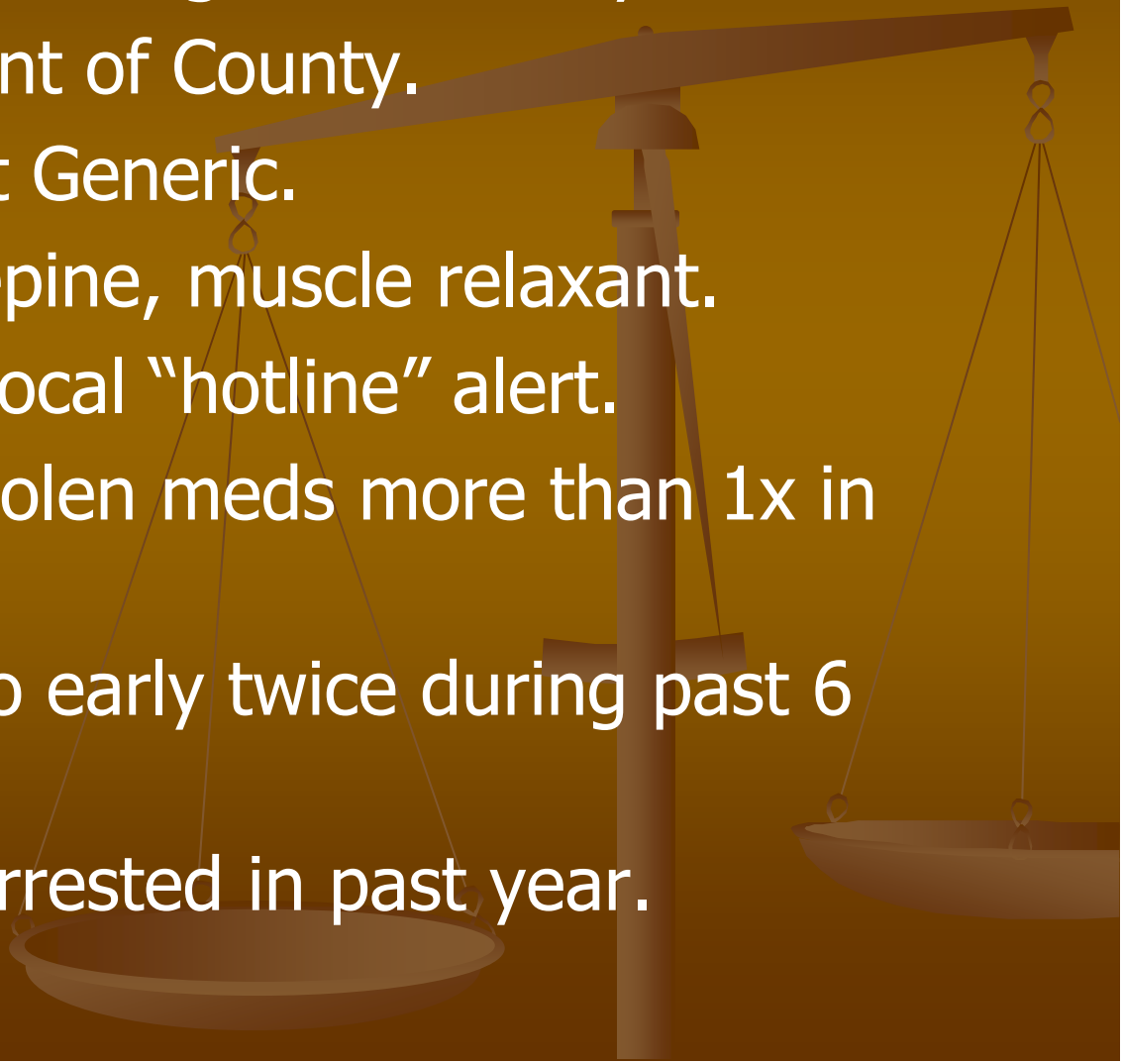
Implementing VIGIL in Pharmacy

- Goal: Build a bigger buffer between the obviously legitimate patient who is being appropriately managed, and the obvious diverter/abuser who should be denied access to controlled substances.
- Classify Patients by Level of Risk and Care
  - Low Risk—Standard Care
  - Medium Risk—Special Care
  - High Risk—Extra Care



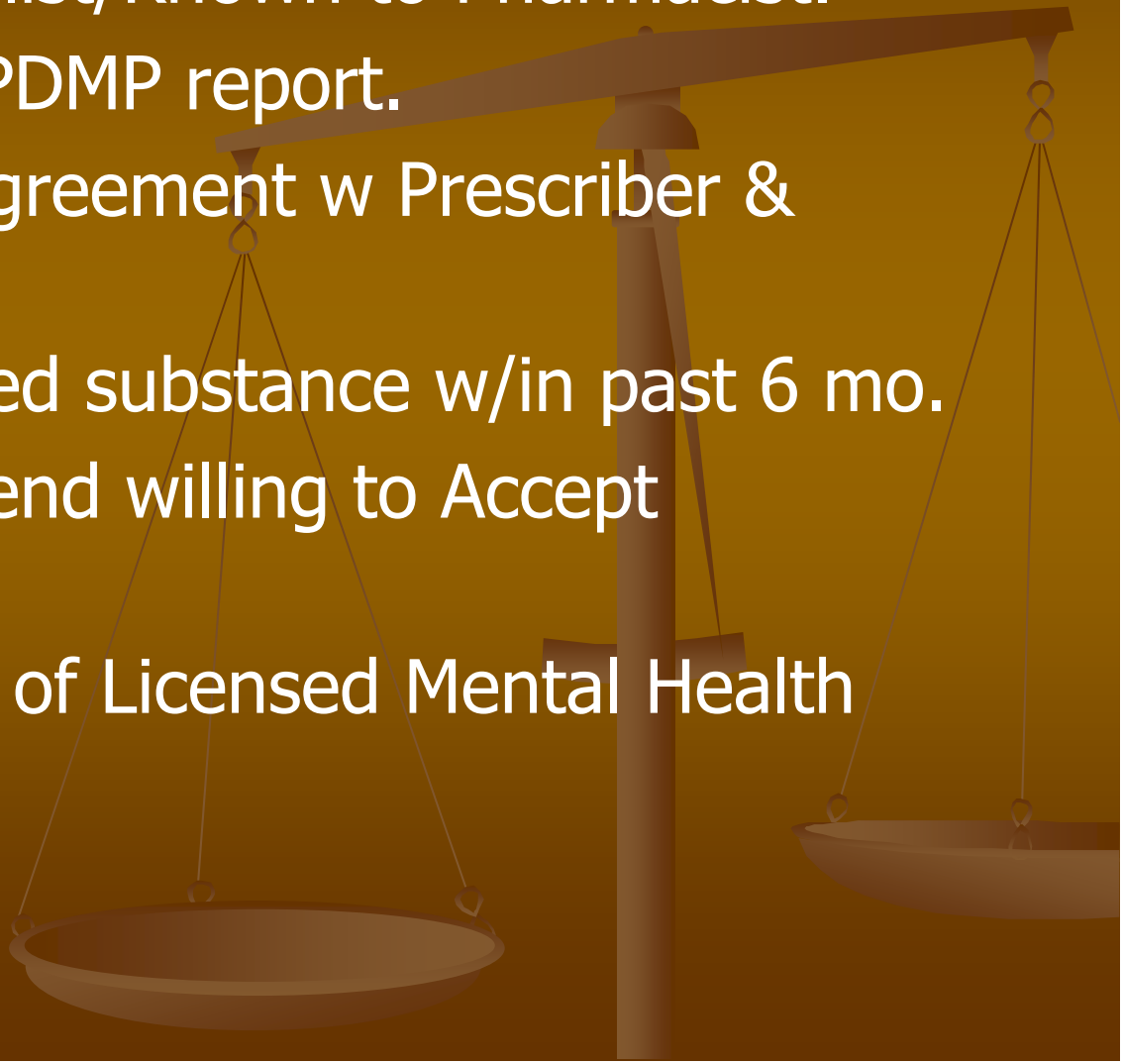
Negative Factors for Classification

- Patient pays cash although covered by Medicaid.
- Not a Legal Resident of County.
- Unwilling to Accept Generic.
- Opioid, benzodiazepine, muscle relaxant.
- Patient subject of local “hotline” alert.
- Report of lost or stolen meds more than 1x in past 6 mo.
- More than 20% too early twice during past 6 mo.
- Patient has been arrested in past year.



Positive Factors for Classification

- Prescriber is Specialist/Known to Pharmacist.
- Non-problematic ePDMP report.
- Written Med Use Agreement w Prescriber & Patient.
- Rx for non-controlled substance w/in past 6 mo.
- Family Member/Friend willing to Accept Responsibility.
- Patient Under Care of Licensed Mental Health Professional.



Managing Risk and Care

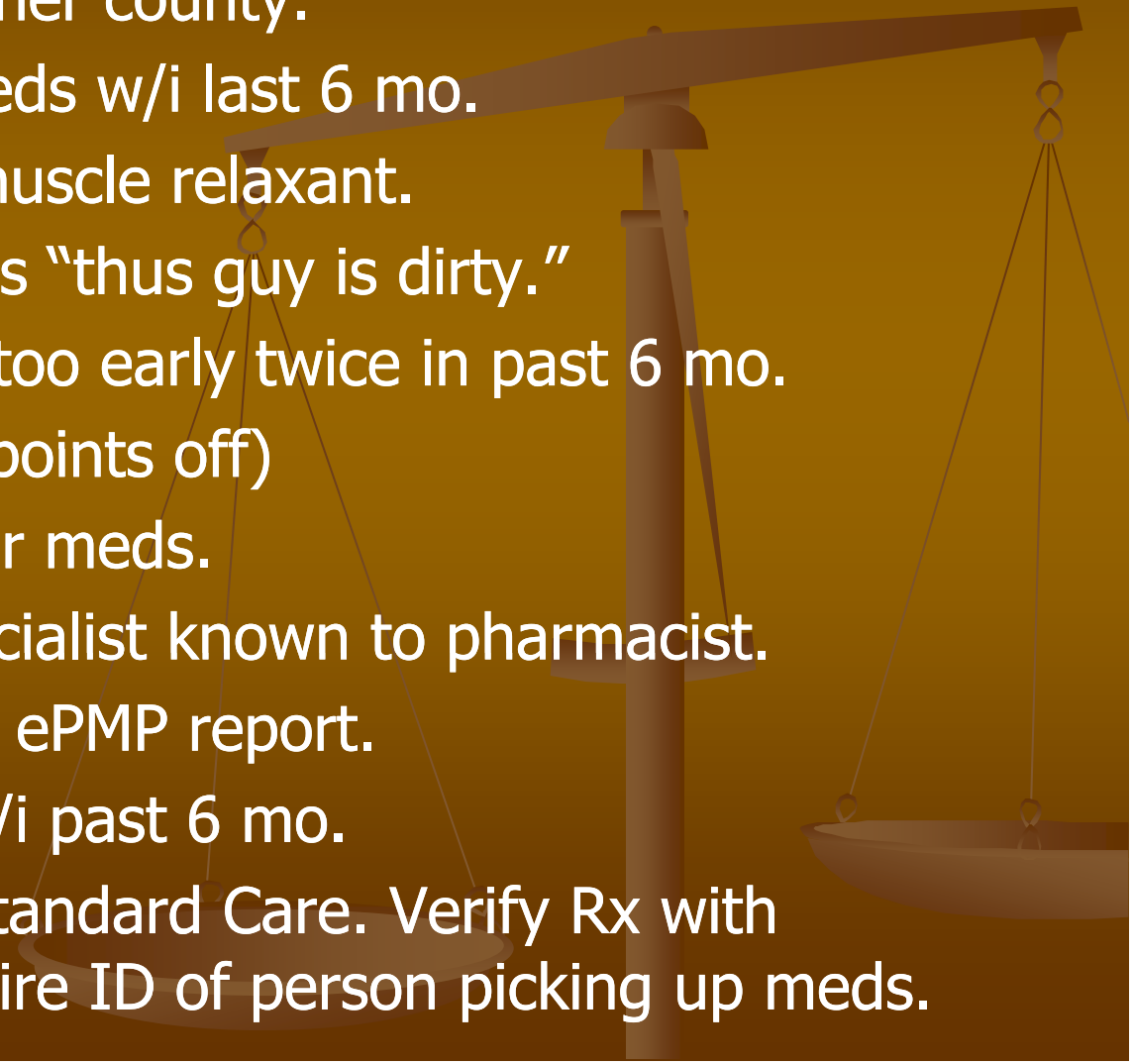
Score (Example)	Risk	Care Level	Approach
0-4	Low	Standard	Verify, ID
5-9	Medium	Special	Limited Days Supply (7, 14, 28)
10+	High	Extra	Medical Records (HIPAA Release)

Hypothetical Patient A

- Negative Factors (10 points)
  - Resident of another county.
  - Pays cash for $700.00 prescription.
  - Insists on brand name products.
  - Reported lost meds w/i last 6 mo.
  - Opioid, benzo, muscle relaxant.
- Positive Factors (0 points off)
  - None
- Result: High Risk; Extra Care; Limit Quantity & Review Med Records.

Hypothetical Patient B

- Negative Factors (10 points)
  - Resident of another county.
  - Reported lost meds w/i last 6 mo.
  - Opioid, benzo, muscle relaxant.
  - Local hotline says “thus guy is dirty.”
  - More than 20% too early twice in past 6 mo.
- Positive Factors (8 points off)
  - Medicaid pays for meds.
  - Prescriber is specialist known to pharmacist.
  - Non-problematic ePMP report.
  - Rx for non-CS w/i past 6 mo.
- Result: Low Risk. Standard Care. Verify Rx with prescriber and require ID of person picking up meds.



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