

Pill Mill Litigation



Kay Van Wey
Dallas, Texas



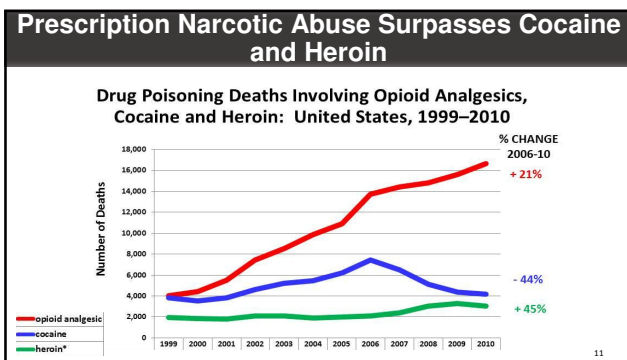
Scope of the Problem

We Are in The
Midst Of A
Prescription
Painkiller Overdose
Epidemic.



How Many People Do You Think Die Each Year Of Prescription Drug Overdoses?	• 100,000
How Many People Are Admitted To The ER for Prescription Drug Overdoses?	• 17,000 per year
Since 1999, The Amount Of Prescription Painkillers Prescribed And Sold In The U.S. Has Nearly.	• Quadrupled
True or False: The Amount Of Pain That Americans Are Reporting Has Quadrupled Since 1999?	• FALSE - The amount of prescription painkillers prescribed has nearly quadrupled.
What Are The Most Widely Abused Drugs Today?	• Cocaine, Heroin, Meth, Crack, Opioid Analgesics
Which Country In The World Consumes The Most Painkillers?	• Sweden, France, Japan, United States , Holland
What is the cost of the problem?	<ul style="list-style-type: none"> • The non-medical use \$72.5 billion • Workplace costs \$25 billion • Criminal justice costs \$5 billion





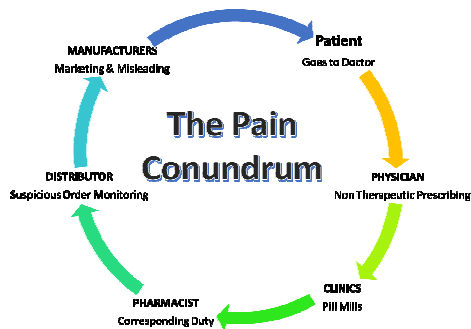
Who is at fault for causing the problem?

Are Junkies or Accidental Addicts to Blame?



13

The Pain Conundrum



14

Who is at Risk?



- History of alcohol or substance abuse (personal or family)
- Co-existing mental illness or cognitive impairment

15

Drug Seeking Patients



- **Patients** – should be honest
- **Doctor** – must screen and inform
- **Drug** – deprives patient of free will

16

Prescription Opioid Abuse: A First Step to Heroin Use?

- Opioids have effects similar to heroin when taken in doses or in ways other than prescribed
- Nearly half of young people who inject heroin reported abusing prescription opioids before starting to use heroin
- Some individuals reported taking up heroin because it is cheaper and easier to obtain than prescription opioids
- Many report that crushing prescription opioid pills to snort or inject the powder provided their initiation into these methods of drug administration
- OxyContin earned the name "hillbilly heroin."

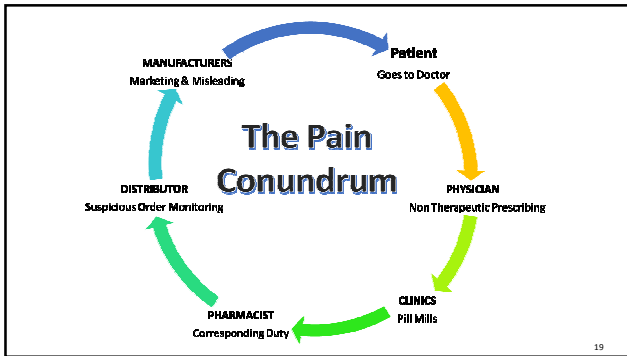


17

Are Doctors Part Of The Problem?




18



Two Types of Doctors

Criminals –

- Intent to deal drugs for profit



Stephen and Linda Schneider

Negligent Doctors -

- Could be an impaired physician
- Has a drug or alcohol problem, mental illness, financial problems, marital problems.
- Practices below the Standard of Care
- Improper boundaries- unable to say NO
- Truly naïve (few and far between)

Chronic Intractable Pain Treatment Act - It is ILLEGAL to prescribe opioids for intractable pain without a legitimate medical purpose if knew or should have known patient not seeking for legitimate medical purpose.

20

Duty of a Physician

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

PART 1306 — PRESCRIPTIONS

GENERAL INFORMATION

§1306.04 Purpose of issue of prescription.

- Must determine that a legitimate medical purpose exist
- Must be acting in the “usual course of professional practice”
- Must take reasonable measures to prevent diversion

21

Texas Controlled Substances Act



- A practitioner may not prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioners direction and supervision except for a valid medical purpose and in the course of medical practice.

22

Federal and State Laws – Common Theme



- A valid physician-patient relationship must exist.
- The prescription must be issued for a valid medical need.
- The prescription must be therapeutic for the patient's condition.
- The physician and the pharmacists have a corresponding responsibility to determine the prescription is valid.

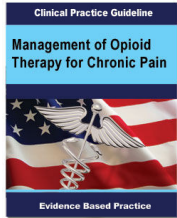
23

Administrative Regulations

NEWLY ADOPTED GUIDELINES...SECTION 170....

24

Clinical Guidelines



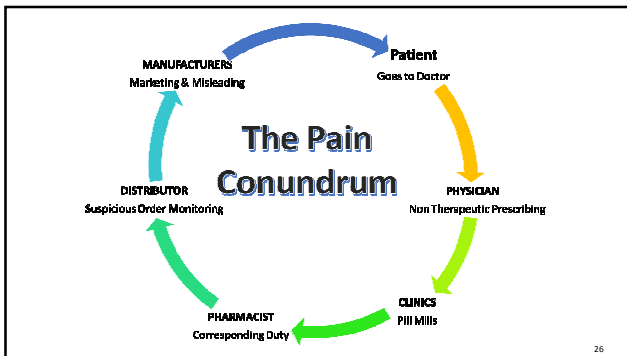
Recommendations

1.1 Prior to initiating COT, clinicians should conduct a history, physical examination and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction.

1.2 Clinicians may consider a trial of COT as an option if CNCP is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms.

1.3 A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing, should be performed and documented prior to and on an ongoing basis during COT.

25



26

Can You Spot the Pill Mill?



Pill Mill



Pill Mill

How Can You Tell The Difference Between A Pill Mill And A Legitimate Medical Clinic?



- Huge crowds of people waiting to see the doctor
- Cash only
- Sketchy medical records
- Patients mostly seen by PA's, NP's or foreign medical graduates not licensed in U.S.
- No medical equipment.
- No diagnostic work up
- Disproportionately high number of patients receiving opioids.
- High quantities of drugs prescribed. For example, 120 Lortab, 60 xanax, 60 soma.
- High quantities of known drugs of abuse prescribed.

THE LAW RELATING TO PILL MILL CLINICS

- Must review at least 33% of the patient files
- A physician with an unrestricted Texas medical license must physically be in the clinic at least 33 % of the clinic's operating hours.
- Must not have been disciplined for inappropriately prescribing, dispensing, administering, supplying or selling a controlled substance.
- The law only applies to clinics that issue prescriptions for opioids, benzodiazepines, barbiturates or carisoprodol monthly for at least 50% of their patients.
- Hospices, hospitals not included. Others exempt, such as surgeons who prescribe pain killer to probably 100% of their patients or oncologists.
- Suboxone not included.



29

BUT, Is the law Being Enforced???



PHARMACISTS

Pharmacists' Responsibilities when Dispensing Controlled Substance Prescriptions



32

Federal Law



CFR 1306.04(a)

- 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.

33



- control a controlled substance in the practice.

34

[illegible]

“Red Flags” Check List

Texas State Board of Pharmacy
 “Red Flags” Check List for Prescribers
 YOU MIGHT BE A PILL MILL IF...

Check all that apply:

Your pharmacy fills prescriptions for controlled substances who frequently write identical prescriptions for numerous people, indicating a lack of individualized dosing. Long lines are common at your pharmacy with most people presenting prescriptions for controlled substances. Multiple people arrive at the pharmacy in the same vehicle, or one person is picking up prescriptions for multiple people. People receive the same controlled substances from multiple prescribers. Multiple people with the same address present prescriptions from the same prescriber. People often seek early refills. You only advise on the prescriber's representation that prescriptions are legitimate. You feel compelled to hire “security” to prevent problems. People pay with cash or credit card more often than through insurance. Your pharmacy charges and people are willing to pay more for controlled substances than they would at nearby pharmacies. People comment about the price of the drugs on the street, refer to the drugs by their “street names”, or ask for a specific colored pill or tablet. Multiple people, particularly those who are not regular patients, bring in prescriptions for controlled substances from the same prescriber. Drugs presented are inconsistent with the prescriber's area of practice (e.g., fentanyl from a dentist). The prescriber of the drugs is located a significant distance from your pharmacy.

[illegible]

WHOLESALE DISTRIBUTORS

ANTI-DIVERSION SYSTEMS- SUSPICIOUS ORDER MONITORING PROGRAM

CODE OF FEDERAL
REGULATIONS

21

Part 1301 to 1304
Revised as of April 1, 2005
Food and Drugs

Controlled Substances – 21 CFR 1301.74(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

38

Suspicious Order Monitoring Program 5 Key Elements

- Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency
- Statistically based model Defensible SOM Model
- Determine legitimacy of existing and potential new customers (customers and customer's customers) Appropriate Due Diligence and "Know Your Customer" Activities
- Dispensing Monitoring System
- Questionnaires
- On-site
- Red Flags Appropriate Review and/or Investigations of Pended Orders
- Procedures to identify investigative process, process to clear orders, DEA reporting, closing accounts, etc. Clear, Comprehensive SOM SOPs
- Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse Management Support and Employee Training

39

DEA - Enforcement

- **Cardinal Health** – Civil Fine \$34 million for distributing more than 8 million units of hydrocodone
- **Amerisource Bergan** – Accused of distributing 3.8 million doses of hydrocodone products to rogue internet pharmacies
- **Masters Pharmaceuticals** – paid \$500,000 to settle charges



40

MANUFACTURERS

In Guilty Plea, OxyContin Maker to Pay \$600 Million



From left, Kenneth D. Cohen, the top lawyer for Purdue Pharma, Dr. Philip D. Goldstein, the company's former medical director, and Matthew Friedman, Purdue's president.



In 2007, the company and three of its top executives pled guilty in federal court to criminal charges that they misled regulators, doctors and patients about the drug's risk of addiction and its potential to be abused.

The company paid \$600 million in fines and the President, CEO and General Counsel paid a combined \$34.5 million.

42

Where is the FDA Coming From?

U.S. Food and Drug Administration
Protecting and Promoting Your Health

FDA NEWS RELEASE
For Immediate Release: Feb. 10, 2014
Media Inquiries: Media@FDA.gov, 202-205-2091
Email: Media@FDA.gov
Consumer Inquiries: 800-338-2222

Is a New Pain Pill's Approval 'Genuinely Frightening'?
<http://www.fda.gov/oc/ohrt/2014/02/10/20140210.htm>

FDA announced safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics.
New label warning to include reminder about additional conditions.
The U.S. Food and Drug Administration today announced changes to safety labeling changes and new postmarket study requirements for all extended-release and long-acting (ER/LA) opioid analgesics marketed for pain.

The FDA is working to address its unique safety labeling challenges and communicate important information to patients, clinicians, and the public. The agency is working to ensure that patients are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use. The agency is also working to ensure that clinicians are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use. The agency is also working to ensure that the public is aware of the risks of ER/LA opioid analgesics and is able to make informed decisions about their use.

The updated label includes information about the risks of ER/LA opioid analgesics, including the risk of addiction, abuse, and misuse. The updated label also includes information about the risks of ER/LA opioid analgesics, including the risk of addiction, abuse, and misuse. The updated label also includes information about the risks of ER/LA opioid analgesics, including the risk of addiction, abuse, and misuse.

The FDA's primary goal for this labeling procedure is to ensure that patients are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use. The FDA's primary goal for this labeling procedure is to ensure that patients are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use. The FDA's primary goal for this labeling procedure is to ensure that patients are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use.



New pain pill's approval: 'Genuinely frightening'

By Stephanie Smith, CNN
Updated 5:17 PM ET, Wed February 26, 2014



Story Highlights

- ER/LA opioid analgesics are used to treat chronic pain.
- The FDA is working to address its unique safety labeling challenges and communicate important information to patients, clinicians, and the public.
- The agency is working to ensure that patients are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use.
- The agency is also working to ensure that clinicians are aware of the risks of ER/LA opioid analgesics and are able to make informed decisions about their use.
- The agency is also working to ensure that the public is aware of the risks of ER/LA opioid analgesics and is able to make informed decisions about their use.

Marketing Practices May Encourage Diversion By Distributors

- Chargebacks- distributor pays full price, but gets a kickback when the drug is sold..... A typical manufacturer transfers hundreds of millions of chargeback payments annually.
- Additional fees to distributors for "detailing" a product on sales calls to customers
- Additional fees for increasing a manufacturer's market share within a designated geographic area or customer segment.

Failure to Warn



