

Pill Mill Litigation



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Scope of the Problem

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





The Dallas Morning News | Dallas.com

The changing war on drugs

Michael Botticelli explains the focus on misuse of prescription medication

Michael Botticelli, director of the White House Office of National Drug Control Policy, is reorienting the focus of the U.S. "war on drugs" to make Americans more aware of the dangers posed by domestic prescription drug abuse, as opposed to international illicit drug trafficking. He shared his perspectives with Points during a recent visit to Dallas.

POINT PERSON

What are you seeing in the drug market? We're seeing a shift in the focus of the war on drugs. It used to be about international trafficking, but now it's about domestic prescription drug abuse. We're seeing a lot of people who are addicted to painkillers and other prescription drugs. This is a public health crisis that we need to address.

How do you see the future of the drug market? I think we're going to see a continued focus on prescription drug abuse. We need to do more to educate the public about the dangers of these drugs and to provide better pain management options for patients who need them.

The Dallas Morning News

Sunday, July 5, 2015



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The Dallas Morning News | Dallas.com

The changing war on drugs

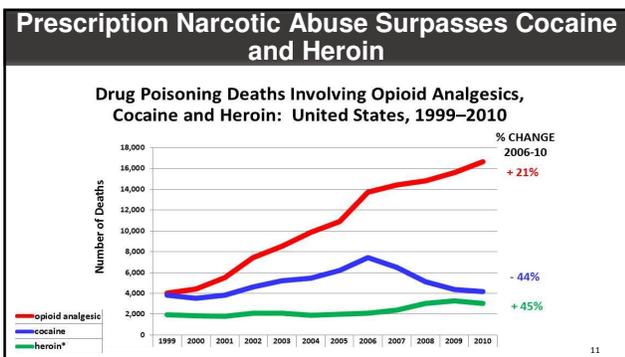
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The Dallas Morning News

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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





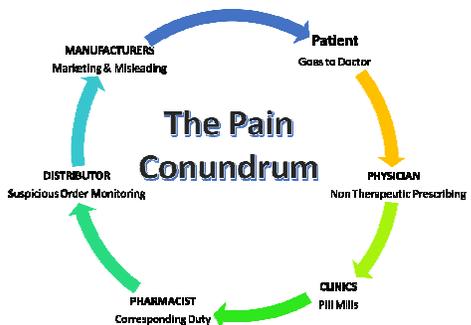
Who is at fault for causing the problem?

Are Junkies or Accidental Addicts to Blame?



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The Pain Conundrum



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Who is at Risk?



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

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Drug Seeking Patients



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

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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."

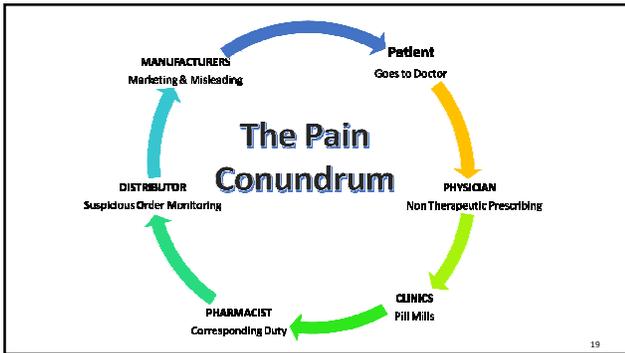


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Are Doctors Part Of The Problem?



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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.

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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

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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.**

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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.

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Administrative Regulations

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

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Clinical Guidelines



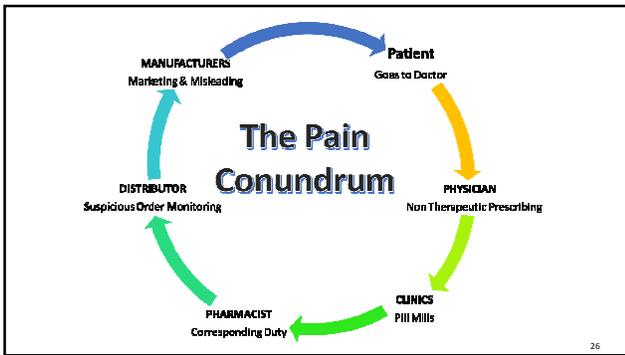
Recommendations

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.

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Can You Spot the 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.



BUT, Is the law Being Enforced???



PHARMACISTS

Pharmacists' Responsibilities when Dispensing Controlled Substance Prescriptions



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Federal Law

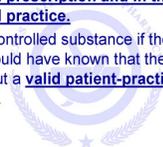


CFR 1306.04(a)

- 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.**

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Texas Law



- A pharmacist may not:
 - dispense or deliver a controlled substance except under a **valid prescription and in the course of professional practice.**
 - dispense a controlled substance if the pharmacist knows or should have known that the prescription was issued without a **valid patient-practitioner relationship.**

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"Red Flags" Check List

Texas State Board of Pharmacy
2016-2017 Red Flag Checklist for Pharmacies
10/1/2016

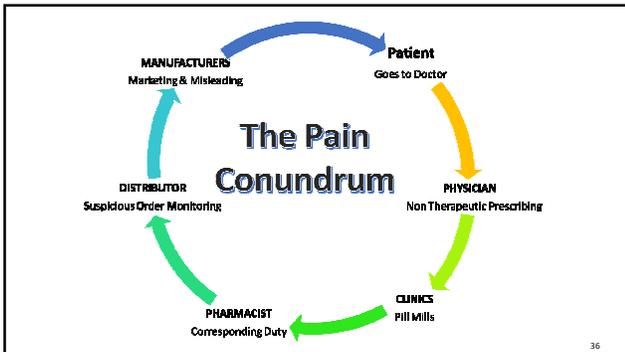
Check all that apply:

- 1. Long lines are common at your pharmacy with most people presenting prescriptions for controlled substances.
- 2. Multiple people arrive at the pharmacy in the same vehicle, or one person is picking up prescriptions for multiple people.
- 3. People receive the same controlled substances from multiple prescribers.
- 4. Multiple people with the same address present prescriptions from the same prescriber.
- 5. People often seek early refills.
- 6. You rely solely on the prescriber's representation that prescriptions are legitimate.
- 7. You feel compelled to hire "security" to prevent problems.
- 8. People pay with cash or credit card more often than through insurance.
- 9. Your pharmacy charges and people are willing to pay more for controlled substances than they would at nearby pharmacies.
- 10. 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 liquid.
- 11. Multiple people, particularly those who are not regular patrons, bring in prescriptions for controlled substances from the same prescriber.
- 12. Drugs prescribed are inconsistent with the prescriber's area of practice (e.g., fentanyl from a dentist).
- 13. The prescriber of the drugs is located a significant distance from your pharmacy.

**Texas State Board of Pharmacy
"Red Flag" Checklist for Pharmacies
YOU MIGHT BE A PILL MILL IF...**

Check all that apply:

- Your pharmacy fills prescriptions for prescribers who frequently write identical prescriptions for numerous people, indicating a lack of individual 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.
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WHOLESALE DISTRIBUTORS

ANTI-DIVERSION SYSTEMS- SUSPICIOUS ORDER MONITORING PROGRAM



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.

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

DEA - Enforcement

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



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MANUFACTURERS

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



From left, Thomas D. Stone, the top lawyer for Purdue Pharma; Dr. Paul G. Goldenstein, the company's former medical director; and Michael 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.

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Where is the FDA Coming From?

100. Approved Drug Applications: Protecting and Promoting Your Health

FDA NEWS RELEASE
For Immediate Release: Feb. 10, 2014
Media Inquiries: Morgan L. Conroy, 301-796-0301 conroy.morgan@fda.hhs.gov
<http://www.fda.gov/oc/ohrt/ohrt.html>
Consumer Inquiries: 800-338-2255
<http://www.fda.gov/oc/ohrt/ohrt.html>

FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics.
New label warning to include reminder about potential overdose
The U.S. Food and Drug Administration today announced changes to the labeling, packaging and use instructions for extended-release and long-acting (ER/LA) opioid analgesics intended for pain.

The FDA is requiring its manufacturers to update safety labeling changes and postmarket studies to include reminder about potential overdose for extended-release and long-acting (ER/LA) opioid analgesics intended for pain. The U.S. Food and Drug Administration today announced changes to the labeling, packaging and use instructions for extended-release and long-acting (ER/LA) opioid analgesics intended for pain. The FDA is requiring its manufacturers to update safety labeling changes and postmarket studies to include reminder about potential overdose for extended-release and long-acting (ER/LA) opioid analgesics intended for pain.

The updated labeling states that ER/LA opioids are indicated for the management of moderate to severe pain that is continuous, long-lasting and severe and for which alternative treatment options are inadequate.

The FDA's primary goal for labeling prescription drugs is the optimal use of medications by the general public. And the FDA is committed to the safety, efficacy and quality of the products it regulates and approves in the FDA's Center for Drug Evaluation and Research. These labeling changes are part of the FDA's ongoing work to improve the safety, efficacy and quality of the products it regulates and approves in the FDA's Center for Drug Evaluation and Research.

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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.

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Failure to Warn

