

# OVERPRESCRIBING IN CALIFORNIA: WHY ARE WE HERE?

---

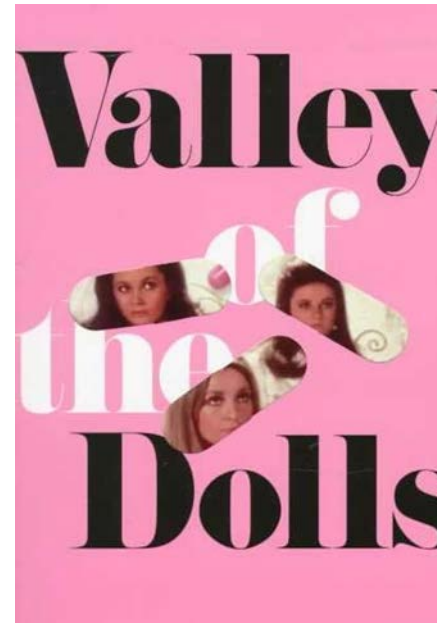
Laura Sweet  
Deputy Chief  
Medical Board of California

# Presentation Objectives:

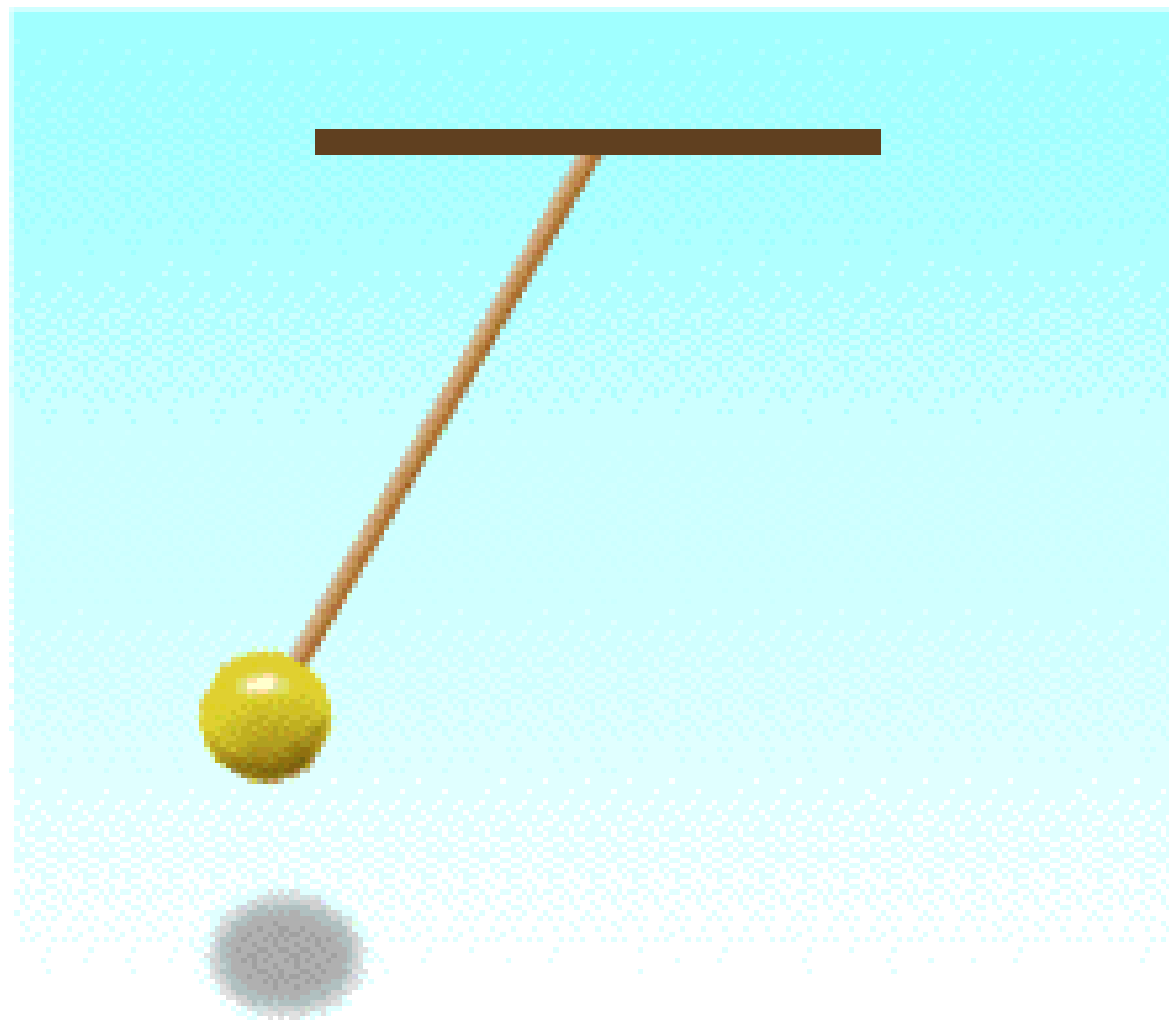
- Chronologic review of prescribing legislation in California.
- Current physician responsibilities.

# 1960's

- “Mother’s Little Helper”
- Nembutal, Seconal, Dexedrine



# Reining in



# 1970's

Federal Comprehensive Drug Abuse Prevention and Control Act passed:

- Drugs divided into Schedules I through V based upon potency, addiction and abuse potential.
- Laws developed to curtail false and fictitious prescriptions.

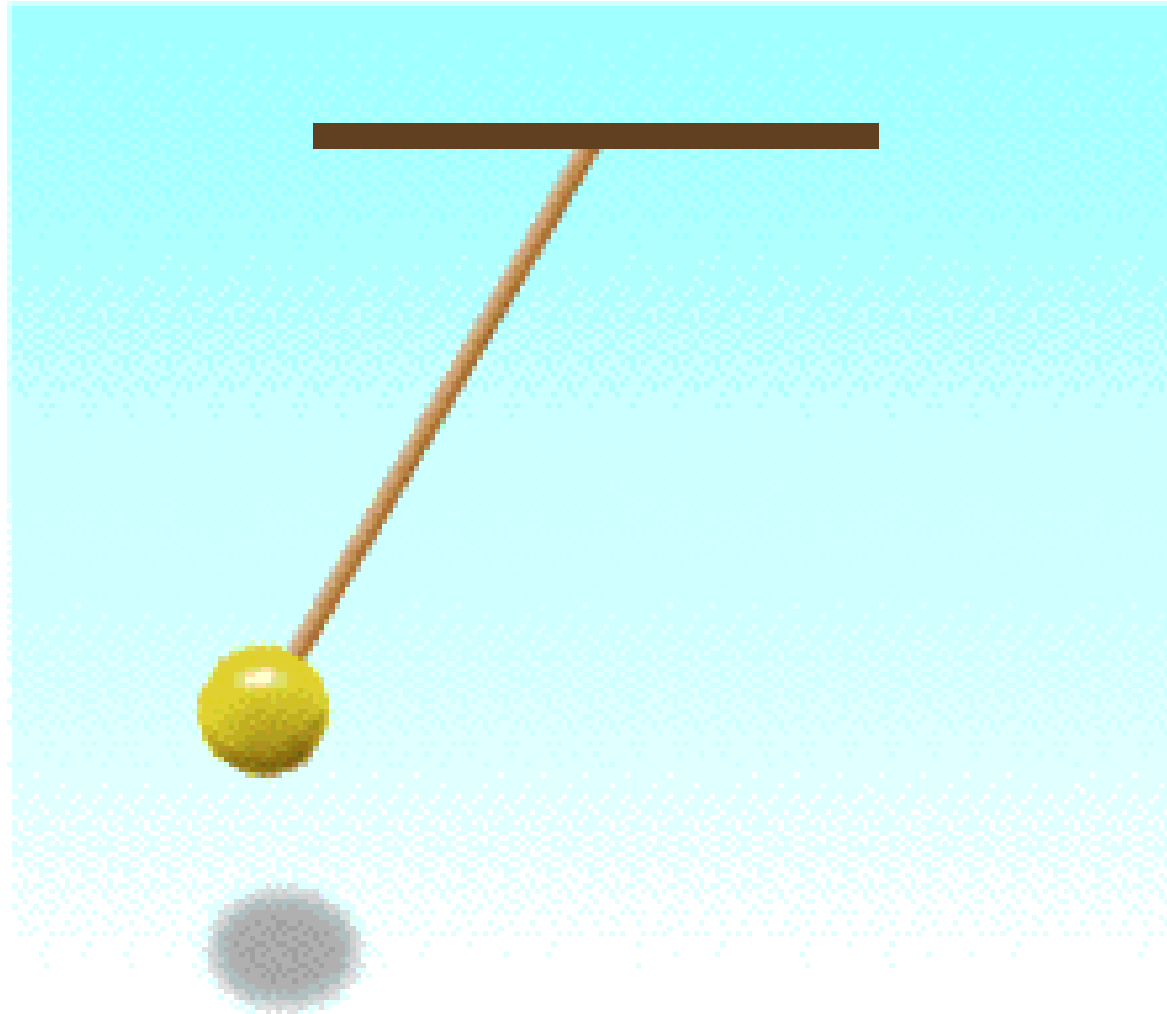
# 1980's

**1984:** Laws too effective?

Compassionate Pain Relief Act introduced to Congress to make heroin legal for terminally ill patients. Law did not pass but research indicated patients unable to obtain appropriate medication and physicians reluctant to use opioids for fear of being investigated.

**1985:** Medical Board created guidelines for treatment of chronic intractable pain, but nobody (almost nobody) read or implemented them.

# Free Rein in the Making



# 1990

## 1st Pain Legislation in CA: Intractable Pain Treatment Act



- Business & Professions Code Section 2241.5
- Patients allege under-medication
- Studies confirm MDs are under-prescribing
- MDs cite fear of regulatory agencies



# Key Provisions of IPTA:

- A physician may prescribe or administer controlled substances for a condition causing ***intractable*** pain.
- Prescribing or administering controlled substances is not a basis for disciplinary action, if the prescriber complies with laws:
  - Drugs for therapeutic purposes only
  - MD cannot treat patient for chemical dependency
  - MD must keep complete/accurate records
  - Prescriptions cannot be false/fictitious
  - MD must prescribe and dispense consistent with public health and welfare
  - MD must follow CA Controlled Substances Act

# 1994

## Medical Board of California's Statement on Pain Management



1. Pain is often under-treated for a variety of reasons.
2. Citizens of CA who suffer from pain should be able to obtain relief currently available.
3. Although other drugs/treatments available, opioid drugs are the cornerstone.
4. Large doses may be necessary.
5. Strong analgesics require careful evaluation.

## Medical Board of California's Statement on Pain Management (cont'd)

6. Physical dependence and tolerance are normal and do not equal "addiction."
7. MDs who follow guidelines should not be concerned re: regulatory scrutiny.
8. If appropriate prior exam and medical need, there is no basis for disciplinary action.
9. MBC will stop abuse of controlled drugs.



# SEVEN EASY PRESCRIBING GUIDELINES:

1. Take an adequate history & physical exam.
2. Have a treatment plan with objectives;  
individualize the plan to each patient.
3. Give info. to the patient; Informed Consent.
4. Periodically review the course of treatment.
5. Obtain consultation as appropriate.
6. Keep accurate and complete records.
7. Comply with Controlled Substance laws.

**Published in October 1994 and April 1996 *Action Report***

# 1996

69% of physicians surveyed stated the potential for disciplinary action made them more conservative in their use of opioids for pain management.

## 1996-1997

MBC Budget Act: “Funds appropriated by this item are to be used to provide an annual training component for all investigative and executive staff on the requirements of the Intractable Pain Act of 1990 ...”

***“...the Legislature intends that ...persons who make decisions regarding pain management that affect patients and doctors know the distinction between patients who suffer from intractable pain and those who are violating the law in order to obtain drugs for illegal purposes ...”***

# 1997

## 2nd pain legislation: “Pain Patient’s Bill of Rights” (H&S 124960 and 124961)



- Patient suffering from severe chronic intractable pain has the option to request or reject any or all modalities.
- Patient has the option to choose opioid medications to relieve their pain.
- MD may refuse to prescribe opioids but shall inform the patient there are other MDs who specialize in the treatment of pain.
- If prescribing, follow Guidelines.

# 1998

- CURES developed and implemented by Department of Justice, Bureau of Narcotic Enforcement, Board of Pharmacy.

# 1999

3rd pain legislation: H&S 11159.2 (eff. 1-1-99)

- Schedule II drugs written on single RX
- Patient terminally ill
- “11159.2 exemption” written on script
- Exempt from security RX forms (eff. 2007)



# 2000

## Wisconsin Pain & Policy Studies Group

- Published report card assessing each state's pain policies for consistency and clarity. California given a "C."
- MBC sponsored legislation to fix some of the legal ambiguity: AB 2198 (eff. 2006).



# 2001

## H&S 1254.7

- Pain is 5<sup>th</sup> vital sign
- Every health facility shall ensure pain is assessed consistent with other vital signs

*Legislative intent: pain be assessed and treated promptly, effectively, as pain persists.*

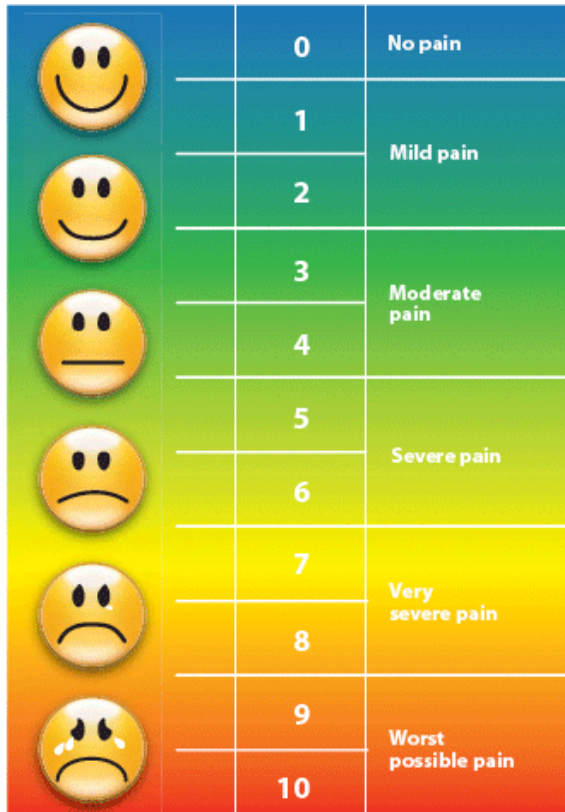


FIGURE 1. An example of a pain scale

# 2001



- \$1.5 million jury verdict for physician who failed to treat elderly patient's pain.
- Family sued for elder abuse (not malpractice).
- Case lead to A.B. 487

# AB 487

- Intent: broaden MD knowledge in care and treatment of patients in pain.
- 12 CME hours required (radiologists and pathologists exempted) to be completed by 12-31-06.
- Statute required MBC to establish standards for investigating prescribing cases (MBC already had standards in its EOM that the task force approved.)
- Multi-disciplinary task force created to approve standards, review Pain Management Guidelines. Members included everyone who has been invited here today (and lobbying groups for pain patients).

# 2002-2003

## Task Force Revisions

- The 7 identified guidelines - *unchanged*.
- Annotations added to guide all physicians.
- The MBC gave final approval to new guidelines in August 2003.

# Investigation Standards

- Investigators requesting an expert reviewer for an MBC case involving pain management issues shall use at least **two experts** and ensure that **one** physician and surgeon is "board certified" in the **areas of pain management** (i.e., American Board of Anesthesiology or the American Board of Pain Medicine) and **one** physician is board certified in the **same specialty** as the physician under investigation.

In addition, on February 2, 1996, the MBC approved the American Board of Pain Medicine (a non ABMS member specialty board) to advertise board certification. The MBC extended the approval to February 2, 2005. Therefore, physicians who are certified by the American Board of Pain Medicine may qualify as expert reviewers.

# Investigation Standards (cont'd)

- When an investigator requests an expert opinion, the **investigator shall provide** the **selected expert reviewers** with the case documents to be reviewed, and provide a copy of the following legal code sections and Board guidelines included in this EOM Section:
  - Business & Professions Code section 2190.5 (**Mandatory Continuing Education Classes in Pain Management and Treatment; Exemptions**)
  - Business & Professions Code section 2241.5 (**Intractable Pain Treatment Act**)
  - Health And Safety Code section 11159.2 (**Treatment of Terminally III Patient With Schedule II Controlled Substances For Pain Relief; Prescriptions**)
  - Health And Safety Code section 124961 (**Pain Patient's Bill of Rights**)
  - Guidelines For Prescribing Controlled Substances For Intractable Pain

# 2005

## Senate Bill 151

*Intent: increase patient access to appropriate pain medication and prevent diversion of controlled substances for illicit use*

- Eliminated triplicates (seen as stigma)
- All C.S. written on New Tamper Proof Prescriptions
- Simplified prescribing rules
- Retained Terminal illness exemption
- Made CURES permanent
- Extended CURES to Schedule III
- All controlled substance scripts valid for 6 months
- Oral and faxed rx's for schedule III-IV ok



# 2006

## AB 2198

- Laws made consistent with changes to the MBC Guidelines
- Deleted reference to “intractable” pain and broadens to impact all types of pain
- “Good faith” prior exam is changed to “appropriate prior examination”
- Changed B&P 2241 in allowing the prescription of controlled substances in treating addict who is in pain
- Defines “addict” (impaired control over drug; compulsive use; continued use despite harm)

# 2009



- ▶ CURES Prescription Drug Monitoring Program (PDMP) database became available online. Access available to prescribers, pharmacists, law enforcement personnel.
- ▶ Once an application received and approved, the requestor has real-time access to the database.

# DID YOU KNOW?

---

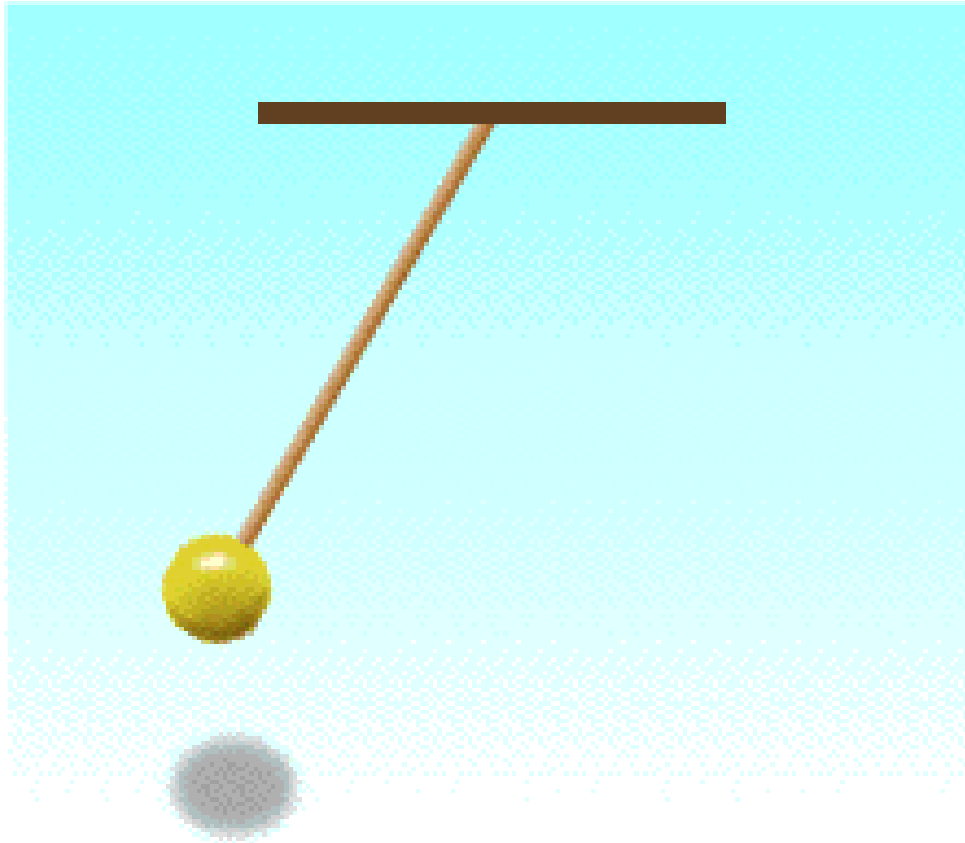
Only 6.09 % registration for CURES among eligible prescribers (this includes pharmacists, veterinarians, physicians)

# The Ones Who Got Away ...



- Pill counting alone and misunderstanding of pain management “defense” led to acquittal/dismissal of charges.

# Unbridled Prescribing and Unintended Consequences?



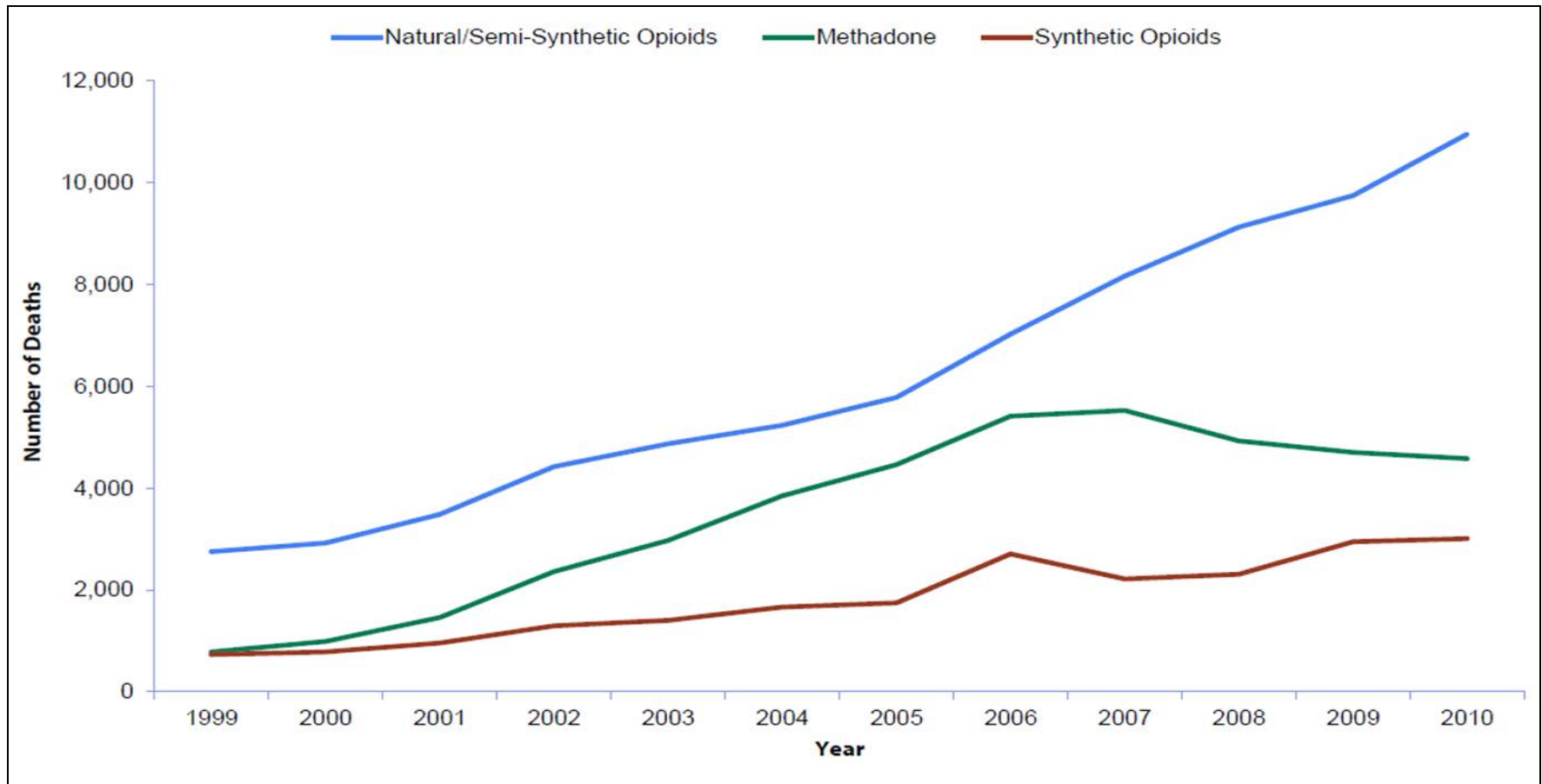
# 2010

- Approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes.
- Of this number, 22,134 of these deaths were attributed to Prescription Drugs (16,651 attributed to opioid overdoses/ 75.2 %).
- Prescription drug abuse is the fastest growing drug problem in the United States.

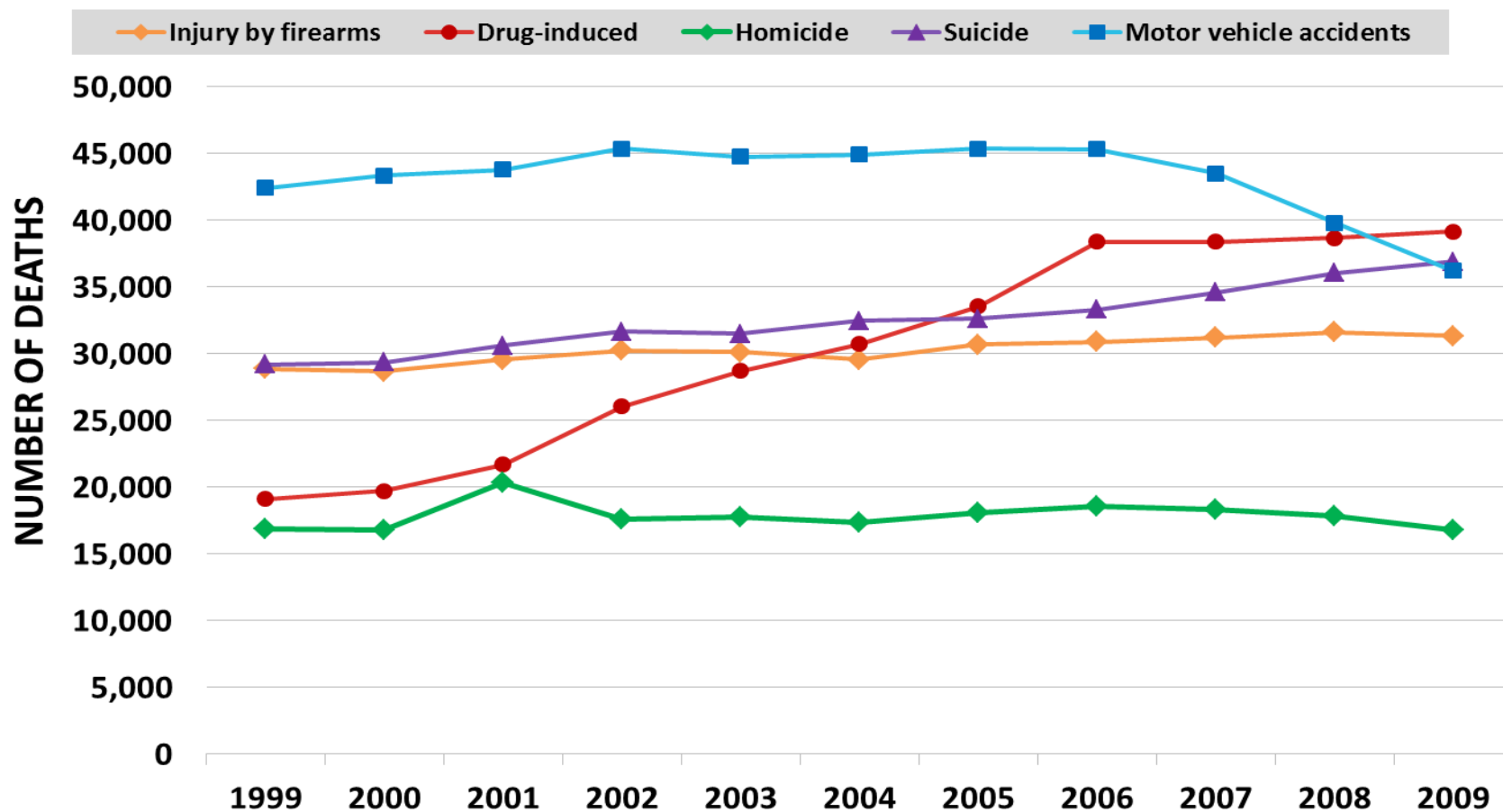
SOURCE: CDC Drug Overdose Deaths in the United States, 2010 (October 2012)

U.S. Drug Enforcement Administration/Operation  
Division/Office of Diversion Control

# U.S. Drug Overdose Deaths by Type of Opioid Involved, 1999-2010



# Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)



Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually exclusive.



# Emergency Room Data 2004-2010

- Increase of 115%: ER visits attributable to pharmaceuticals alone: 626,472 to 1,345,645 (i.e., with no other type of drug or alcohol)

*No significant change in ER visits attributable to cocaine, heroin, marijuana or methamphetamines*

- Rx Drugs most frequently implicated:

- Oxycodone products 255% increase
- Hydrocodone products 149% increase
- Fentanyl products 117.5% increase
- Zolpidem 154.9 % increase
- Alprazolam 148.3% increase
- Clonazepam 114.8 % increase
- Carisoprodol 100.6% increase

For patient 20 and younger, misuse/abuse of pharmaceuticals increased 45.4 %

For patients 20 and older, the increase was 111%.

# Economic Impact

- **\$53.4 BILLION:** 2006 estimated cost in the US from non-medical use of prescription opioids
  - \$42 billion – Lost productivity
  - \$8.2 billion – Criminal Justice costs
  - \$2.2 billion – Treatment costs
  - \$944 million – Medical complications

Five drugs: OxyContin, oxycodone, hydrocodone, propoxyphene and methadone accounted for 2/3 of the economic burden.

# Emerging Issues: Prescription Opiates and Heroin

- The number of 18 to 24 year olds admitted to treatment for heroin increased from 42,637 in 2000 to 67,059 in 2009.<sup>1</sup>
- The number of persons who were past year heroin users in 2011 (620,000) was higher than the number in 2007 (373,000).<sup>2</sup>
- Epidemiologists in 15/21 US cities report increases in heroin, notably among young adults and outside of urban areas.<sup>3</sup>
- Injection drug users report prescription opioid use predates heroin use and tolerance motivates them to try heroin.<sup>4</sup>



1. Banta, Green, CJ 2012. Adolescent Abuse of Pharmaceutical Opioids Raises Questions About Prescribing and Prevention. Arch Pediatr Adolesc Med. 2012 May 7. [Epub ahead of print].  
2. Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. linked to 2/13/2013. <http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresultsAlts2011.htm#Fig2-4> pending citation/cleared data.  
3. Proceedings of June 2012, NIDA CEWG (Unpublished Data from NIDA).  
4. Lankenau SP, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.

# Getting to Heroin

Oxycodone  
Combinations  
Percocet®  
\$7-\$10/tab

OxyContin®  
\$80/tab

Roxicodone®  
Oxycodone IR  
15mg, 30mg  
\$30-\$40/tab

Hydrocodone  
Lorcet®  
\$5-\$7/tab

Heroin  
\$10/bag



# A U.S. Problem?



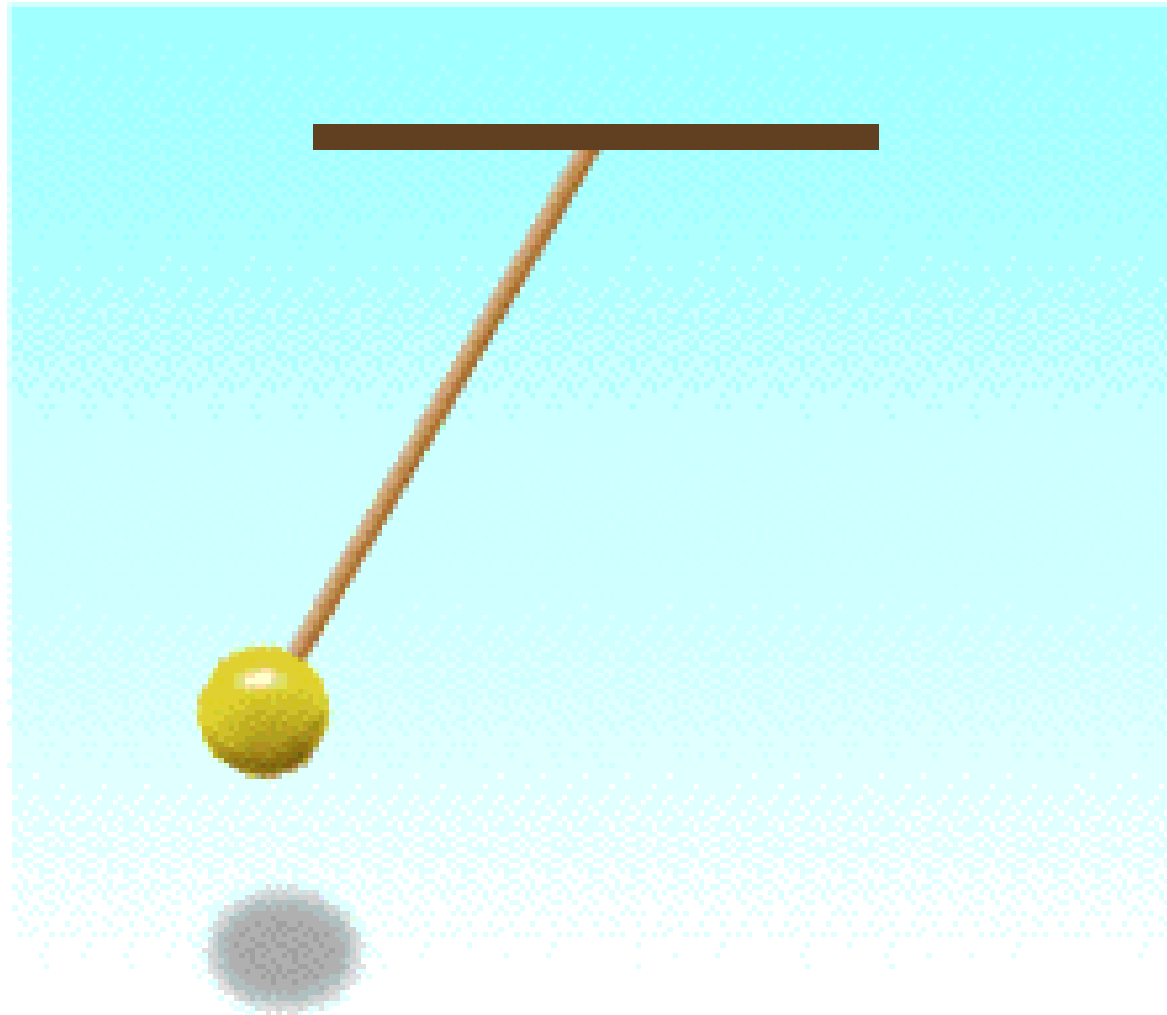
- The United States makes up only 4.6 % of the world's population, but consumes 80% of its opioids --- and 90% of the world's hydrocodone, the opiate in Vicodin.
- Gil Kerlikowske, the national drug czar, says the current culture of writing narcotic prescriptions for moderate pain, which began about a decade ago, needs to be changed and doctors need to be retrained.



# 2012

- MBC-lead investigations or co-investigations have resulted in charges being filed against several physicians/osteopaths throughout the state.
- Many substantial cases (2<sup>nd</sup> degree murder) still pending.
- Ambiguity in the law/guidelines and lack of resources still present investigation challenges for law enforcement and standard of practice challenges for physicians and surgeons.

# Reining in (reprise)



2013

- Senate Bill 809

- Senate Bill 62

- Senate Bill 670

????



# “Four D’s” of Prescription Drug Abuse

1. Dishonest : Physician uses their medical license to “deal drugs”
2. Disabled: Physician whose judgment is impaired by mental illness or their own abuse of drugs, alcohol, etc.
3. Dated: Physician mis-prescribes because of incompetency or failure to keep up with medical developments
4. Duped: Physician is easily manipulated by conniving patient(s)

# WHERE ARE WE NOW?

---

Current Prescribing Guidelines with annotations

# History and Physical Examination

- A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.
- ***Annotation One:*** Rxing CS for pain may require referral
- ***Annotation Two:*** The complexity of the H&P exam may vary based on location (e.g., ER, OR, night, weekend versus the continuing care situation)

# Treatment plan, objectives

- The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.
- ***Annotation One:*** Physicians and surgeons may use control of pain, increase in function and improved quality of life as criteria to evaluate the tx plan
- ***Annotation Two:*** When the patient is requesting opioid medications and inconsistencies identified in the hx, etc. the P&S who withholds opioid meds should document basis for decision

# Informed Consent

- The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
- ***Annotation:*** A written consent or pain agreement is not required (but may make it easier to document pt education, the tx plan and informed consent)

# Periodic Review

- **The physician and surgeon should periodically review the course of pain treatment ... Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.**
- ***Annotation One:* Patients with pain who are managed with CS should be seen monthly, quarterly, or semiannually as required by the SOC**
- ***Annotation Two:* Satisfactory response to treatment may be demonstrated by the patient's decreased pain, increased level of function or improved quality of life. Input from family or other caregivers should be considered in determining the pt's response to tx**

# Consultation

- **The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.**
- ***Annotation One:* Coordination of care in prescribing chronic analgesics is of paramount importance.**
- ***Annotation Two:* In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code sections 2241 and 2241.5.**

# Records

- The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.
- *Annotation One*: Documentation of the periodic reviews should be done at least annually or more frequently if warranted
- *Annotation Two*: Pain levels, levels of function, and quality of life should be documented. Documentation should include both pt's and caregiver's subjective complaints and physician's objective findings.



# Compliance with Controlled Substances Laws & Regulations

- **To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.**
- ***Annotation One:* There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or CA law.**
- ***Annotation Two:* Physicians and surgeons who supervise PAs or NPs should carefully review the respective supervision requirements.**

# Postscript

- **While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain - including intractable pain - there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). In summary, a physician and surgeon must follow the same standard of care when prescribing and/or administering a narcotic controlled substance to a "known addict" patient as he or she would for any other patient.**
- **The physician and surgeon must:**
  - **perform an appropriate prior medical examination;**
  - **identify a medical indication;**
  - **keep accurate and complete medical records, including treatments, medications, periodic reviews of treatment plans, etc;**
  - **provide ongoing and follow-up medical care as appropriate and necessary.**

# Postscript (cont'd)

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.