Pain Management

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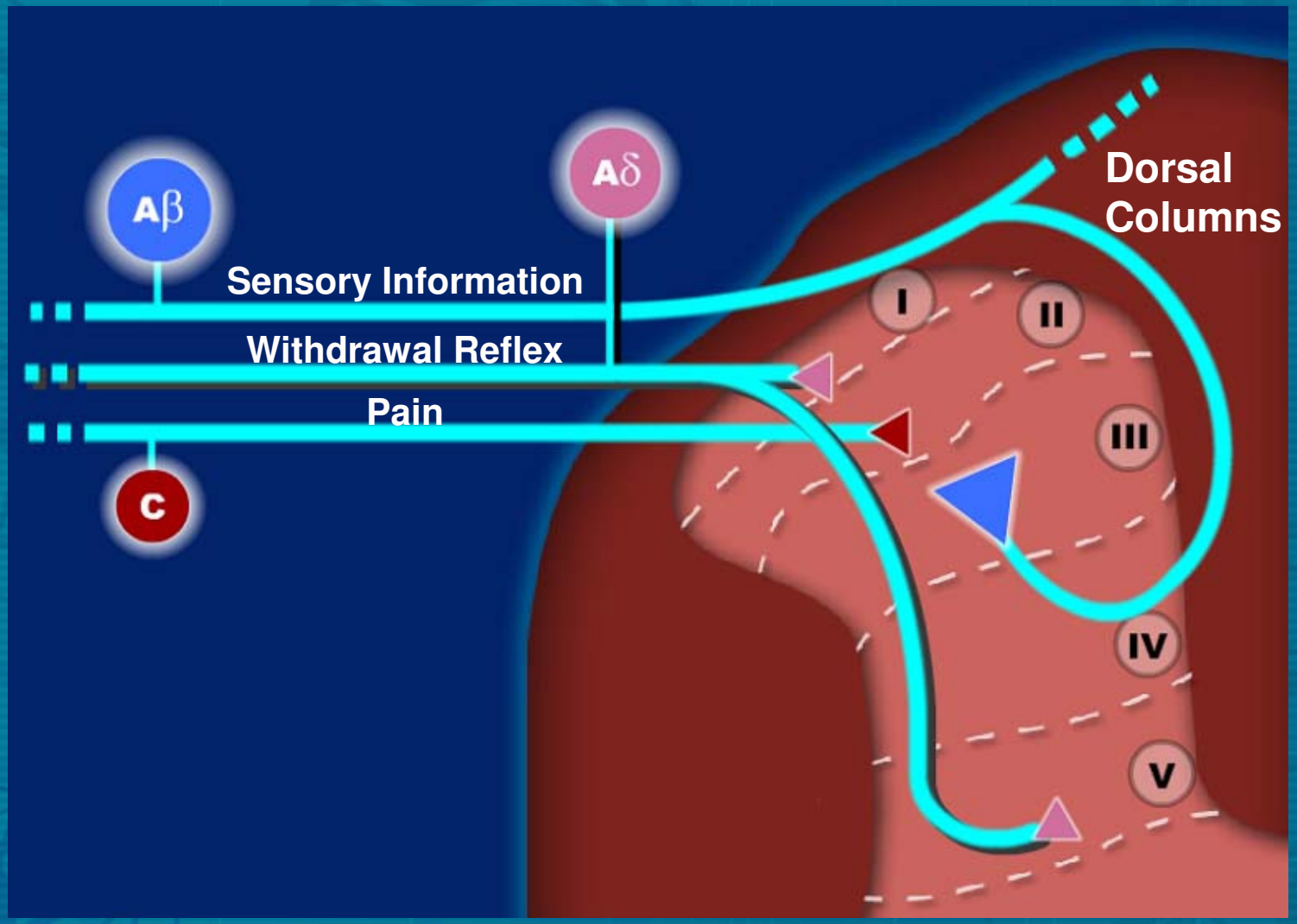
The Problem

- 110,000 million chronic pain patients in the United States (2011 Institute of Medicine Report)
- 6000 pain specialists
- 120,000 primary care providers

Why It Hurts

- Pain is protective and vital to survival
  - Alerting system
  - Signals damage or danger
  - Hereditary sensory and autonomic neuropathy Type IV; lack A-delta and C fibers
- Normal pain described as eudynia

Normal Pain Pathways in the Dorsal Horn



Mannion RJ, Woolf CJ. *Clin J Pain*. 2000;16(suppl 3):S144-S156.

Why It Hurts

- Anatomy and pain pathways key to relieving pain
  - Discover source of pain
  - Do something to the source or pathways
    - rest, ice, topical agents, medication, injection, surgery
    - alternatives - acupuncture, herbals
    - block or interrupt sign - rhizotomy, cordotomy
- Successful outcomes

Why It Hurts

- Sometimes pain does not improve in healing of tissues
- Source had not been identified
  - Look harder - better understanding of pathways, better tools
    - animal studies, scans, biopsies, single nerve experiments, PET

Patient A - Low pain threshold

Normal MRI of spine

Severe back pain

Patient B - High pain threshold

Prominent bulging disc

No pain or symptoms

Clauw et. al. Spine 1999

Barriers to Treatment

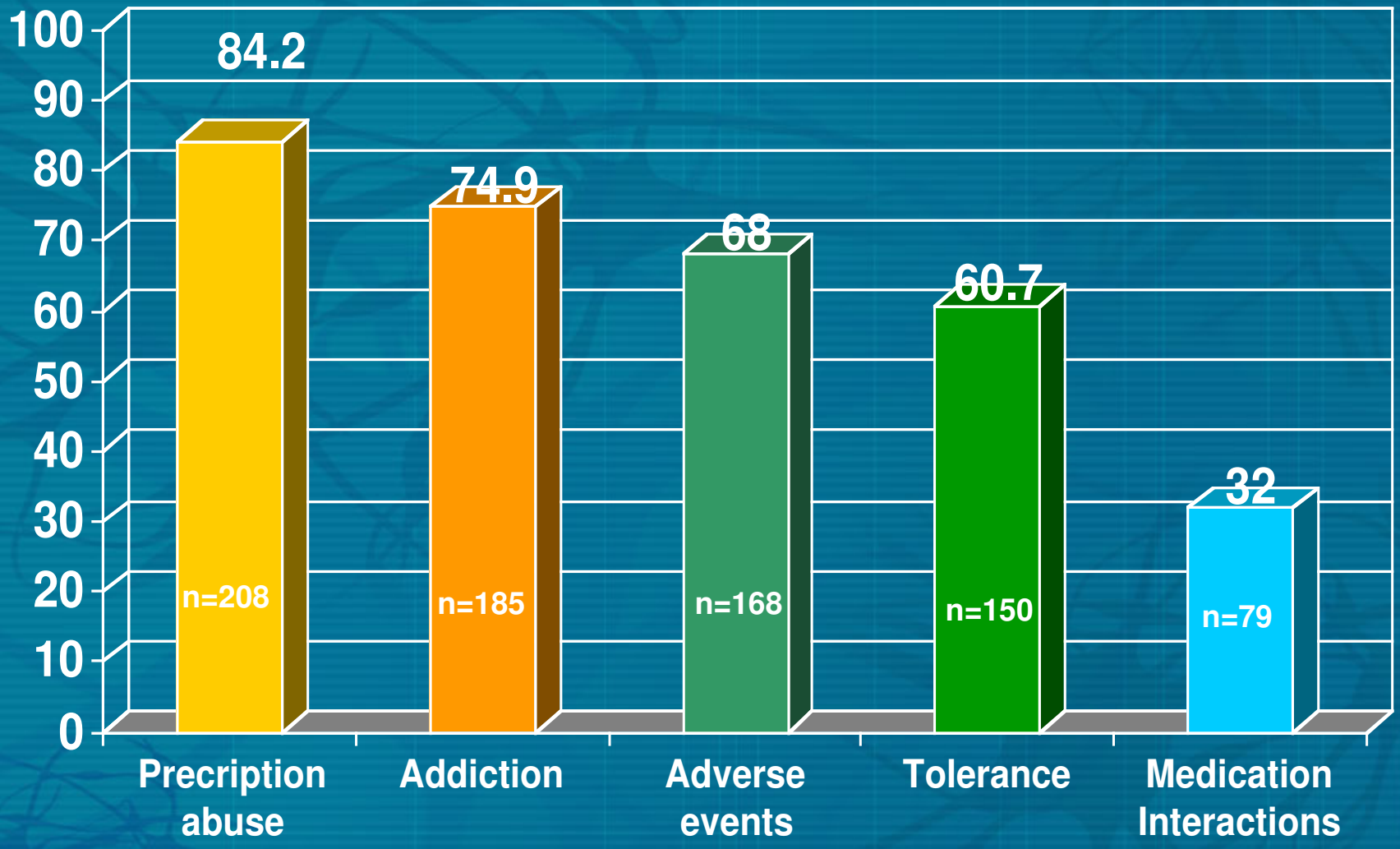
- Knowledge
- Regulation
- Bias

Chronic Pain Conundrum

The most difficult issue now facing physicians "…whether and how to prescribe opioid therapy for chronic pain that is not associated with terminal disease, including pain experienced by the increasing number of patients with cancer in remission."

Ballantyne JC, Mao J. *N Engl J Med.* 2003;349:1943-1953.

Top Concerns Among PCPs (N=248)



Bhamb B, et al. Curr Med Res Opin 2006;22(9):1859-65.

Opioids in Chronic Pain

- Strong push to use more opioids
  - Federation of State Medical Boards
  - Medical Boards encourage use – Intractable Pain Acts

Opioid Analgesia—1990s

Old Teaching

1. All patients get addicted to narcotics
2. Side effects limit effectiveness
3. Save until pain is really bad—tolerance
4. Pain is not life threatening

New Thoughts

1. Almost no one gets addicted to opioids
2. Side effects can be managed
3. Treat pain early - tolerance is exaggerated
4. Pain kills

Opioid Analgesia—2000-2012

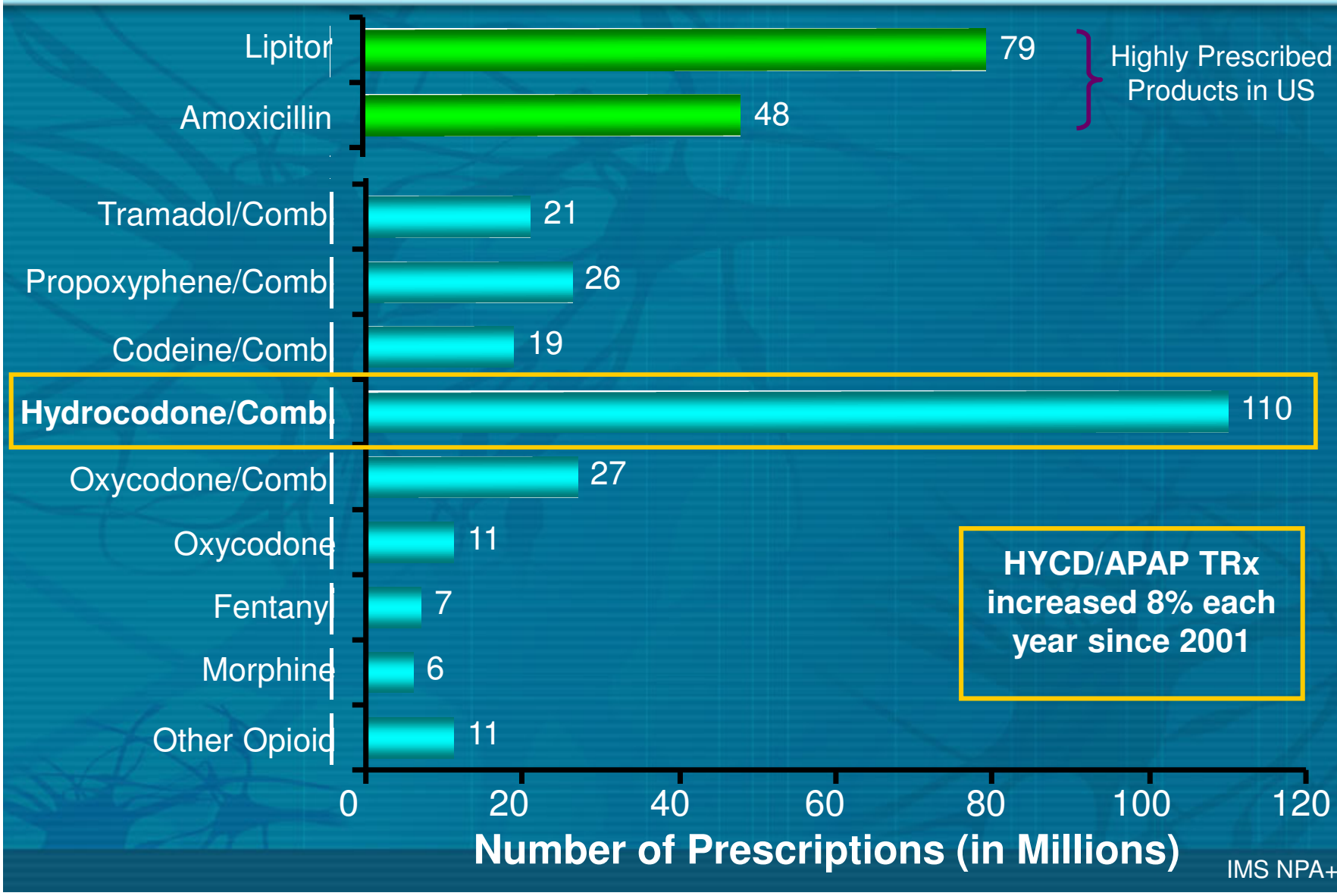
Old Teaching

1. All patients should be given a trial of opioids
2. No ceiling effects for opioids
3. High pain levels require opioids as first-line agents
4. Even addicts do well on opioid therapy

New Thoughts

1. In some patients, risks may be too high for opioids
2. As doses increase, effects lessen; hypersensitization
3. Pain levels alone do not dictate opioids
4. Significant practice issues in monitoring patients on opioids

Hydrocodone/APAP is the Most Prescribed Opioid and the Most Prescribed Product in US

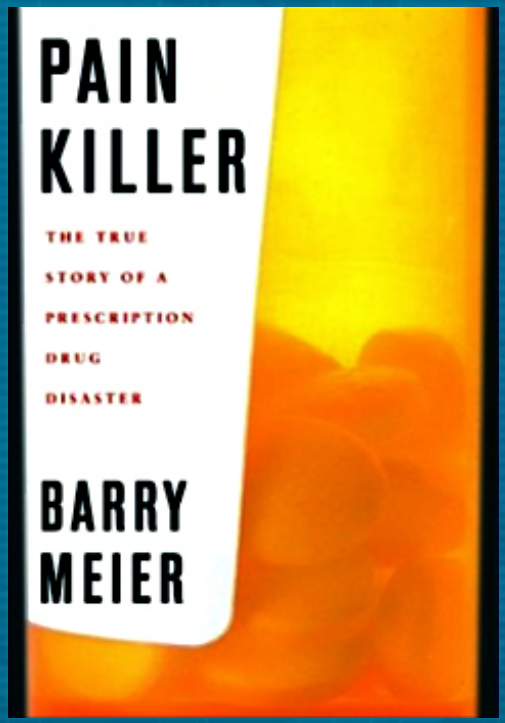


IMS NPA+, 2005

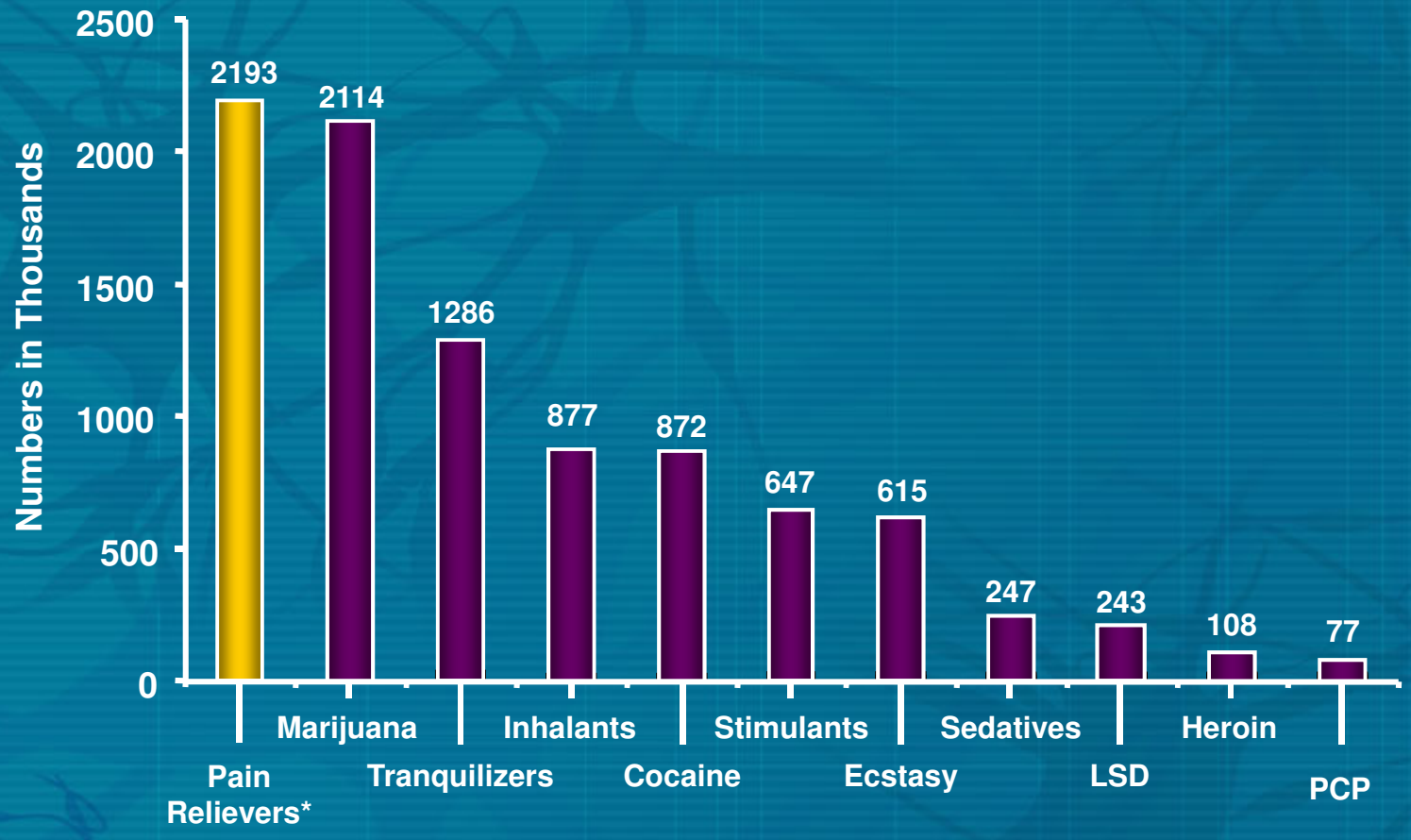
Opioids in Chronic Pain

- Strong push to use more opioids
  - Federation of State Medical Boards
  - Medical Boards encourage use – Intractable Pain Acts
- Still controversial
  - Increased use and awareness of prescription drug abuse
  - Physician and, patient fear, bias, misunderstanding
  - Regulatory oversight

Pain, Abuse, Misuse and Diversion



New Illicit Drug Use in the United States: 2005



*526,000 new nonmedical users of OxyContin®.

SAMHSA, OAS. NSDUH, 2005. Available at: www.oas.samsa.gov/nsduh.htm. Accessed February 15, 2007.

Does Prescribing Drive Opioid Abuse?

- 30% to 45% of prescription opioid abusers report their first opioid prescription was from a doctor for pain[1]
- Prevalence of comorbid substance abuse among pain patients on opioids is 20% to 40%[2]
- Most prescription opioid abusers obtain drugs from either their own prescriptions or those of friends and family[4]
- Majority of abusers were at apparent high risk prior to first exposure[3]

[1]Potter JS et al. *Drug Alcohol Depend*. 2004;76:213-215; [2]Hays LR. *J Addict Dis.* 2004;23:1-9; [3]Jamison RN et al. *J Pain Symptom Manage*. 2000;19:53-62; [4]Substance Abuse and Mental Health Services Administration. Results from the 2009 National Survey on Drug Use and Health: Volume I. Summary of National Findings (Office of Applied Studies, NSDUH Series H-38A, HHS Publication No. SMA 10-4586Findings). Rockville, MD; 2010.

Risk Evaluation and Mitigation Strategy (REMS)

- Engine behind REMS is misuse, abuse, addiction, diversion and death (political in election year)
- Unintended consequence – patients, providers
- Voluntary program targeting all prescribers of long-acting opioids – 2-3 hours of training
- 350,000 DEA registrants who prescribe Schedule 2 drugs (long acting opioids)
- Goal is 25% in first year
- If education goal is not achieved, may become mandatory

DEA, Drug Enforcement Administration
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310870.htm

Case Study 1

- 77-year-old woman with osteoarthritis of the hip taking 3 hydrocodone tablets/week
- States that she would take more but is worried about addiction
  - Need to know environment; who is living with patient

Case Study 2

- 45-year-old man with failed back syndrome on 8 oxycodone/acetaminophen tablets daily
- Always shows up for office visits appearing appropriate, never calls in early or reports lost pills
- Continues to work in construction because he “has to”

Case Study 3

- 55-year-old man with diabetic peripheral neuropathy with A_1C of 10.2% despite your best efforts (nonadherence)
- Oxycodone ER 80 mg 2 to 3 times daily plus hydrocodone/acetaminophen 10/325 mg 10 times daily
- Social Security disability and constantly testing you about early refills, lost medication
- Wife on Social Security disability and takes opioids for fibromyalgia

ER, extended release

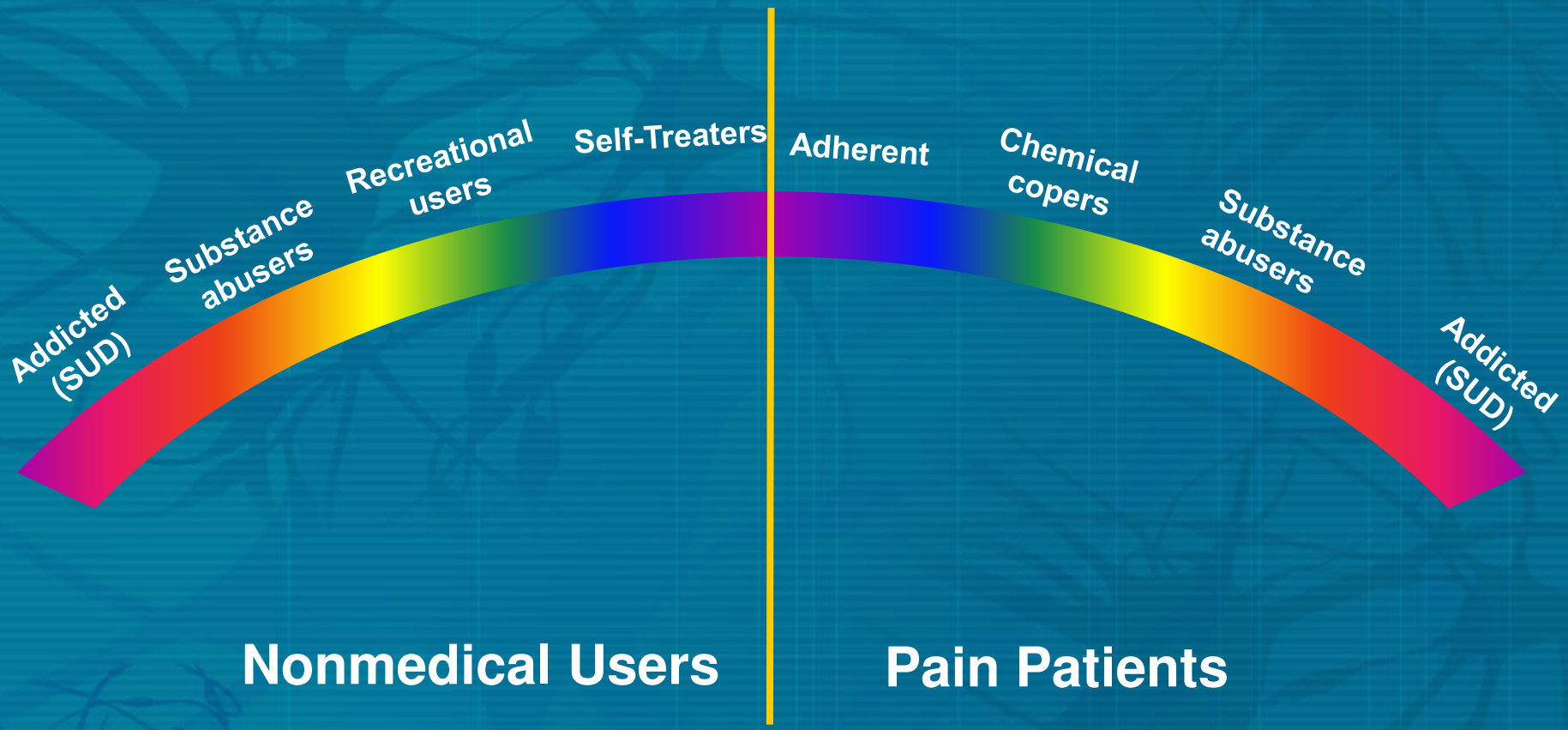
Case Study 4

- 47-year-old man with low back pain new to your office and out of medication on Friday afternoon
- Requesting refills on medication
  - Methadone 10 mg 4 qid
  - Oxycodone 15 mg 3 tid
  - Carisoprodol 2 qid
  - Valium 10 mg 2 bid

Assessment Issues

- How did we get from a 77-year-old taking 3 hydrocodone tablets/week to a 47-year-old on multiple medications without and old record?
- Risk assessment
  - Why
  - How
- Strategy to deal with risk
  - Refer – how can you be involved in this care
  - Increase surveillance

Population of Prescription Opioid Users Is Heterogeneous



Passik SD, Kirsh KL. *Exp Clin Psychopharmacol.* 2008;16:400-404.

Assessment

- Detect comorbid psychiatric illness
- Develop a management plan
- Ideally, the patient will agree to adhere to the treatment plan
  - *Complete abstinence from illicit drug use may be unrealistic*

Passik SD, Kirsh KL. *CNS Drugs.* 2004;18:13-15.

Assessment Parameters

- History
- Screening tools
- Pill counts, urine drug testing
- Prescription monitoring programs
- Specialty help when available

Passik SD, Kirsh KL. *CNS Drugs.* 2004;18:13-15.

Screening Instruments

- Several clinical tools are available that estimate risk of noncompliant opioid use[1,2,3]
- The results determine how closely a patient should be monitored during the course of opioid therapy[3]
  - *Scores implying a high risk of abuse are not reasons to deny pain relief*[3]

[1]Webster LR, Webster RM. *Pain Med.* 2005;6:432-442; [2]Coambs RE et al. *Pain Res Manage.* 1996;1:155-162; [3]Butler SF et al. *Pain.* 2004;112:65-75.

Tools to Measure Risk

- Screener and Opioid Assessment for Patients with Pain (SOAPP)[1]
- Diagnosis, Intractability, Risk Efficacy (DIRE)[2]
- Opioid Risk Tool (ORT)[3]
- Screening, Brief Intervention, and Referral to Treatment (SBIRT)[4]
- Current Opioid Misuse Measure (COMM)[5]

[1]Butler SF et al. *Pain.* 2004;112:65-75; [2]Belgrade MJ et al. *J Pain*. 2006;7:671-681; [3]Webster LR, Webster RM. *Pain Med.* 2005;6:432-442; [4]Vaca FE, Winn D. *West J Emerg Med.* 2007;8:88-92; [5]Butler SF et al. *Pain.* 2007;130:144-156.

Opioid Risk Tool

1. Family hx of substance abuse		
Alcohol	❑ 1	❑ 3
Illegal drugs	❑ 2	❑ 3
Prescription drugs	❑ 4	❑ 4
2. Personal hx of substance abuse		
Alcohol	❑ 3	❑ 3
Illegal drugs	❑ 4	❑ 4
Prescription drugs	❑ 5	❑ 5
3. Age between 14-45 yrs	❑ 1	❑ 1
4. Hx of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychologic disease		
ADD, OCD, bipolar, schizophrenia	❑ 2	❑ 2
Depression	❑ 1	❑ 1
Scoring totals:		

Administration

- On initial visit
- Prior to opioid therapy

Scoring (risk)

- 0-3: low (6%)
- 4-7: moderate (28%)
- ≥8: high (>90%)

ADD, attention deficit disorder; Hx, history; OCD, obsessive-compulsive disorder

Webster LR, Webster RM. *Pain Med.* 2005;6:432-442.

Accuracy in Predicting Discharge for Aberrant Drug-Related Behaviors

Measure Accuracy Rate	%
Clinical interview	77%
SOAPP	72%
ORT	45%
DIRE	17%

DIRE, Diagnosis, Intractability, Risk, and Efficacy inventory; ORT, Opioid Risk Tool; SOAPP, Screener and Opioid Assessment for Patients with Pain

Moore TM et al. *Pain Med.* 2009;10:1426-1433.

Urine Drug Testing – Good Review

- Christo PJ et al. Urine drug testing in chronic pain. *Pain Physician*. 2011;14:123-143.

Why Urine Drug Testing in Pain Management?

- Adjunct to patient self-reporting (unreliable)
- Validates, de-stigmatizes
- Assists in confirming
- May unmask
  - Addiction
  - Pseudo-addiction
  - Drug diversions
  - Self-medication for other illnesses
- Several available at NHC
  - Pain not occupational
  - Expensive

Interpreting Urine Drug Tests

- Know what to expect and how to interpret results
- Parent compound and or metabolite should show up in the urine
  - Oxycodone - oxymorphone
  - Hydrocodone - hydromorphone
  - Codeine - morphine
- Is the substance present that you expect?
- Are there substances present that you do not expect?

Positive and Negative Urine Toxicology Results

- **Positive forensic testing**
  - Legally prescribed medications
  - Over-the-counter medications
  - Illicit drugs or unprescribed medications
  - Substances that produce the same metabolite as that of a prescribed or illegal substance
  - Errors in laboratory analysis
- **Negative compliance testing**
  - Medication bingeing
  - Diversion
  - Insufficient test sensitivity
  - Failure of laboratory to test for desired substances

Heit HA, Gourlay DL. *J Pain Symptom Manage.* 2004;27:260-267.

Detection Times of Common Drugs of Misuse

Drug	Approximate Retention Time
Amphetamines	• 48 hours
Barbiturates	• Short-acting (eg, secobarbital), 24 hours • Long-acting (eg, phenobarbital), 2-3 weeks
Benzodiazepines	• 3 days if therapeutic dose is ingested • Up to 4-6 weeks after extended dosage (≥ 1 year)
Cannabinoids	• Moderate smoker (4 times/week), 5 days • Heavy smoker (daily), 10 days • Retention time for chronic smokers may be 20-28 days
Cocaine	• 2-4 days, metabolized
Ethanol	• 2-4 hours
Methadone	• Approximately 30 days
Opiates	• 2 days
Phencyclidine	• Approximately 8 days • Up to 30 days in chronic users (mean value = 14 days)
Propoxyphene	• 6-48 hours

Gourlay DL, Heit HA. *Pain Med*. 2009;10 Suppl 2:S115-123.

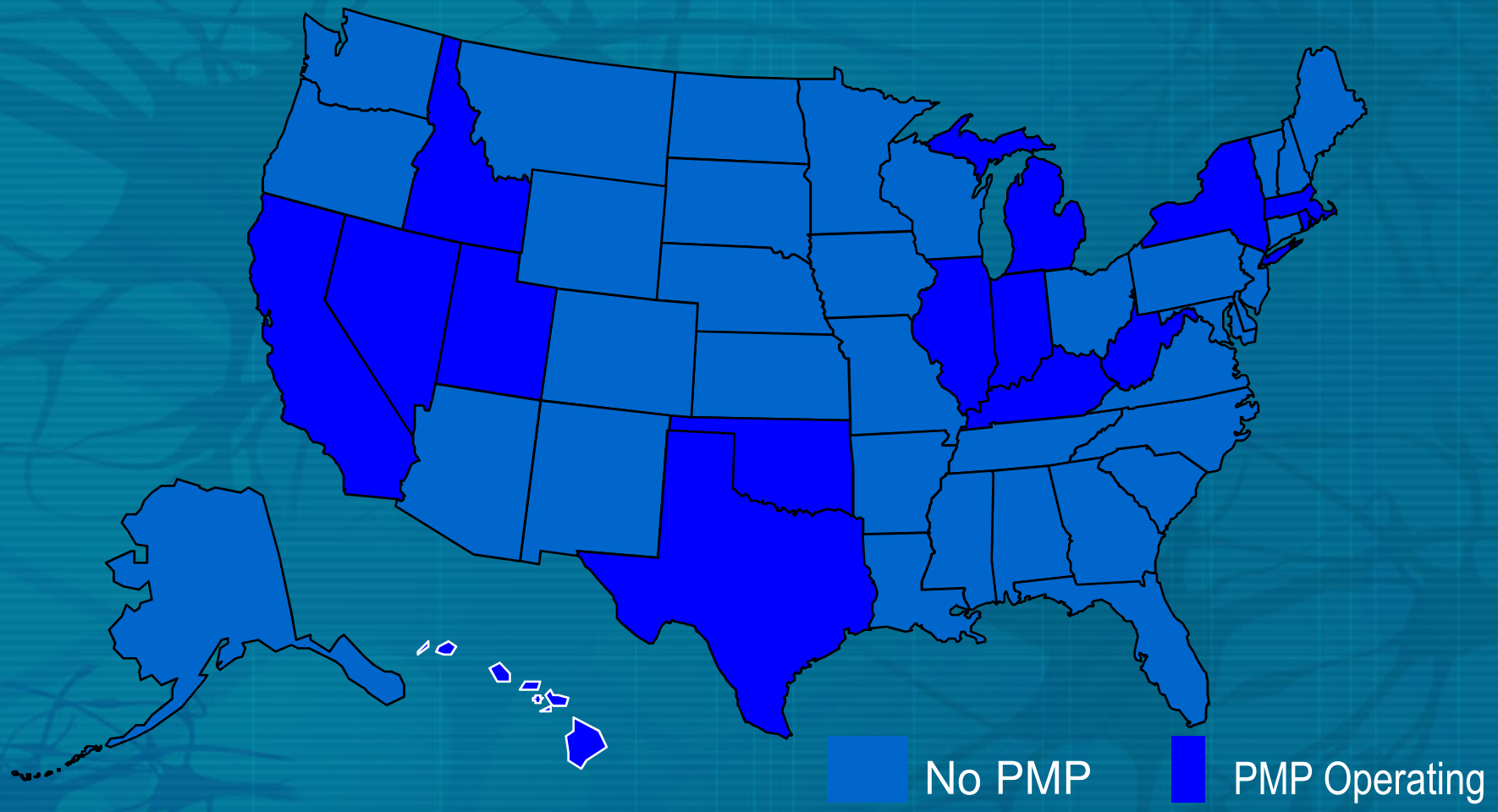
Drug Cross-Reactants

Drug	Cross-Reactant
Cannabinoids	NSAIDs, dronabinol, pantoprazole
Opioids	Poppy seeds, chlorpromazine, rifampin, dextromethorphan quinine
Amphetamines	Ephedrine, methylphenidate, trazodone, bupropion, desipramine, amantadine, ranitidine, phenylpropanolamine,
PCP	Chlorpromazine, thioridazine, meperidine, dextromethorphan, diphenhydramine, doxylamine
Benzodiazepine	Oxaprozin, some herbal agents
Ethanol	Asthma inhalers (in some cases)
Methadone	Propoxyphene, quetiapine

NSAIDs, nonsteroidal anti-inflammatory drugs; PCP, phencyclidine

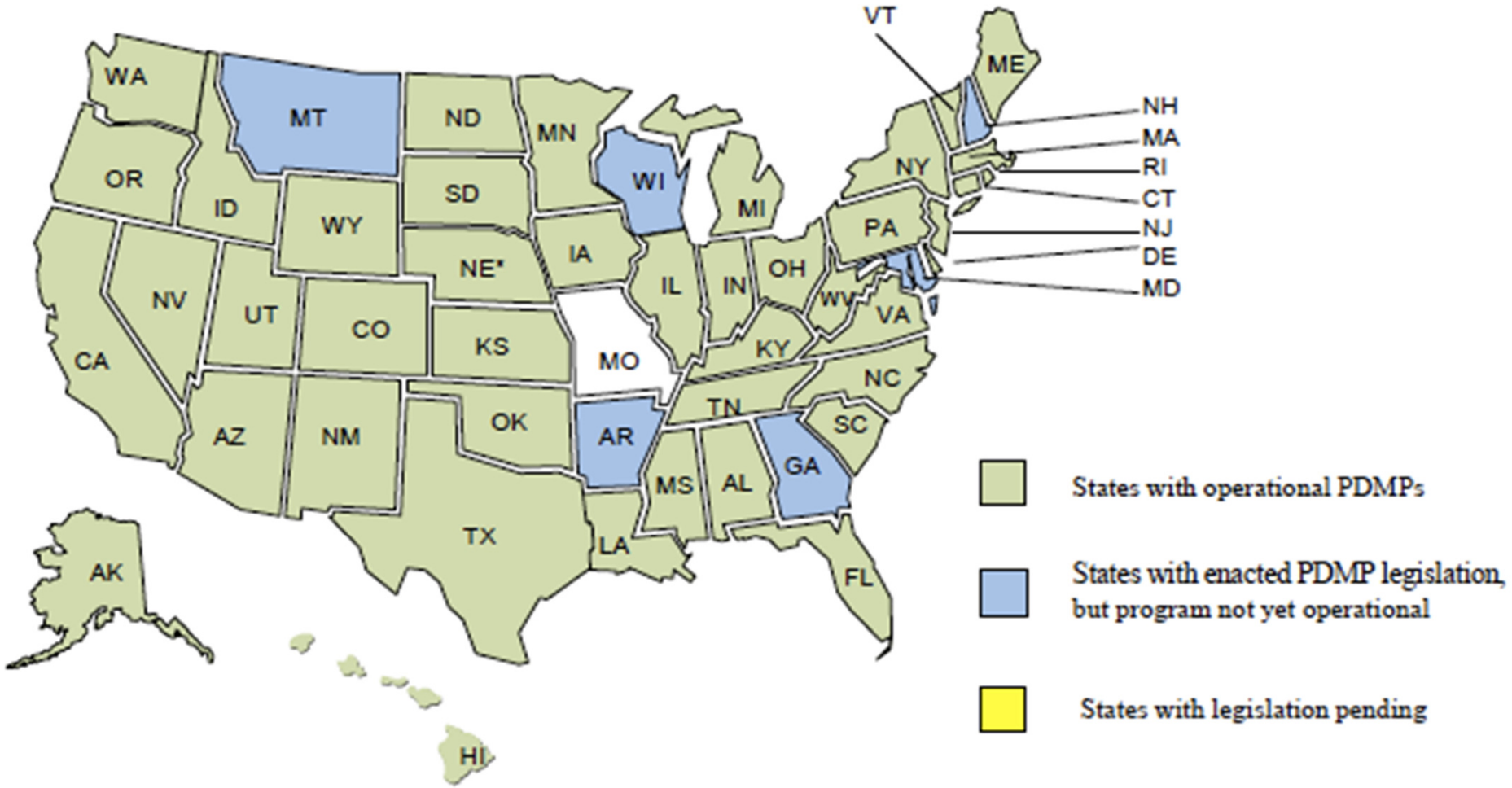
Manchikanti L et al. *Pain Physician*. 2008;11:S155-S180.

State Prescription Drug Monitoring Programs Status, 2003



National Alliance for Model State Drug Laws.

State Prescription Drug Monitoring Programs Status, July 2012



National Alliance for Model State Drug Laws. Status of State Prescription Monitoring Programs - State Map. July 2012. Reprinted with permission. © 2012 The National Alliance for Model State Drug Laws (NAMSDL).

CURES: Prescription Drug Monitoring California

CURES: A**cronym** for the Controlled Substance Utilization Review and Evaluation System

https://pmp.doj.ca.gov/pdmp/index.do

Tools & Resources
Health Information Privacy (HIPAA Guidelines)
FAQ's

PDMP (CURES)

User Agreement

The California Prescription Drug Monitoring Program (PDMP), **CURES**, is committed to assisting in the reduction of pharmaceutical drug diversion without affecting legitimate medical practice and patient care. The CURES system is designed to identify and deter drug abuse and diversion through accurate and rapid tracking of Schedule II through IV controlled substances. The role of the PDMP entrusts that well informed prescribers and pharmacists can and will use their professional expertise to evaluate their patients care and assist those patients who may be abusing controlled substances.

The information obtained herein is only made available to Practitioners, Pharmacists, Law Enforcement, and Regulatory Boards as specified under Health and Safety (H&S) Code Section 11165(a) by the Department of Justice, Bureau on Narcotic Enforcement. All users of the PDMP system shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients as specified under H&S Code Section 11165(c). Any request for or release of controlled substance history shall be made in accordance with the Department of Justice guidelines, and is subject to the provisions of the Confidentiality of the Medical Information Act (Civil Code 56 et seq.).

Dissemination or distribution of this information to anyone other than the registered user is strictly prohibited. Disciplinary, civil or criminal actions will be taken by the Department of Justice and/or appropriate Regulatory Board.

HIPAA and all confidentiality and disclosure provisions of California Law cover the information contained in this database. All users must comply with HIPAA Privacy Rule Requirements when using the Prescription Monitoring Program System. US Department of Health and Human Services, HIPAA guidelines are located at http://www.hhs.gov/ocr/privacy/

By Logging into the PDMP system you understand and agree to the above terms.

Login Information

Username

Password case-sensitive

Login

Forgot password | New users register here

Tools & Resources

Patient Activity Report
Theft or Loss of Prescriptions

FAQ's

Welcome to the PDMP Application

CURES

The California Prescription Drug Monitoring Program, **CURES**, is committed to assisting in the reduction of pharmaceutical drug diversion without affecting legitimate medical practice and patient care. The CURES program, restructured in 2003 and evolved from the California Triplicate Prescription Program following numerous legislative enactments.

The CURES system is designed to identify and deter drug abuse and diversion through accurate and rapid tracking of Schedule II through IV controlled substances. It is a valuable investigative, preventive and educational tool for law enforcement, regulatory boards, educational researchers, and the healthcare community.

The Prescription Drug Monitoring Program system allows pre-registered users including licensed healthcare prescribers and pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient prescription history information to better identify and prevent the abuse of prescription drugs. The role of the Prescription Drug Monitoring Program entrusts that well informed prescribers and pharmacists can and will use their professional expertise to evaluate their patients care and assist those patients who may be abusing controlled substances.

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Notifications & Alerts

Date	Notification
08-02-2011	Counterfeit Prescriptions San Diego Alert 15
08-02-2011	Fraudulent Prescriptions San Diego Alert 16
08-02-2011	Fraudulent Prescriptions San Diego Alert 17
08-02-2011	Fraudulent Prescriptions San Diego Alert 18
06-28-2011	Fraudulent Prescriptions Los Angeles Alert 14

State *of* California Department *of* Justice

Office *of the* Attorney General

Kamala D. Harris

Attorney General

AG Home Page | PDMP Home Page | Patient Activity Report | Change Password | HELP | Logout

Logged in, bimccarb

Tools & Resources

- Patient Activity Report
- Theft or Loss of Prescriptions
- FAQ's

Patient/Client Activity Report

* Indicates Required Fields

Client

Last Name* First Name*

Date of Birth* mm/dd/yyyy Gender

Address

City State Zip

Period in Months* 3

Search Mode

Search Mode (•) Partial match ( ) Exact match

* [ ] I certify, under the penalty of perjury, that I am a licenced healthcare provider and I am authorized to obtain the above mentioned patient's dispensed controlled substance history.

Search Reset

Low Back Pain Initial Presentation

- 52-year-old presents with acute low back pain
- Patient reports he has had recurrent minor injuries which resolve quickly
- Current pain is 6/10 in the right low back radiating down right leg to lateral foot
- Examination is unremarkable except for right of midline tenderness at L5-S1 and a positive right straight leg raise
- Prescribed stretches, rest, ice, anti-inflammatory, muscle relaxant
- Off work 7 days due to physical job and no availability of modified duty
- Follow-up appointment scheduled for 1 week

Low Back Pain, First Follow-Up Visit

- Pain does not resolve in 1 week
- Patient now reports that due to the pain, he has had a disruption of sleep, mood, and his hobbies – irritable
- Hydrocodone/acetaminophen prescribed, more time off work (2 weeks), and physical therapy is ordered

Low Back Pain, Second Follow-Up Visit

- 2 weeks later – mild improvement in sleep with hydrocodone/acetaminophen
- Pain is 5/10 with decreased radiation in the right leg, and he is able to move around the house more
- Patient is walking daily, but still unable to return to his physically demanding job
- Referred to physical medicine subspecialist

Low Back Pain, Third Follow-Up Visit

- Pain 6/10 mainly axial low back pain on the right
- Pain radiates to right leg with prolonged standing or walking
- Sleep, mood, hobbies all disrupted
- Lost job, now on disability
- Has been on anti-inflammatories, muscle relaxants, hydrocodone for 6 weeks

What Are the Requirements and How Should They Be Implemented

- Diabetes has measurable outcomes and national standards
- Pain management has no applicable standards only guidelines

Federation of State Medical Boards

- 2004 Model Policy for the Use of Controlled Substances for the Treatment of Pain
- 28 state medical boards have adopted the model policy verbatim, and 10 other states have adopted guidelines with similar language
  1. Evaluation of the patient
  2. Treatment plan
  3. Informed consent and agreement for treatment
  4. Periodic review
  5. Consultation
  6. Medical records
  7. Compliance with controlled substances laws and regulations

Federation of State Medical Boards. 2004 Model Policy for the Use of Controlled Substances and Treatment of Pain. Available at: www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf

Medical Record Should Contain 10 Parts

1. History and physical examination
2. Diagnostic, therapeutic, and laboratory results
3. Evaluation and consultation
4. Treatment objectives
5. Discussion of risks and benefits of treatment
6. Informed consent
7. Treatment offered
8. Medication - type, date, dosage, quantity
9. Instructions and treatment agreement
10. Periodic review

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52-Year-Old Patient With Chronic Low Back Pain

- Wife reports to their family physician that her husband is now excessively consuming alcohol at night. He slurs his speech, has fallen down, and he is verbally abusive

Wife's Report

- Important collateral information
  - Importance of opioid agreement to talk to spouse, family
- Opioid agreement
  - Understanding about other drug use including alcohol, marijuana
- Information
  - Alcohol problem
  - Makes treatment more difficult
- Discuss with patient
  - Referral

Fourth Follow-Up Visit and Chart Note

- Always been anxious, even as a child
- Positive family history for depression
- Previous episodes of depression resulted in loss of job
- Patient states that medication helps decrease pain and increase function, but it also helps him handle anxiety and sleep better
- Experimented with alcohol and marijuana when younger and improved anxiety, but
  - "I did not like taking that illegal stuff"
  - "Besides, it really messed up my family"

Fourth Follow-Up Visit and Chart Note

- Overuse of alcohol reported
- Discussed with patient
  - Patient agreed to stop all alcohol
  - Agreed to attend Alcoholics Anonymous
- Patient's pain has decreased, and function has improved on current regimen
- Urine drug test
- Consider chemical dependency referral

Opioid Risk Tool

	Female	Male
1. Family hx of substance abuse		
Alcohol	❑ 1	x 3
Illegal drugs	❑ 2	x 3
Prescription drugs	❑ 4	❑ 4
2. Personal hx of substance abuse		
Alcohol	❑ 3	x 3
Illegal drugs	❑ 4	x 4
Prescription drugs	❑ 5	❑ 5
3. Age between 14-45 yrs	❑ 1	❑ 1
4. Hx of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychologic disease		
ADD, OCD, bipolar, schizophrenia	❑ 2	❑ 2
Depression	❑ 1	x 1
Scoring totals:		14

Administration

- On initial visit
- Prior to opioid therapy

Scoring (risk)

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Summary

- REMS is coming
- Opioid abuse is a problem
- Unintended consequences could be devastating
- Primary care has to do a better job
- Consultations especially psychosocial services vital to increase primary care competence and comfort

REMS, Risk Evaluation and Mitigation Strategies