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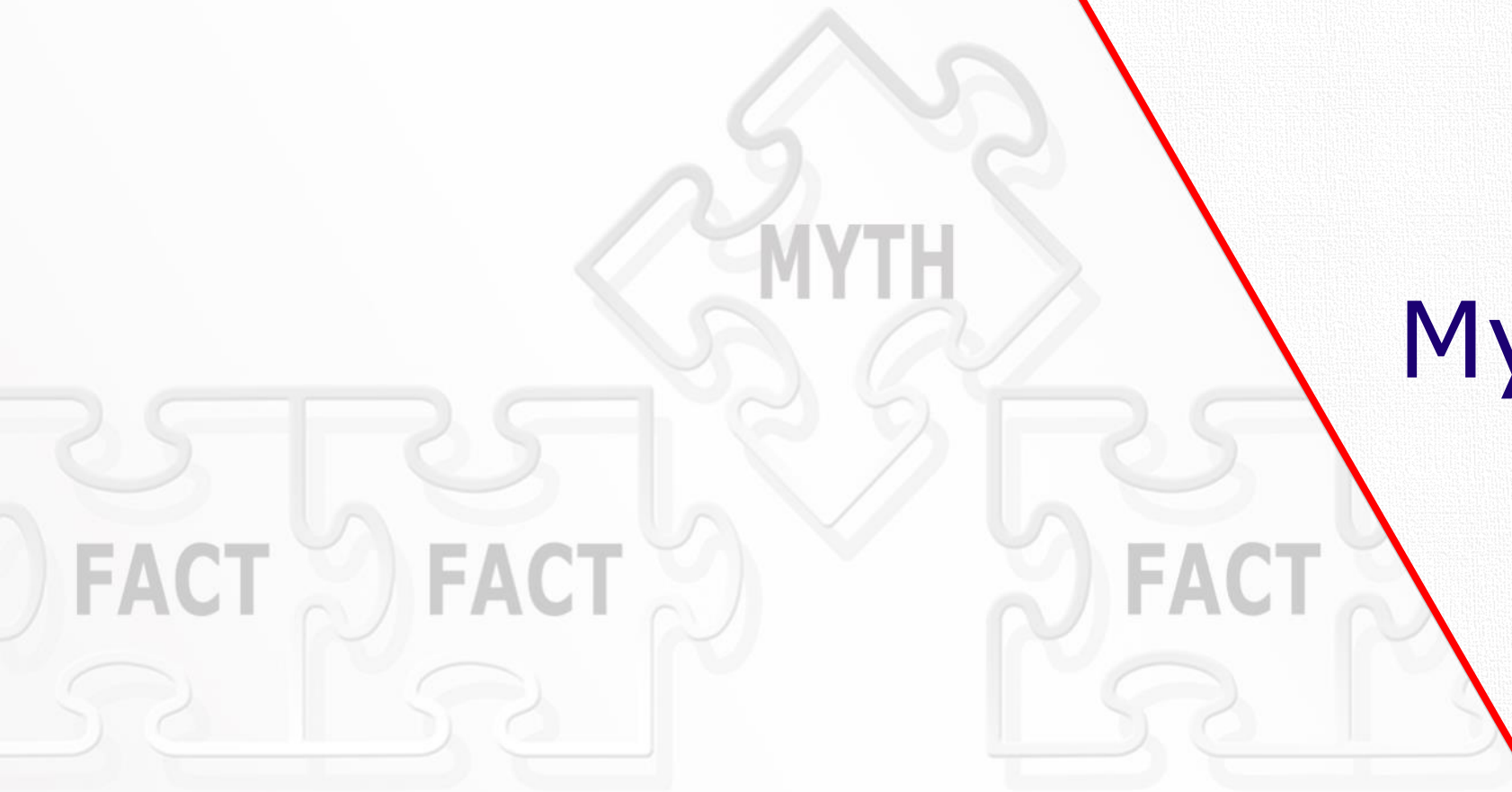

Myths and Facts about Opioids

Collaborators

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Milken Institute School of Public Health
THE GEORGE WASHINGTON UNIVERSITY

GEORGETOWN UNIVERSITY

More resources available at the DC Center for Rational Prescribing

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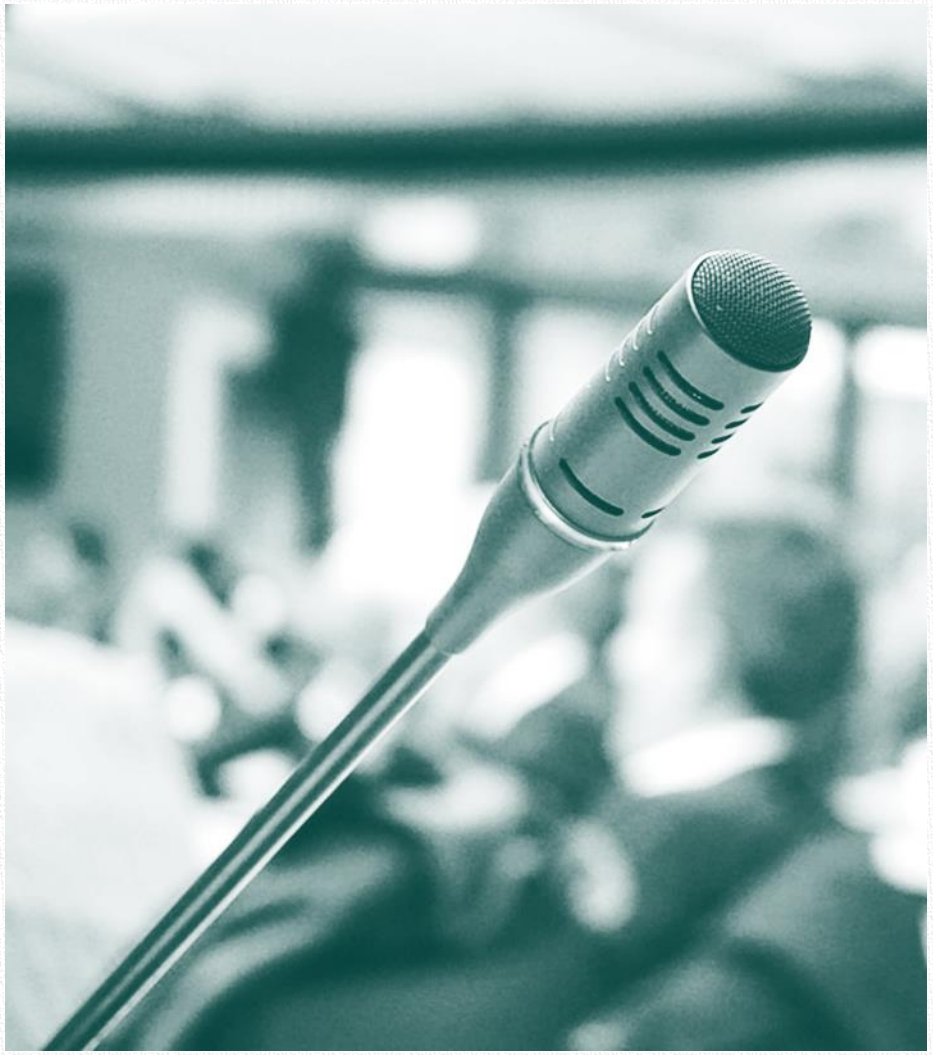
Presented by



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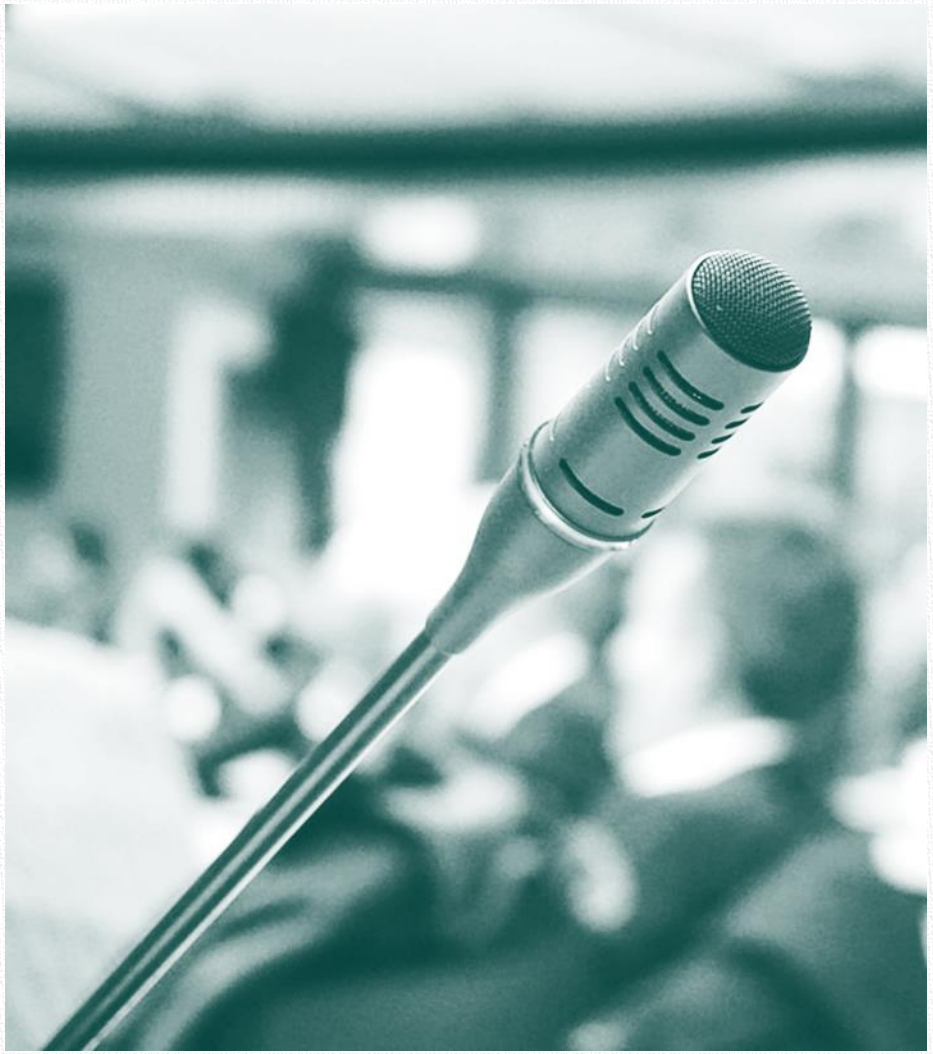

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- Anna Lembke, MD
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- Christina Prather, MD
- Shauna White, PharmD, RPh
- Susan Wood, PhD

Harrison Narcotics Act

- Passed in 1914
- Aimed at curbing cocaine and heroin abuse and addiction
- Required all importers, exporters, distributers, and manufacturers of opium to pay a tax

(Council on Foreign Relations 2016)

Important Information

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The slides will progress at their own pace.

Do not attempt to speed up the video.

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The video can be paused and resumed later.

Learning Objectives

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- **Describe** The public health impact of opioid abuse in the United States.
- **Outline** The history of opioid prescribing and promotion.
- **Describe** Neuroadaptation as it relates to opioids.
- **List** common and severe adverse effects of opioids.

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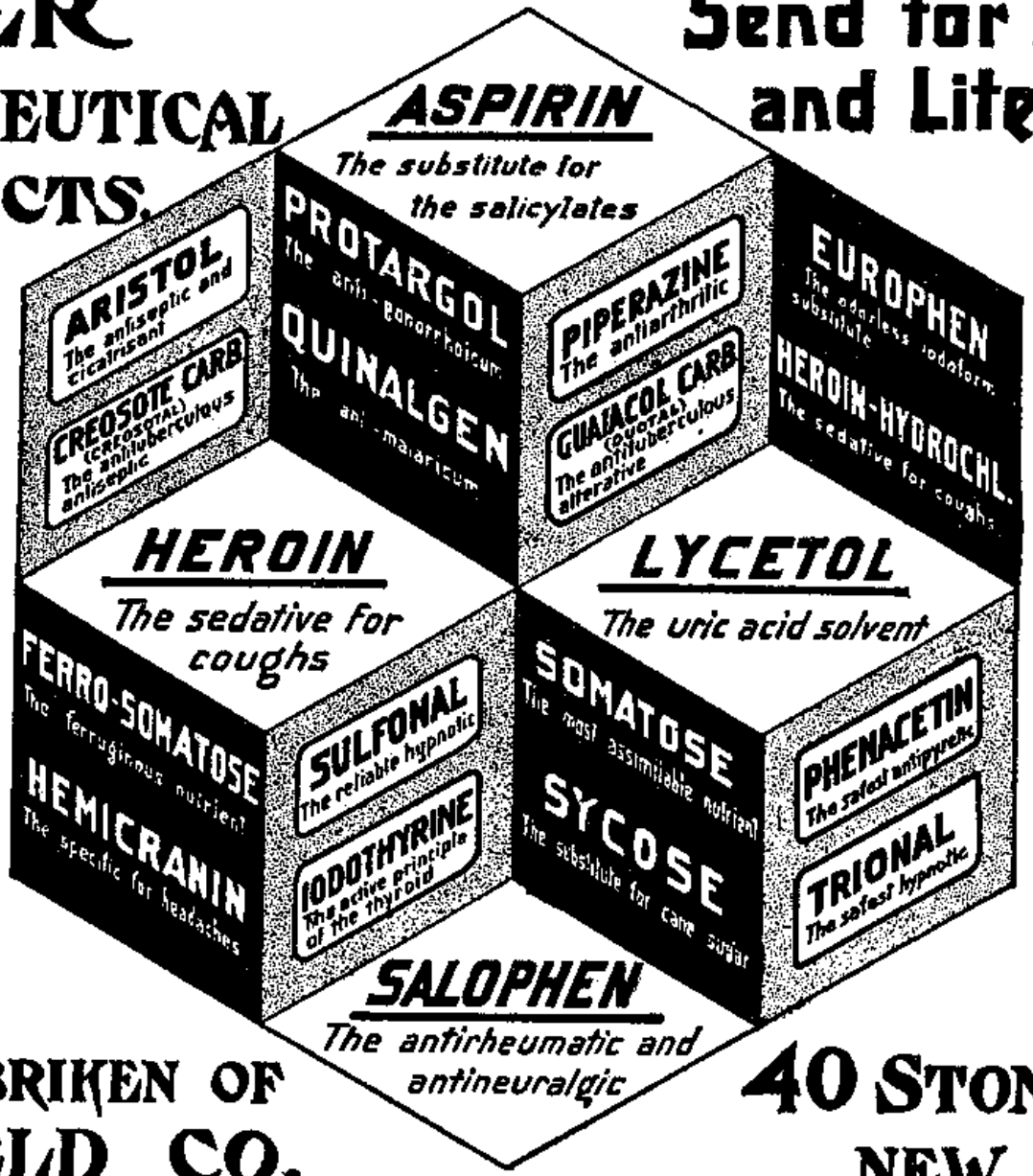

FARBENFABRIKEN OF ELBERFELD CO.

40 STONE STREET, NEW YORK.

Harrison Narcotics Act

- Passed in 1914
- Aimed at curbing cocaine and heroin abuse and addiction
- Required all importers, exporters, distributers, and manufacturers of opium to pay a tax

(Council on Foreign Relations 2016)

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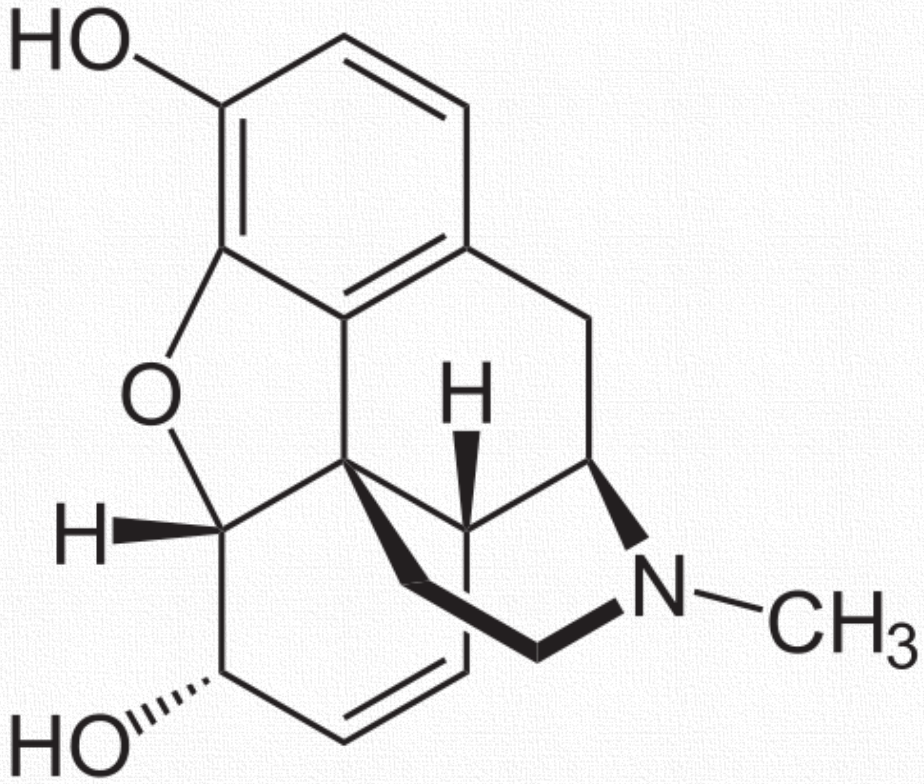
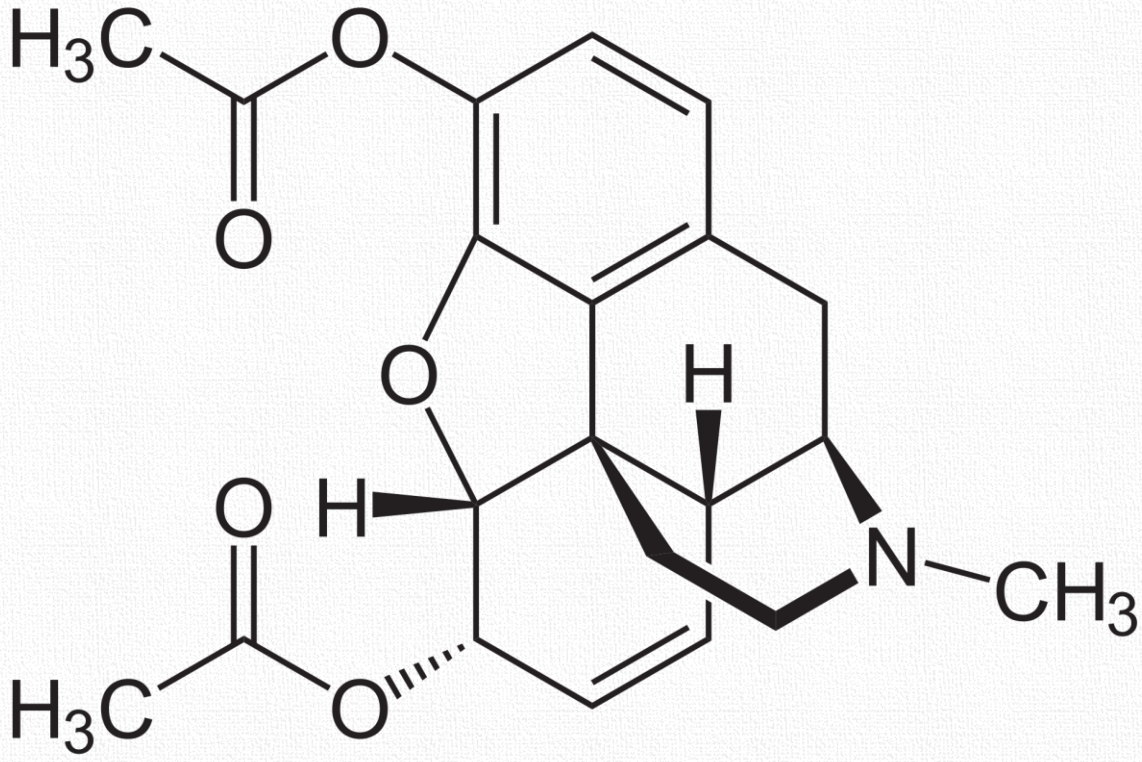


Morphine

vs.



Heroin


Pristiq
Plavix
Migraine
Provigil
Lipitor
Previgil
Januvia
Nasacort AQ
Lunesta
Zyrtec
Levitra
Xenical
Orlistat
Zyprexa
Levitra
Uroxatral
EMERGENCY
Lexapro
Benicar
Aciphex
Solodyn

PharmedOut

Physician Payment Sunshine Act

- Federal program that collects gifts given to physicians and teaching hospitals from pharmaceutical and device companies.

- In 2015, Open Payments reported $7.52 billion in gifts to physicians and teaching hospitals.
- To see all gifts, visit openpaymentsdata.cms.gov or projects.propublica.org/docdollars/

(CMS 2016)

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
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Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

NEJM 1980; 302(2):123.

Pain, 25 (1986) 171–186
Elsevier

PAI 00878

Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases

Russell K. Portenoy and Kathleen M. Foley

Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, and Department of Neurology, Cornell University Medical College, New York, NY 10021 (U.S.A.)

(Received 10 June 1985, accepted 28 October 1985)

Summary

Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy. Oxycodone was used by 12 patients, methadone by 7, and levorphanol by 5; others were treated with propoxyphene, meperidine, codeine, pentazocine, or some combination of these drugs. Nineteen patients were treated for four or more years at the time of evaluation, while 6 were maintained for more than 7 years. Two-thirds required less than 20 morphine equivalent mg/day and only 4 took more than 40 mg/day. Patients occasionally required escalation of dose and/or hospitalization for exacerbation of pain; doses usually returned to a stable baseline afterward. Twenty-four patients described partial but acceptable or fully adequate relief of pain, while 14 reported inadequate relief. No patient underwent a surgical procedure for pain management while receiving therapy. Few substantial gains in employment or social function could be attributed to the institution of opioid therapy. No toxicity was reported and management became a problem in only 2 patients, both with a history of prior drug abuse. A critical review of patient characteristics, including data from the 16 Personality Factor Questionnaire in 24 patients, the Minnesota Multiphasic Personality Inventory in 23, and detailed

Pain Specialist: Many Doctors Underprescribe For Chronic Pain

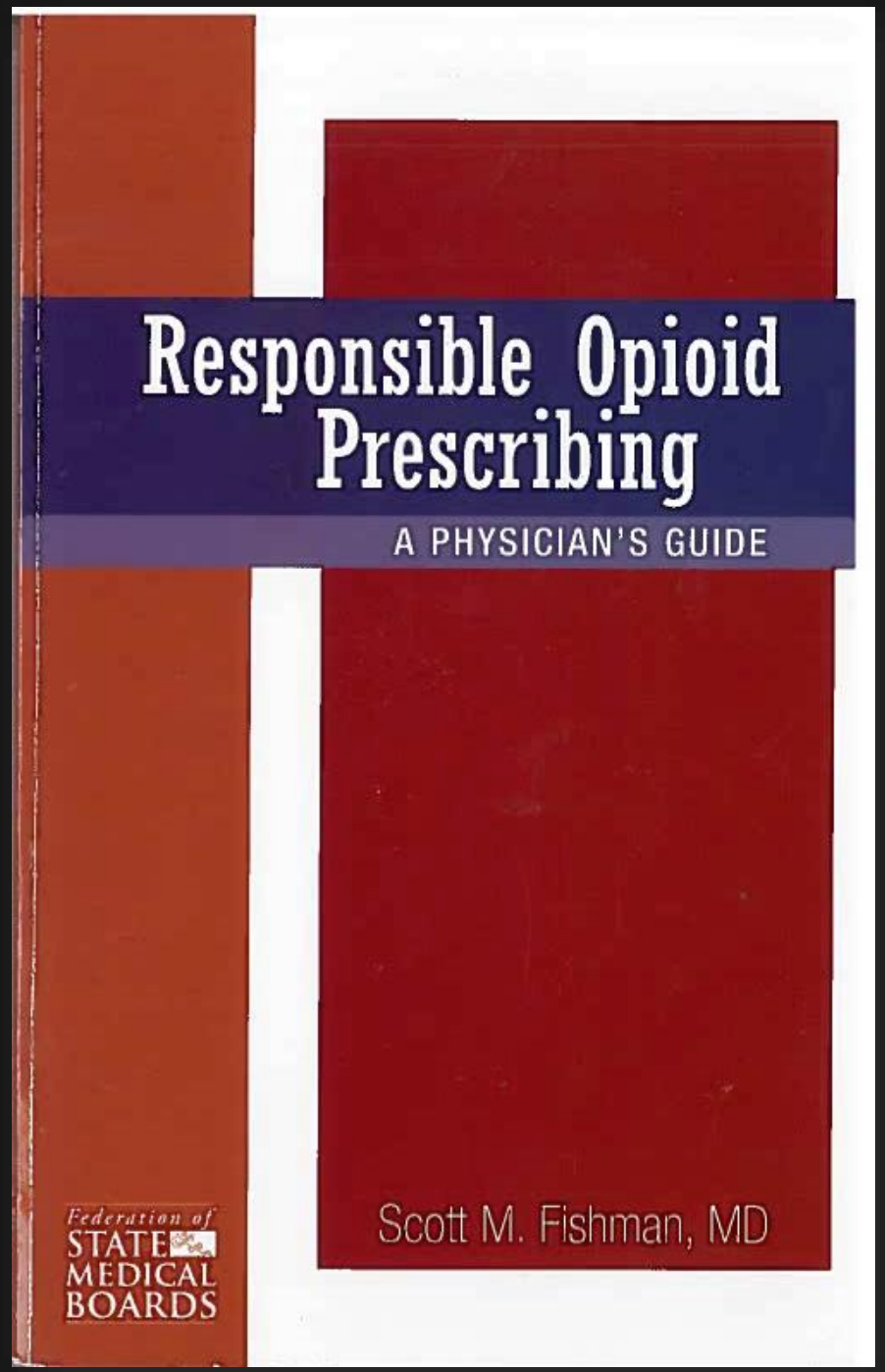
Inadequate pain treatment is a public health crisis

Drug war shouldn't claim new victims

Don't blame people for their pain, report says

Treating the Pain Epidemic

By JOHN TIERNEY NOVEMBER 5, 2009 3:23 PM



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Mayday Fund
National Pain Foundation
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Purdue Pharma L.P.
SAMHSA/CSAT (Substance Abuse and Mental Health Services Administration/Center for Substance Abuse Treatment)

Pain Analog Scale

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0 1 2 3 4 5 6 7 8 9 10

No Pain

Mild, annoying pain

Nagging, uncomfortable, troublesome pain

Distressing, miserable pain

Intense, dreadful, horrible pain

Worst possible, unbearable, excruciating pain

Pain as the 5th Vital Sign

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PAIN MANAGEMENT AND SEDATION/EDITORIAL

The Numeric Scoring of Pain: This Practice Rates a Zero Out of Ten

Steven M. Green, MD*; Baruch S. Krauss, MD, EdM

*Corresponding Author. E-mail: steve@stevegreenmd.com.

Measuring Pain as the 5th Vital Sign Does Not Improve Quality of Pain Management

Richard A. Mularski, MD, MSHS,[1,2] Foy White-Chu, MD,[3] Devorah Overbay, MS, RN,[4] Lois Miller, PhD, RN,[4] Steven M. Asch, MD, MPH,[1,2] Linda Ganzini, MD, MPH[5,6]

[1]VA Greater Los Angeles Healthcare System, Department of Medicine, Los Angeles, CA, USA; [2]The University of California, Los Angeles and RAND Health, Los Angeles, CA, USA; [3]Department of Medicine, Oregon Health & Science University, Portland, OR, USA; [4]School of Nursing, Oregon Health & Science University, Portland, OR, USA; [5]Department of Psychiatry, Oregon Health & Science University, Portland, OR, USA; [6]Portland Veterans Affairs Medical Center, Mental Health Division, Portland, OR, USA.

How Reliable is Pain as the Fifth Vital Sign?

Karl A. Lorenz, MD, MSHS, Cathy D. Sherbourne, PhD, Lisa R. Shugarman, PhD, Lisa V. Rubenstein, MD, MSPH, Li Wen, MD, Angela Cohen, MPH, Joy R. Goebel, RN, PhD, Emily Hagenmeier, MSW, Barbara Simon, MA, Andy Lanto, MA, and Steven M. Asch, MD, MPH

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December 2003

PRESCRIPTION DRUGS

OxyContin Abuse and Diversion and Efforts to Address the Problem

What GAO Found

Purdue conducted an extensive campaign to market and promote OxyContin using an expanded sales force to encourage physicians, including primary care specialists, to prescribe OxyContin not only for cancer pain but also as an initial opioid treatment for moderate-to-severe noncancer pain.

"Pseudoaddiction"

- Weissman DE, Haddox JD. Opioid pseudoaddiction -- an iatrogenic syndrome. Pain. 1989;36(3):363-6.

- **This was a single case study of a 17 year old with leukemia.**
  - "Inadequate treatment of the patient's pain led to behavioral changes similar to those seen with idiopathic opioid psychologic dependence."
  - Pseudoaddiction was described as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."

John Fauber's Articles on Opioids

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WATCHDOG REPORTS | SIDE EFFECTS | WATCHDOG UPDATE

Emails point to 'troubling' relationship between drug firms, regulators

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WATCHDOG REPORTS | A JOURNAL SENTINEL WATCHDOG REPORT

Charity's investment a prescription for profits for drug maker

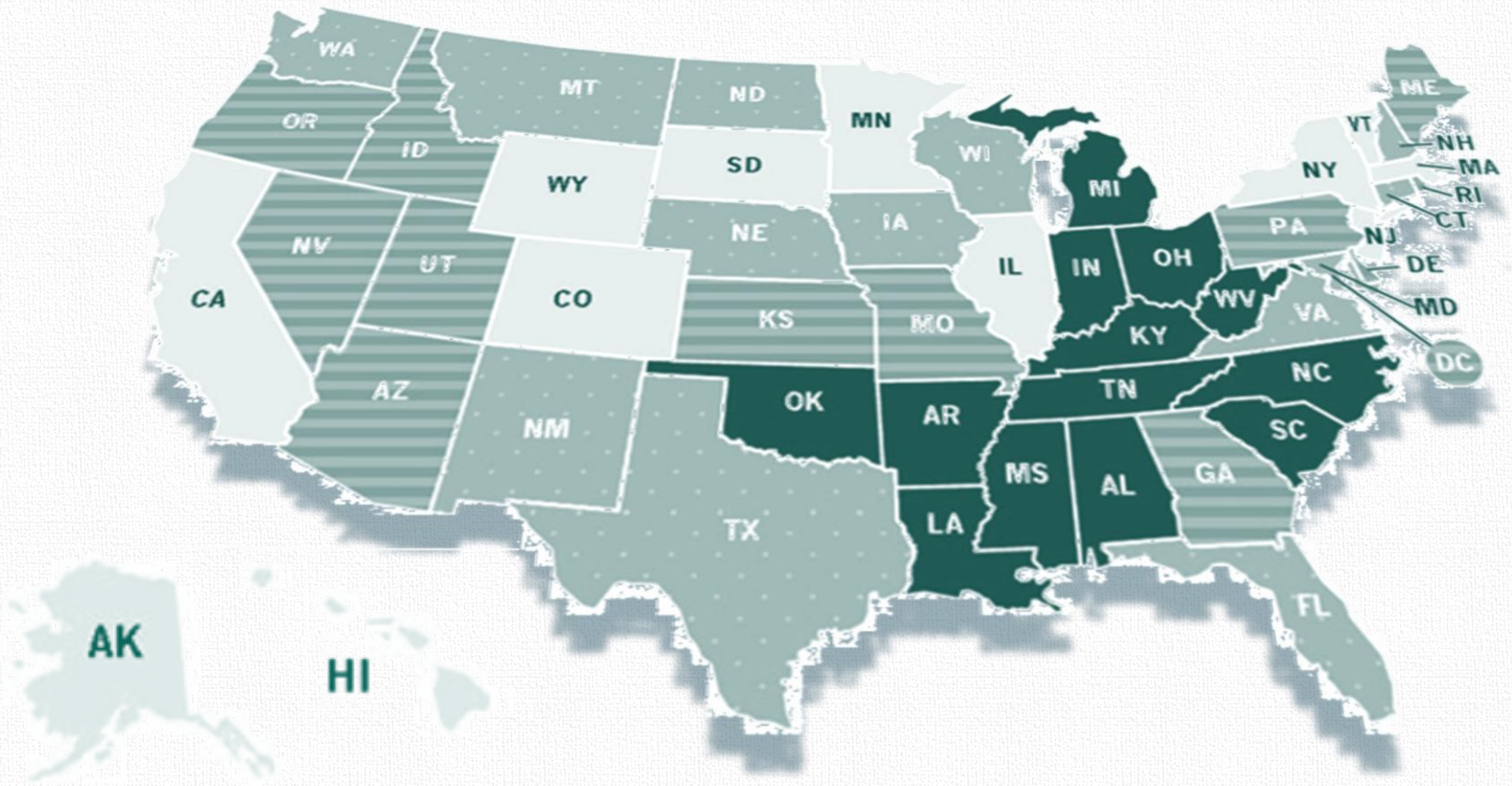
WATCHDOG REPORTS | SIDE EFFECTS | WATCHDOG REPORT

Painkillers, tranquilizers an increasingly fatal mix

WATCHDOG REPORTS | SIDE EFFECTS | A JOURNAL SENTINEL WATCHDOG REPORT

Painkiller boom fueled by networking

Opioid prescription rates vary across states

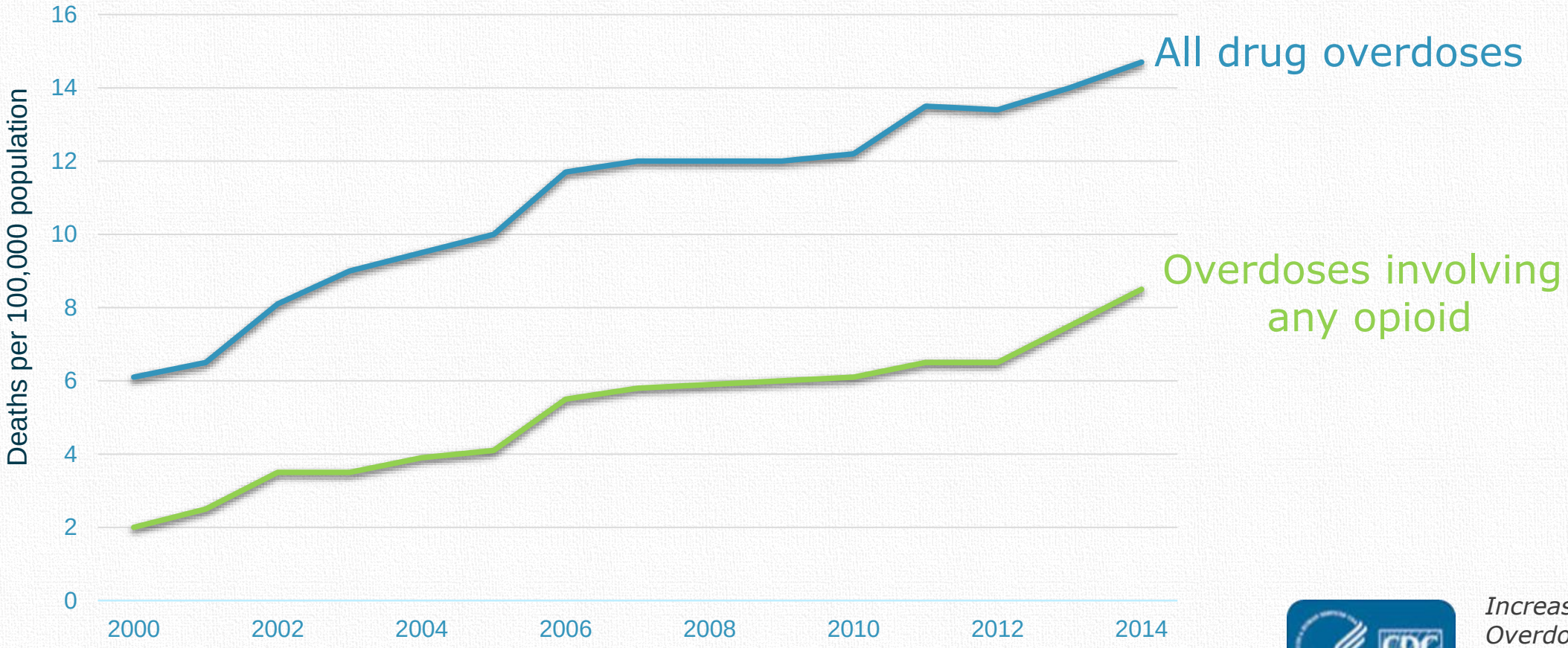


Number of painkiller prescriptions per 100 people

- 52 - 71
- 72 – 82.1
- 82.2 – 95
- 96 – 143

IMS, National Prescription Audit (NPA), 2012

Opioid Overdoses in the United States



Age adjusted rate of drug overdose deaths and drug overdose deaths involving opioids, United States, 2000-2014

Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014, MMWR, 2015.

Scheduled Drugs

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Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
High potential for abuse	High potential for abuse	Potential for abuse less than I and II	Potential for abuse less than III	Potential for abuse less than IV
No currently acceptable medical use	Currently acceptable medical use	Currently acceptable medical use	Currently acceptable medical use	Currently acceptable medical use
	Use may lead to dependence	Use may lead to moderate or low dependence	Use may lead to limited dependence	Use may lead to limited dependence
LSD	Oxycodone	Buprenorphine	Benzodiazepines	Promethazine + codeine
Cannabis	Methadone	Ketamine	Tramadol	Some anticonvulsants
Ecstasy	Amphetamines	Anabolic steroids		

The New York Times

BUSINESS DAY

In Guilty Plea, OxyContin Maker to Pay $600 Million

By BARRY MEIER MAY 10, 2007

The New York Times | http://nyti.ms/1Ttvwi1

The Opinion Pages | OP-ED CONTRIBUTOR

The Opioid Epidemic We Failed to Foresee

THE WALL STREET JOURNAL.

Painkiller Deaths Nearly Quadruple in a Decade

By TIMOTHY W. MARTIN
November 2, 2011

Press Release

For Immediate Release: November 1, 2011
Contact: CDC Online Newsroom
(404) 639-3286

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Prescription painkiller overdoses at epidemic levels

Kill more Americans than heroin and cocaine combined

Prince died from an overdose of a powerful painkiller described as 'heroin on steroids'

Injecting Opana: Indiana's HIV Outbreak and America's Opioid Epidemic

Naloxone Kit

Heroin Use and Overdose Deaths

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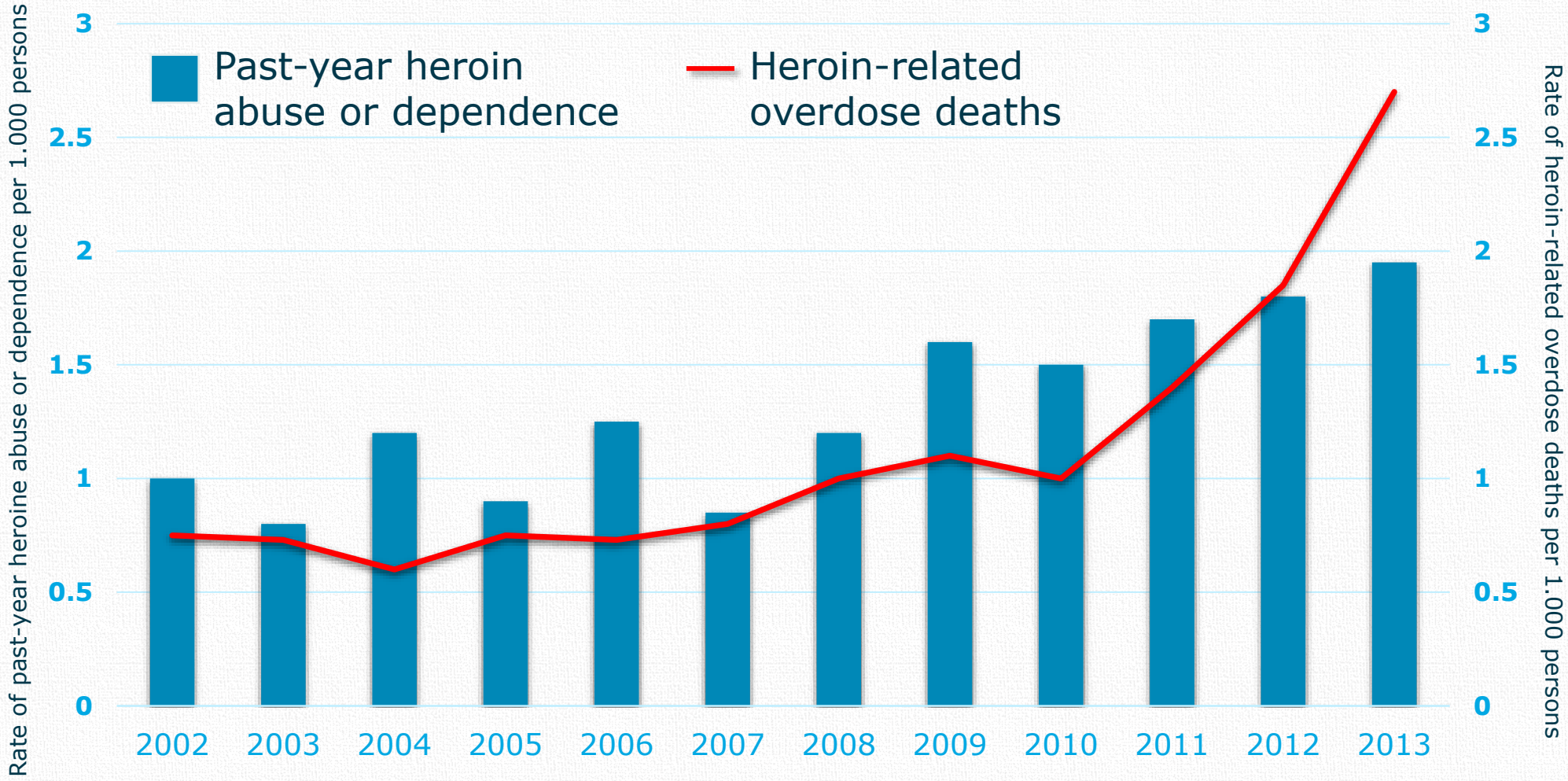

MMWR 2015; 64(26);719-725.

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In the 1960s, 80% of heroin addicts identified heroin as their first opioid.

Cicero TJ. JAMA Psych. 2014; 71(7): 821-6.

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Today, 80% of heroin addicts identify a prescription opioid as their first opioid.

Cicero TJ. JAMA Psych. 2014; 71(7): 821-6.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/d), or concurrent benzodiazepine use are present.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); detailed ratings of the evidence supporting the recommendations are provided in the full guideline publication.[11]

CDC Guideline for Prescribing Opioids for Chronic Pain, 2016

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Adverse Effects of Opioids

- Constipation
- Depression
- Hyperalgesia
- Memory Problems
- Opioid Withdrawal
- Loss of Libido/Sexual Function
- Increased risk of myocardial infarction

Mixing Benzodiazepines Increase Risk of Overdose

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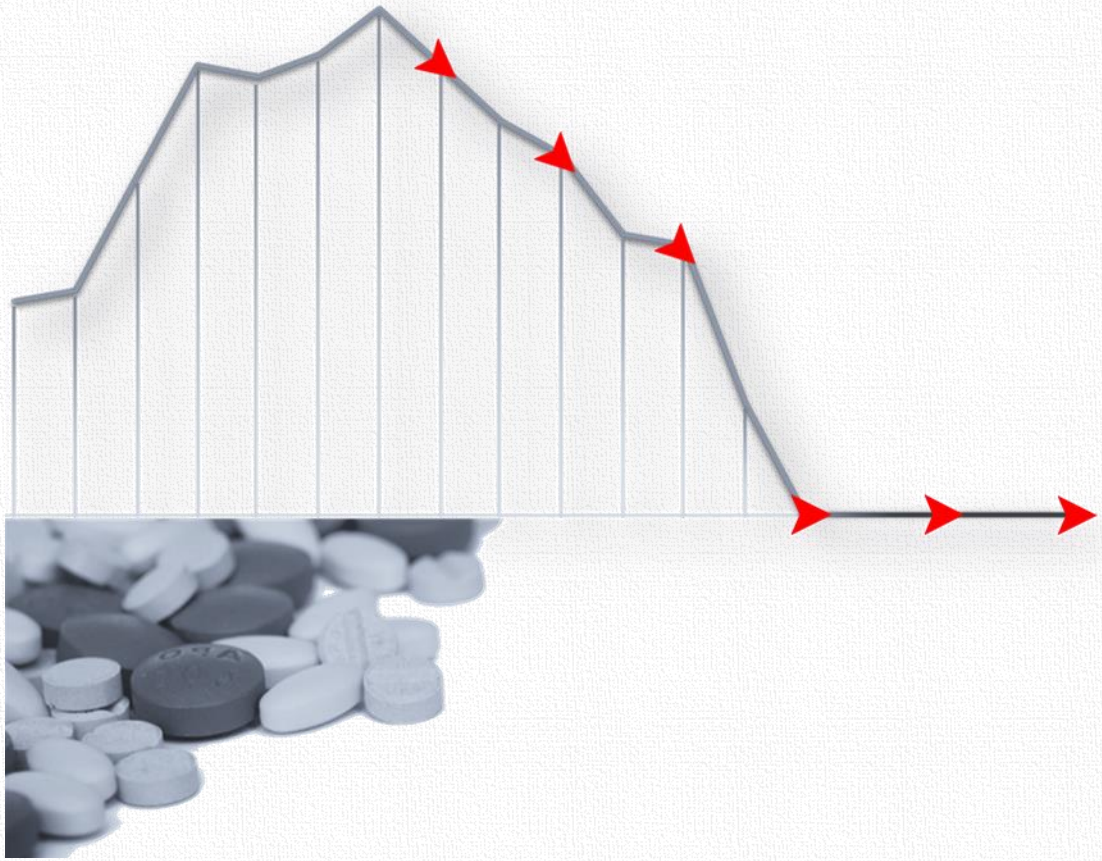
Tolerance



When a patient begins to lose the beneficial effects of a drug.

Dependence

If a patient tries to discontinue a medication, the patient goes into withdrawal.

Myths about Opioids

- ✗ “Magic halo” effect
- ✗ Opioids work for chronic pain
- ✗ No dose is too high
- ✗ Pseudoaddiction

PROVEN TWICE-A-DAY (EVERY 12-HOUR) DOSING TO HELP YOUR PATIENTS STAY AHEAD OF PAIN™

Indication

- OPANA® ER is indicated for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time[1]
- OPANA® ER is not intended for use as a prn analgesic[1]
- OPANA® ER is not indicated for pain in the immediate post-operative period (12-24 hours following surgery) for patients not previously taking opioids because of the risk of oversedation and respiratory depression requiring reversal with opioid antagonists[1]
- OPANA® ER is not indicated for pain in the post-operative period if the pain is mild or not expected to persist for an extended period of time[1]

Important Safety Information[1]

WARNING: OPANA® ER contains oxymorphone, which is a morphine-like opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics.

Oxymorphone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OPANA® ER in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OPANA® ER is an extended-release oral formulation of oxymorphone indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

OPANA® ER is NOT intended for use as a prn analgesic.

OPANA® ER TABLETS are to be swallowed whole and are not to be broken, chewed, dissolved, or crushed. Taking broken, chewed, dissolved, or crushed OPANA® ER TABLETS leads to rapid release and absorption of a potentially fatal dose of oxymorphone.

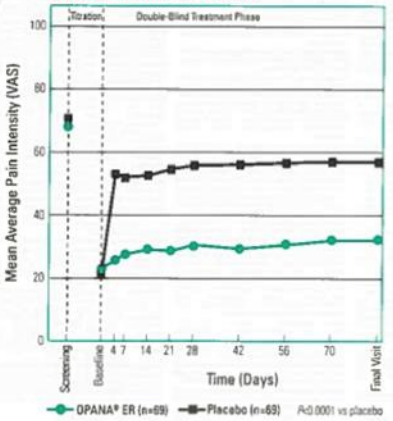
Patients must not consume alcoholic beverages, or prescription or nonprescription medications containing alcohol, while on OPANA® ER therapy. The co-ingestion of alcohol with OPANA® ER may result in increased plasma levels and a potentially fatal overdose of oxymorphone.

- OPANA® ER is **contraindicated** in patients with a known hypersensitivity to oxymorphone hydrochloride, morphine analogs such as codeine, or any of the other ingredients of OPANA® ER; in patients with moderate or severe hepatic impairment or in any situation where opioids are contraindicated such as: patients with respiratory depression (in the absence of resuscitative equipment or in unmonitored settings), acute or severe bronchial asthma, hypercarbia, and in any patient who has or is suspected of having paralytic ileus
- OPANA® ER is not indicated for pain in the immediate post-operative period (the first 12–24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OPANA® ER is only indicated for post-operative use if the patient is already receiving the drug prior to surgery or if the post-operative pain is expected to be moderate or severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate (see American Pain Society guidelines)
- Respiratory depression is the chief hazard of OPANA® ER, particularly in elderly or debilitated patients. OPANA® ER should be administered with extreme caution to patients with conditions accompanied by hypoxia, hypercapnia, or decreased respiratory reserve such as: asthma, chronic obstructive pulmonary disease or cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, central nervous system (CNS) depression, or coma
- Patients receiving other opioid analgesics, general anesthetics, phenothiazines or other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) may experience additive effects resulting in respiratory depression, hypotension, profound sedation, or coma
- OPANA® ER should be used with caution in elderly and debilitated patients and in patients who are known to be sensitive to CNS depressants, such as those with cardiovascular, pulmonary, renal, or hepatic disease. OPANA® ER should be used with caution in patients with mild hepatic impairment and in patients with moderate to severe renal impairment. These patients should be started cautiously with lower doses of OPANA® ER while carefully monitoring for side effects
- The most common adverse drug reactions (≥10%) in all clinical trials for OPANA® ER were nausea, constipation, dizziness (excluding vertigo), vomiting, pruritus, somnolence, headache, increased sweating, and sedation
- Patients and their families should be instructed to flush any OPANA® ER tablets that are no longer needed

Durable analgesic effect demonstrated in *opioid-experienced* patients with moderate to severe pain[1]

80% of patients maintained the analgesic effect of OPANA® ER over a 3-month period[1]

Average Pain Intensity Over Time for Opioid-Experienced Patients[2]



- Mean change from baseline to final visit in average pain intensity (VAS*) was 8 mm for OPANA® ER and 32 mm for placebo ($P<0.0001$)[2]; median change was 2 mm for OPANA® ER and 38 mm for placebo[2]
- Median daily dose of OPANA® ER was 60 mg (20–260 mg)[2]
- Mean stabilized dose of OPANA® ER was 87.2 mg/day[2]
- The most common adverse drug reactions for OPANA® ER (≥5%) in this clinical trial were nausea, constipation, headache, somnolence, vomiting, pruritus, and dizziness

This was a 12-week, randomized, double-blind, placebo-controlled study in 142 opioid-experienced patients with moderate to severe chronic low back pain. Each patient had to be receiving a stable dose of an opioid (≥60 mg morphine equivalents) for pain for at least 2 weeks prior to screening. Following screening there was a 4-week, open-label titration phase during which each patient initially received OPANA® ER every 12 hours at a dose approximately equivalent to the individual's prestudy opioid dose requirement. Patients were titrated as needed at increments of 10 mg every 12 hours every 3–7 days to a stabilized dose. OPANA® (oxymorphone hydrochloride) 5 mg every 4–6 hours prn was provided as supplemental rescue medication. Patients were considered stabilized when they achieved adequate analgesia (40 mm on 100-mm VAS) for 3 of 5 consecutive days while receiving the same dose of OPANA® ER and requiring no more than 2 doses of rescue medication per day. Patients were then randomized to remain on their OPANA® ER dose or receive placebo for the 12 weeks of the double-blind treatment period. Patients were allowed as much supplemental rescue medication as needed (OPANA® 5 mg tablets every 4–6 hours prn) for the first 4 days of this period; thereafter limited to a maximum of 2 doses per day (maximum of 10 mg OPANA® per day).[1,2]

* VAS = visual analog scale.

†**Patients reported a decrease, no change, or a ≤10 mm increase in VAS score from Day 7 until the end of the study[2].**

References: 1. OPANA® ER Full Prescribing Information. Chadds Ford, Pa: Endo Pharmaceuticals; 2006. 2. Data on file, Endo Pharmaceuticals, Inc., Chadds Ford, Pa.

Please see Brief Summary, including boxed WARNING, or visit www.opana.com for full Prescribing Information.

Rx Only
DEA Order Form Required

OPANA® ER
(oxymorphone HCl)

Extended-release tablets
5 mg, 10 mg, 20 mg, 40 mg

ENDO PHARMACEUTICALS
CHADDS FORD, PENNSYLVANIA 19317
www.Endo.com 1-800-462-ENDO

Tramadol

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DOH
DEPARTMENT OF HEALTH
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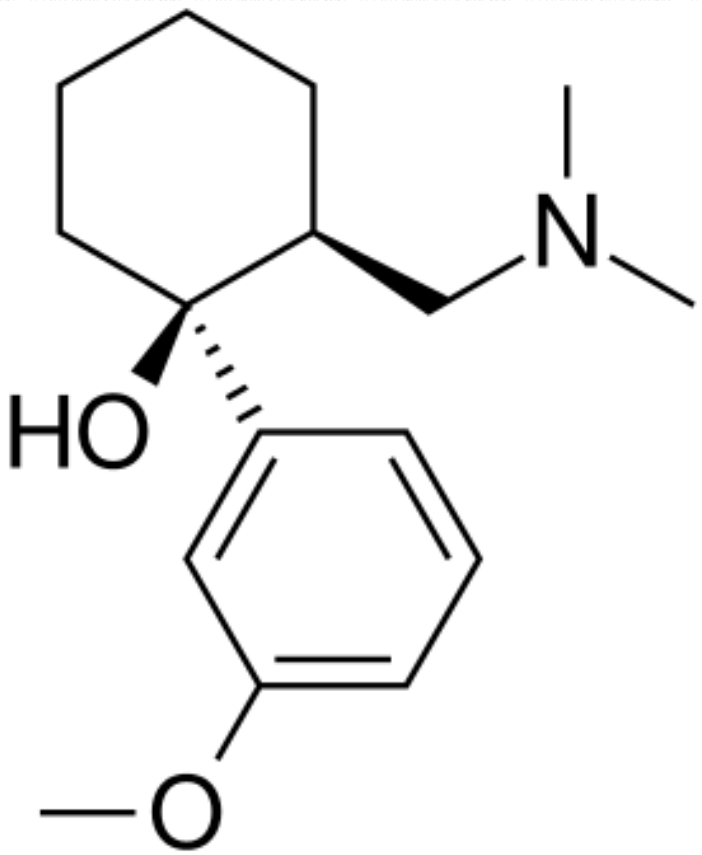
✗ Myth:

Tramadol is a non-addictive, non-opioid alternative.

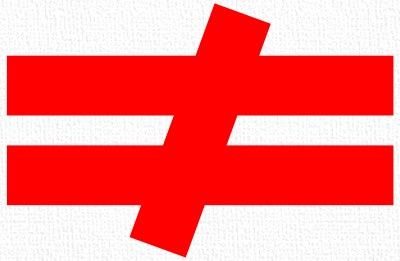


✓ Fact:

Tramadol is metabolized into an opioid and is addictive.

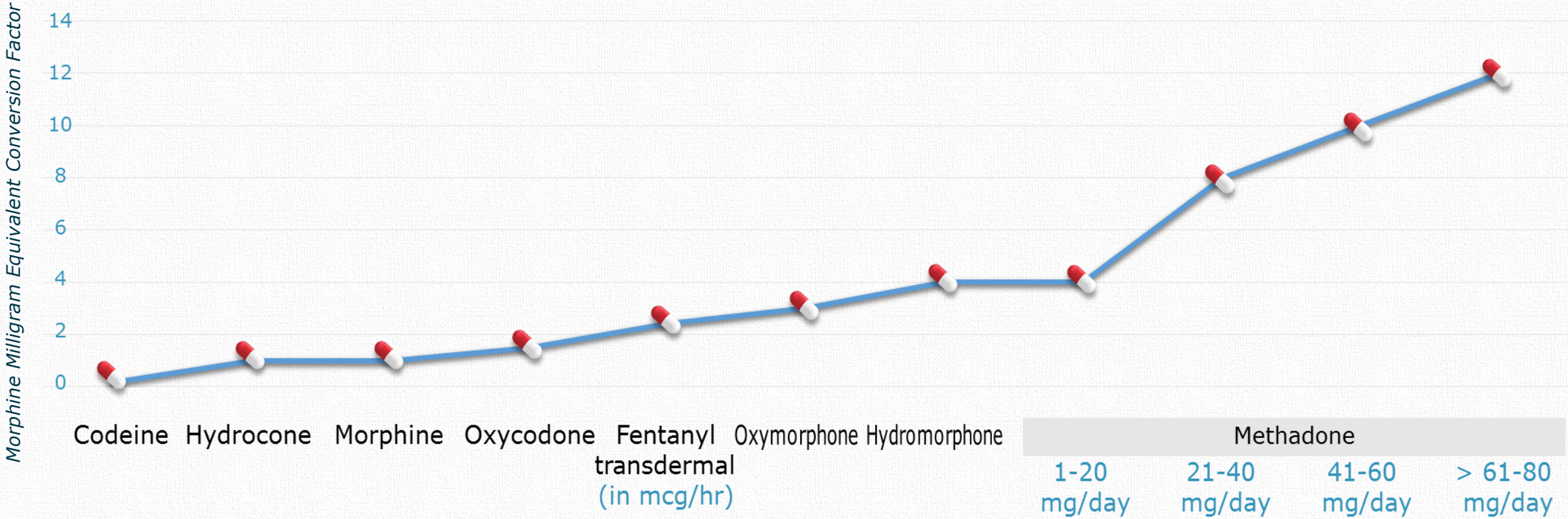
FDA Labeling

Abuse Deterrent



Non-addictive

Opioid Conversion Factors



These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

Rapid-Onset, Short- and Long-Acting Opioids

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Rapid-Onset

- Oral transmucosal fentanyl citrate
- Fentanyl buccal tablet
- Fentanyl buccal soluble film
- Sublingual fentanyl
- Intranasal fentanyl

Short-Acting

- Codeine
- Buprenorphine
- Morphine
- Oxymorphone (Opana)
- Oxycodon (OxyIR, Percocet)
- Tapentadol (Nucynta)
- Hydrocodone (Vicodin)
- Hydromorphone (Dilaudid)

Long-Acting

- Transdermal systems with fentanyl (Duragesic patches)
- Buprenorphine patch (Butrans)
- Extended release morphine (Kadian, MS Contin, Avinza)
- ER oxymorphone (Opana ER)
- ER Oxycodone (Oxycontin)
- Levorphanol (Levo-dromoran)
- Methadone
- ER hydromorphone (Exalgo)

(Archer 2014)

More resources available at the DC Center for Rational Prescribing

doh.dc.gov/dcrx

Other DCRx Modules

Medical Cannabis: An Introduction to the Biochemistry & Pharmacology

Medical Cannabis: Evidence on Efficacy

Medical Cannabis: Adverse Effects and Drug Interactions

Rational Prescribing in Older Adults

Drug Approval and Promotion in the United States

Generic Drugs: Myths and Facts

More resources available at the DC Center for Rational Prescribing

doh.dc.gov/dcrx