Pain Physicians & Opioid Epidemic

Ramsin Benyamin, MD
President,
Millennium Pain Center

Disclaimer

- Founder/President/Medical Director, Millennium Pain Center, Illinois:
  Bloomington-Normal, Decatur, Peoria, Pekin, Urbana-Champaign, Des Plaines, Libertyville, Chicago
- Co-founder, Millennium Pain Management Spain: Barcelona, Valencia

- Clinical Assistant Professor of Surgery, *College of Medicine, University of Illinois*
- Adjunct Professor of Clinical Research*, Illinois Weslyan University*

- Past-President, American Society of Interventional Pain Physicians (ASIPP)
- Board of Directors, SIPMS
- President, Illinois Society of Interventional Pain Physicians

- Board of Examiners, American Board of Interventional Pain Physicians (ABIPP)
- Member, Guidelines committee, ASIPP

- Section Editor (Neuromodulation), " Pain Physician"
- Editorial Board, " Pain Practice"
- Editorial Board, "Journal of Opioid Management"
- Reviewer, "Neurosurgery", "Neuromodulation", " Journal of Neuro-Interventional Surgery"

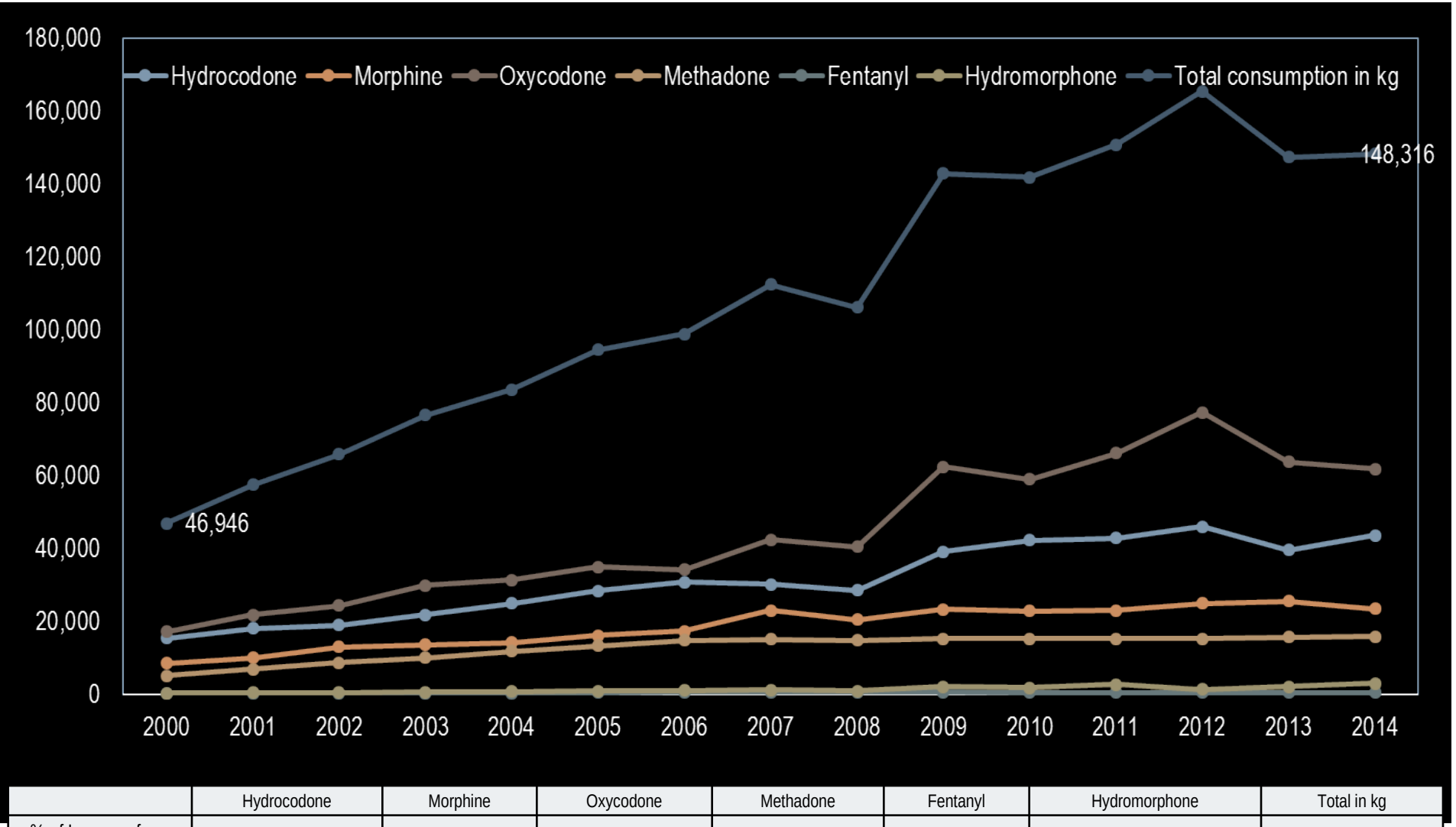
Opioid Epidemic

U.S. with 4.4% of World's Population in 2014

- Consumed 69.1% of World's opioid supply
- Consumed 99.7% of World's hydrocodone supply
- Consumed 73.1% of World's oxycodone supply

Source: Opioid Guidelines, Pain Physician 2017; 20:S3-S92

U.S. opioid consumption in kilograms from 2000 to 2014

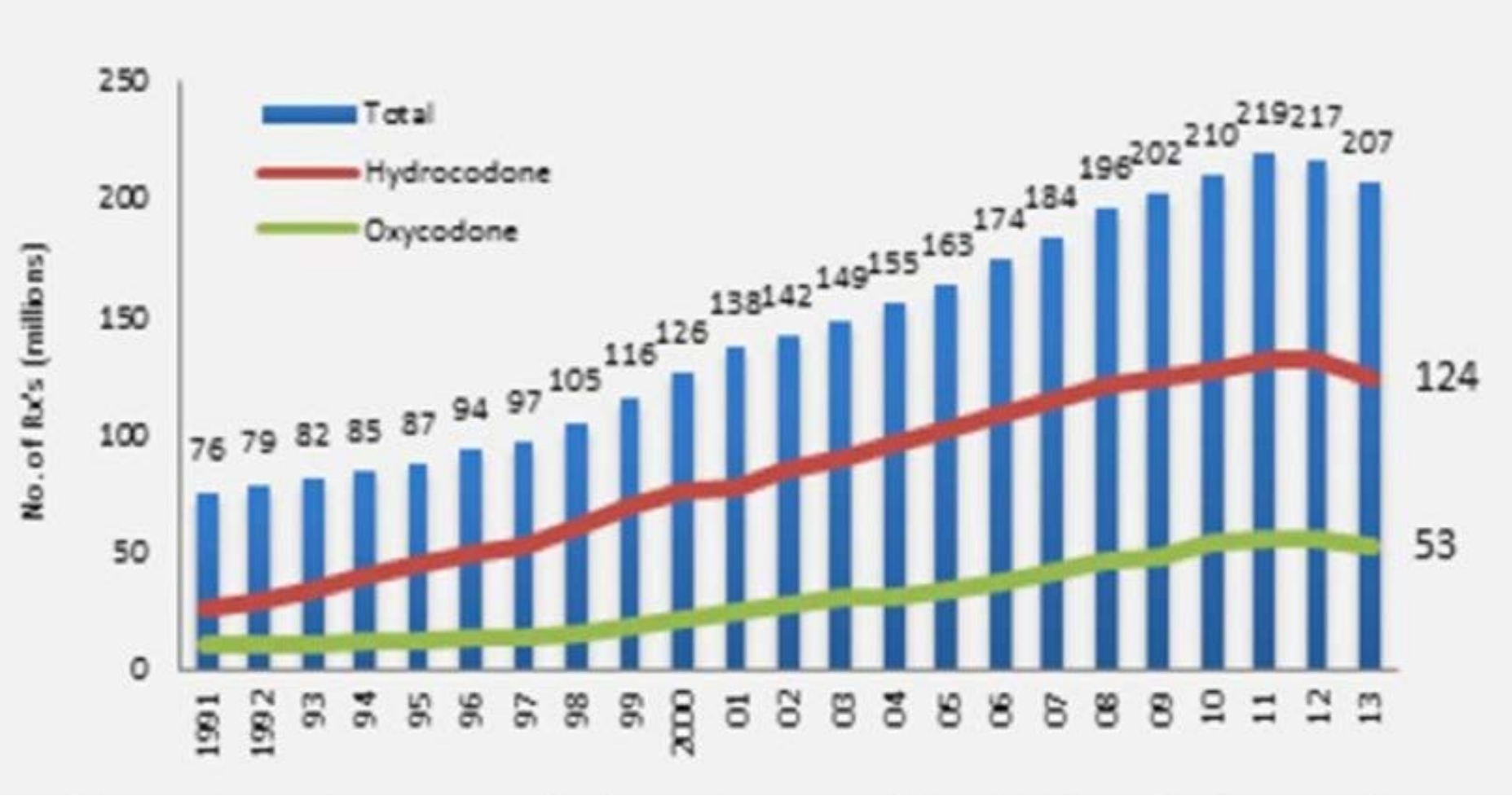


	Hydrocodone	Morphine	Oxycodone	Methadone	Fentanyl	Hydromorphone	Total in kg
% of Increase from 2000-2014	181.6%	175.8%	258.5%	205.2%	172.4%	834.6%	178.4%

Pain Physician 2017; 20:S3-S92

Opioid Prescriptions Dispensed by US Retail Pharmacies

IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.



1 in 3

Part D beneficiaries received at least 1 prescription opioid

Source: OIG analysis of Medicare Part D data, 2017.

Tramadol

14.8 million

Hydrocodone-Acetaminophen*

11.3 million
11.2 million
5.7 million

Oxycodone-Acetaminophen*

5.0 million

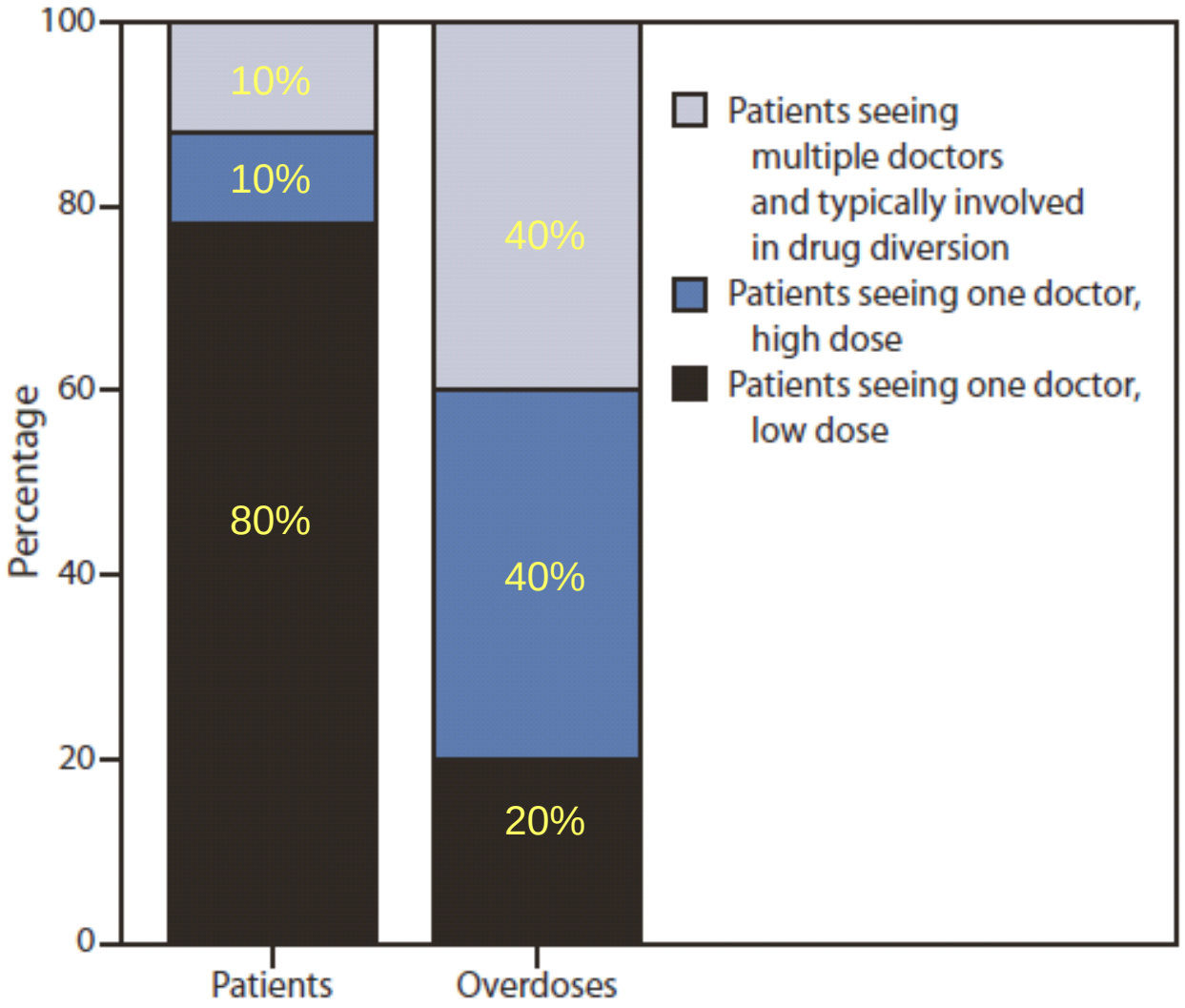
* Tablets also contain 325 mg of acetaminophen.

Source: OIG analysis of Medicare Part D data, 2017.

Most commonly prescribed opioids

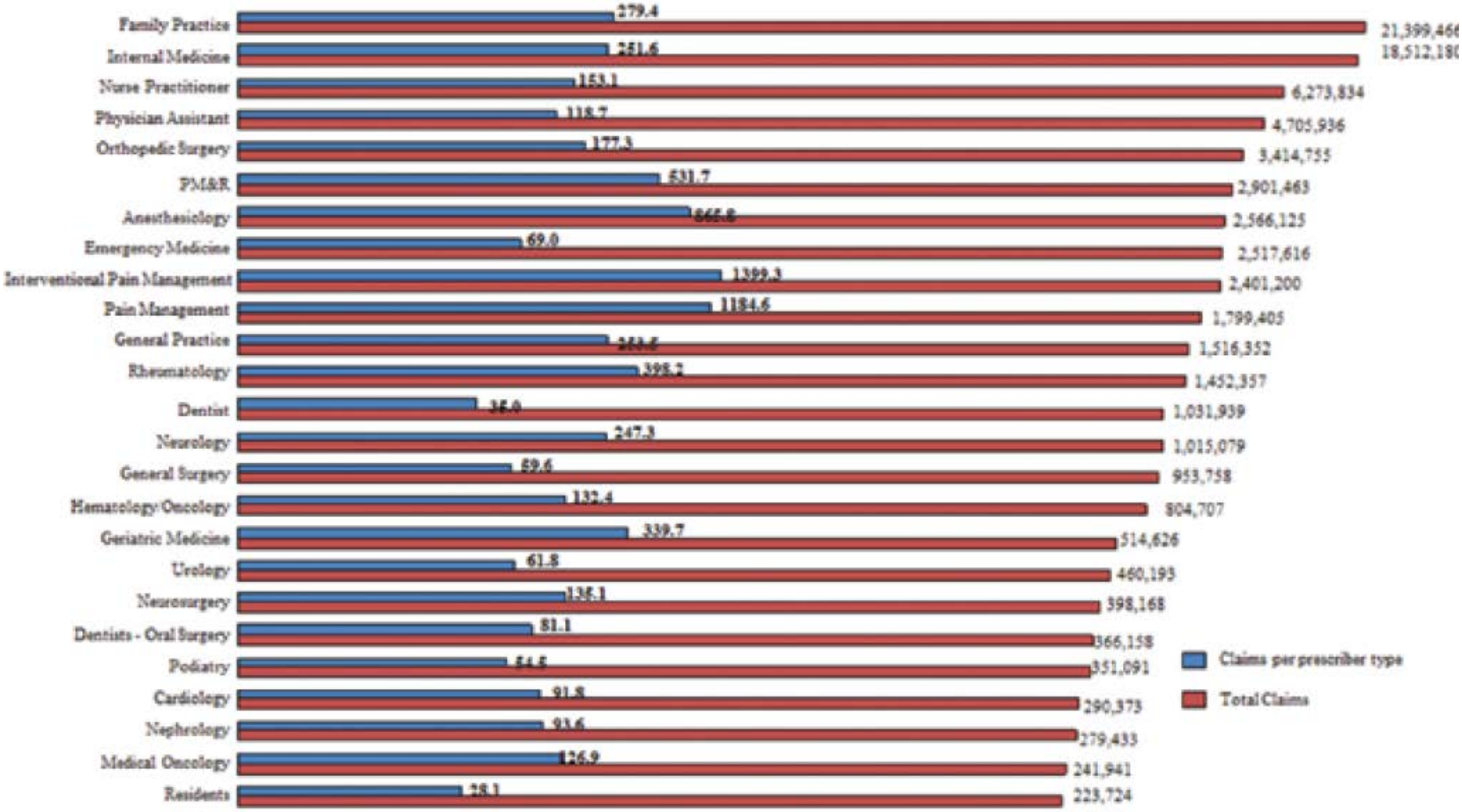
in Part D, 2016

Percentage of patients and prescription drug overdoses, by risk group – United States.



Source: Mortal Wkly Rep 2012; 61:10-13 (34).

Top 25 Prescriber Specialties by Total Medicare Part D Claims for Schedule II Opioids in 2015 Values are reported on logarithmic scale.



Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html

How Did We Get Here?

(Liberalization of 90's)

- State Medical Boards
  - No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed
- Accrediting bodies
  - Fifth vital sign – pain
- Right to pain relief
- Promotion
  - Organizations
  - Industry
- Misinterpretation of evidence
  - Works for me
    - Patients & Physicians
  - Perceived safety
  - Legitimacy

VIEWPOINT

History of The Joint Commission's Pain Standards
Lessons for Today's Prescription Opioid Epidemic

David W. Baker, MD, MPH
Division of Healthcare Quality Evaluation, The Joint Commission, Oakbrook Terrace, Illinois.

Supplemental content

In 2000, as part of a national effort to address the widespread problem of underassessment and undertreatment of pain, The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) introduced standards for organizations to improve care for patients with pain (eAppendix in the Supplement). After initial positive responses and small studies showing the benefits of following the standards, reports emerged about adverse events from overly aggressive treatment of pain. A 2002 report from the Institute for Safe Medication Practices (ISMP) asked, "[I]n our noble efforts to alleviate pain, has safety been compromised?"[1] In response, the standards and related materials were changed to address the problems.

Today, the United States is in the midst of a prescription opioid epidemic. Numerous interventions have been advocated to address the problem. Although these efforts are well intentioned, there are concerns that the pendulum will swing too far in the opposite direction, reversing the country's gains in pain management. This Viewpoint briefly reviews the history of The Joint Commission standards and the lessons learned to help inform efforts to address the prescription opioid crisis.

implementation describing how organizations had successfully demonstrated compliance with a standard, stressing that these were only examples and not required ways to meet a standard.

Early Responses and Successes

The Joint Commission standards were supported by pain management specialists. In one study that made a numerical pain scale mandatory in the postanesthesia care unit (PACU) and required an acceptable pain score for discharge from the PACU,[5] the mean consumption of opiates per patient increased from 40.4 mg (morphine equivalents) in 2000 to 46.6 mg in 2002 with no increase in length of stay, naloxone use, or nausea and vomiting. The standards' recommendation to use patients' self-reported pain according to numerical scales was supported by a study that found emergency department nurses significantly underestimated patients' pain compared with patients' self-report (mean scores of 4.2 vs 7.7, respectively, on a 10-point scale).[6]

Negative Reactions and Unintended Consequences

The Joint Commission standards raised concerns that re-

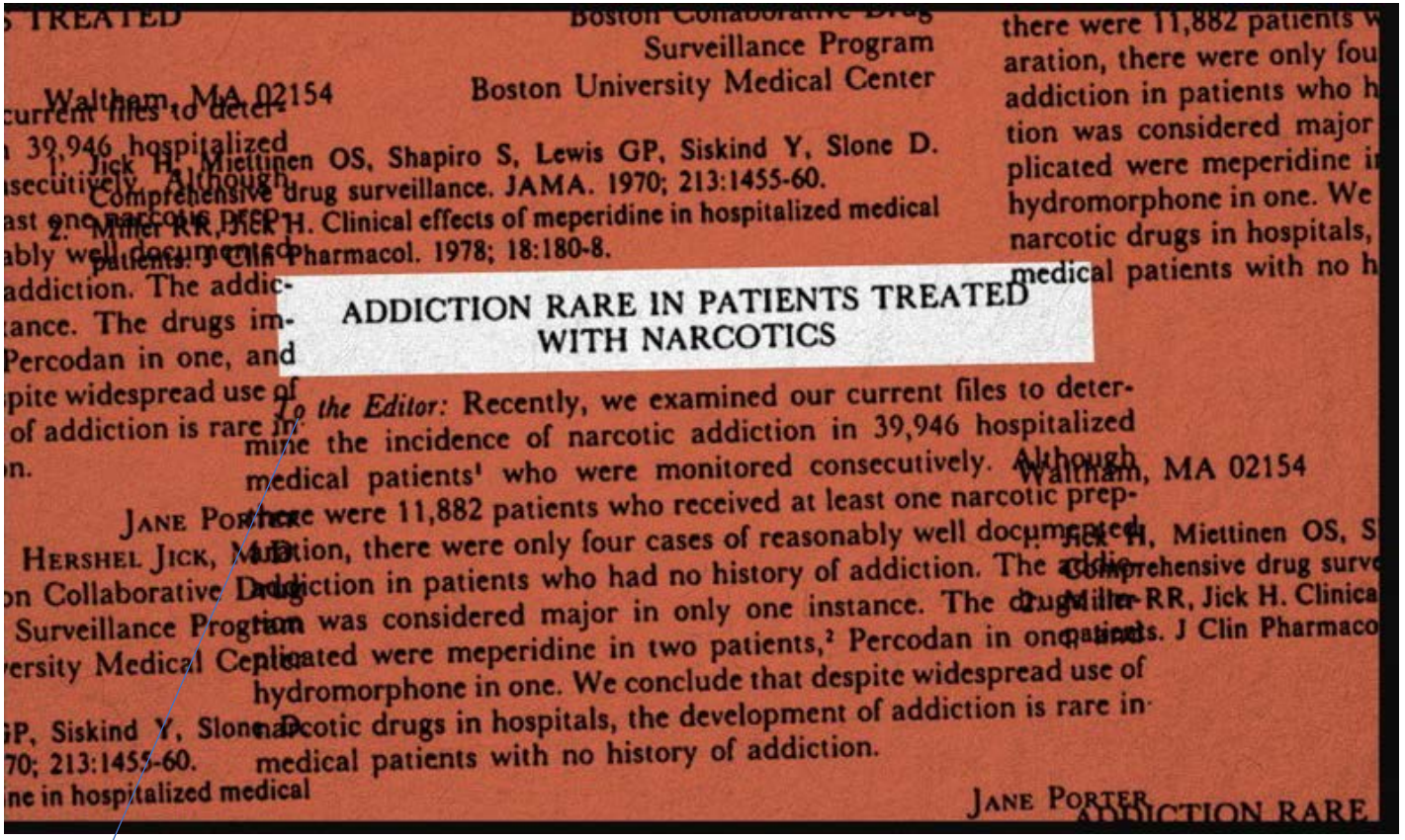
The One-Paragraph Letter From 1980 That Fueled the Opioid Crisis
Because it was published in the most prestigious U.S. medical journal, its influence snowballed in a dangerous way.

What do you do when a letter in a prestigious medical journal has been so routinely mis-cited it's taken on a life of its own? Like when pharmaceutical companies have used its data to spin their dangerous painkillers as safe, and the resulting overprescription fueled an opioid epidemic now consuming the country?

So this week, the *New England Journal of Medicine*, which published the original letter in 1980, is issuing a corrective. It's a new study, a bit meta, from a team led by David Juurlink at the University of Toronto that tracked how the five-sentence letter passed through the game of academic citation telephone to become evidence that opioids are safe for chronic pain. In fact, it said no such thing.

In the 1980s, Hershel Jick, a doctor at Boston University Medical Center, had a database of hospital records that he used to monitor side effects from drugs. Journalist Sam Quinones tells the story in his book, *Dreamland: The True Tale of America's Opiate Epidemic*. Something, perhaps a newspaper article, got Jick interested in looking at addiction. So he asked a graduate student, Jane Porter, to help calculate how many patients in the database got addicted after being treated with pain medicines, and dashed off a letter to the *New England Journal of Medicine*. Its brevity was commensurate with the effort involved. Here it is in full:

He didn't think much of it. Years later, Jick would tell Quinones, "That particular letter, for me, is very near the bottom of a long list of studies that I've done." And for most of the 1980s, the letter didn't attract much attention either.



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.

Surveillance Program
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.

Waltham, MA 02154

JANE PORTER
HERSHEL JICK, MD

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients 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, 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.

A Pain-Drug Champion Has Second Thoughts: "The King of Pain."

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.
12 patients used Oxycodone
7 patients used methadone
5 patients used levorphanol
14 patients used others drugs

None used Hydrocodone

19 patients were treated for four or more years at the time of evaluation, (6 were >7 years).

2/3 required less than 20 morphine equivalent mg/day
only 4 took more than 40 mg/day.

24 patients described partial but acceptable or fully adequate relief of pain (63%),
14 reported inadequate relief.
No patient underwent a surgical procedure for pain management while receiving therapy.

Portenoy RK, Foley KM.. Chronic use of opioid analgesics in non-malignant pain: report of 38 cases. Pain. 1986 May;25(2):171-86.

The Washington Post/Kaiser Family Foundation Survey of Long-Term Prescription Painkiller Users and Their Household Members

Dec 09, 2016 | Bianca DiJulio, Bryan Wu, and Mollyann Brodie

IMPACT ON LIFE OF CHRONIC OPIOID THERAPY:

- Overall, long-term users report mostly positive effects of opioids.
- Virtually all long-term users (92 percent) say the opioids have reduced their pain at least somewhat well.
- A majority of long-term prescription opioids users (57 percent) say their use of the medications has made their:
  - Quality of life better, particularly those who say they started the painkillers for chronic pain (69 percent)
  - But one in six (16 percent) say it has made it worse.

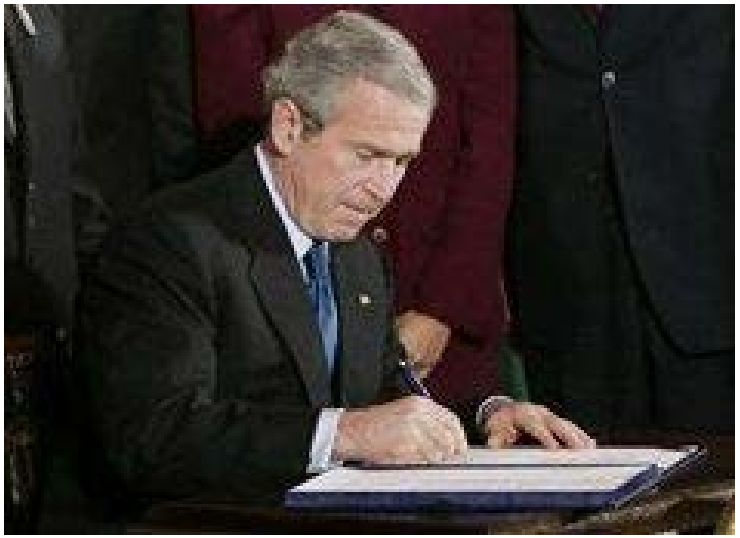
"We frequently hear the remark 'that on the whole, more harm than good is done by medication'. Excluding opium 'which the Creator himself seems to prescribe', wine, which is a food, and the vapors which produce the miracle of anesthesia and ***I firmly believe that if the whole material medica, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind—and all the worse for the fishes***."

Oliver Wendell Holmes MD 1809–94

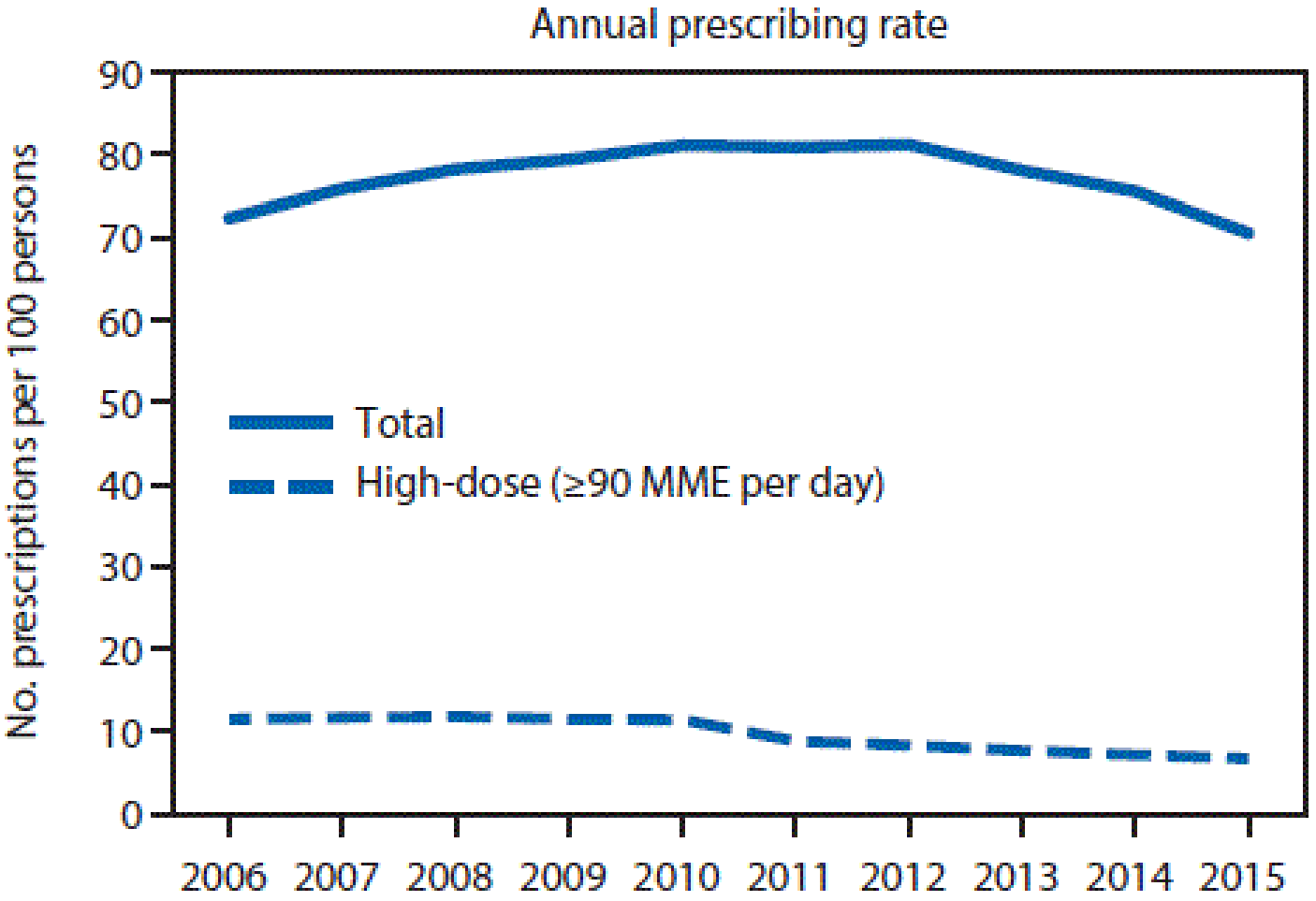
Developments to combat epidemic

NASPER Bill Passed

On August 11, 2005, President Bush improved patient care -- promoting quality pain relief with accountability -- and made history for the American Society of Interventional Pain Physicians (ASIPP), when he signed NASPER prescription drug abuse legislation into law.



Annual opioid prescribing rates — United States, 2006–2



Source: Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015
Weekly / July 7, 2017 / 66(26);697–704

The most entrenched
conflict of interest in medicine
is a disinclination
to reverse a previous opinion.

Yudkin, Richter, Gale. Lancet 2011

President's Commission on Combating Drug Addiction and the Opioid Crisis
March 29, 2017

U.S. Health and Human Services (HHS) Task Force to develop best practices for prescribing pain medication and for managing chronic and acute pain.

Opioids Guidelines

Pain Physician 2017; 20:S3-S92 • ISSN 1533-3159

Guidelines

Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines

Laxmaiah Manchikanti, MD, Adam M. Kaye, PharmD, Nebojsa Nick Knezevic, MD, PhD, Heath McAnally, MD, Konstantin V. Slavin, MD, Andrea M. Trescot, MD, Susan Blank, MD, Vidyasagar Pampati, MSc, Salahadin Abdi, MD, PhD, Jay S. Grider, DO, PhD, Alan D. Kaye, MD, PhD, Kavita N. Manchikanti, MD, Harold J. Cordner, MD, Christopher G. Gharibo, MD, Michael E. Harned, MD, Sheri L. Albers, MD, Sairam Atluri, MD, Steve M. Aydin, DO, Sanjay Bakshi, MD, Robert Barkin, MBA, PharmD, Ramsin M. Benyamin, MD, Mark V. Boswell, MD, PhD, Ricardo M. Buenaventura, MD, Aaron K. Calodney, MD, David L. Cedeno, PhD, Sukdeb Datta, MD, Timothy R. Deer, MD, Bert Fellows, MA, Vincent Galan, MD, Vahid Grami, MD, Hans Hansen, MD, Standiford Helm II, MD, Rafael Justiz, MD, Dhanalakshmi Koyyalagunta, MD, Yogesh Malla, MD, Annu Navani, MD, Kent Nouri, MD, Ramarao Pasupuleti, MD, Nalini Sehgal, MD, Sanford M. Silverman, MD, Thomas T. Simopoulos, MD, Vijay Singh, MD, Daneshvari R. Solanki, MD, Peter S. Staats, MD, Ricardo Vallejo, MD, PhD, Bradley W. Wargo, DO, Arthur Watanabe, MD, and Joshua A. Hirsch, MD

Opioid Selection, Dosage, Duration and Continuation

- Physicians should prescribe immediate-release opioids when starting opioid therapy for chronic pain
- Patients should use the lowest effective dosage
- If prescribed for acute pain, opioids should be taken for short time periods – in these instances, three days or less is typically beneficial, while more than seven days is rarely necessary

Assessing Opioid Risk & Addressing the Harms of Use

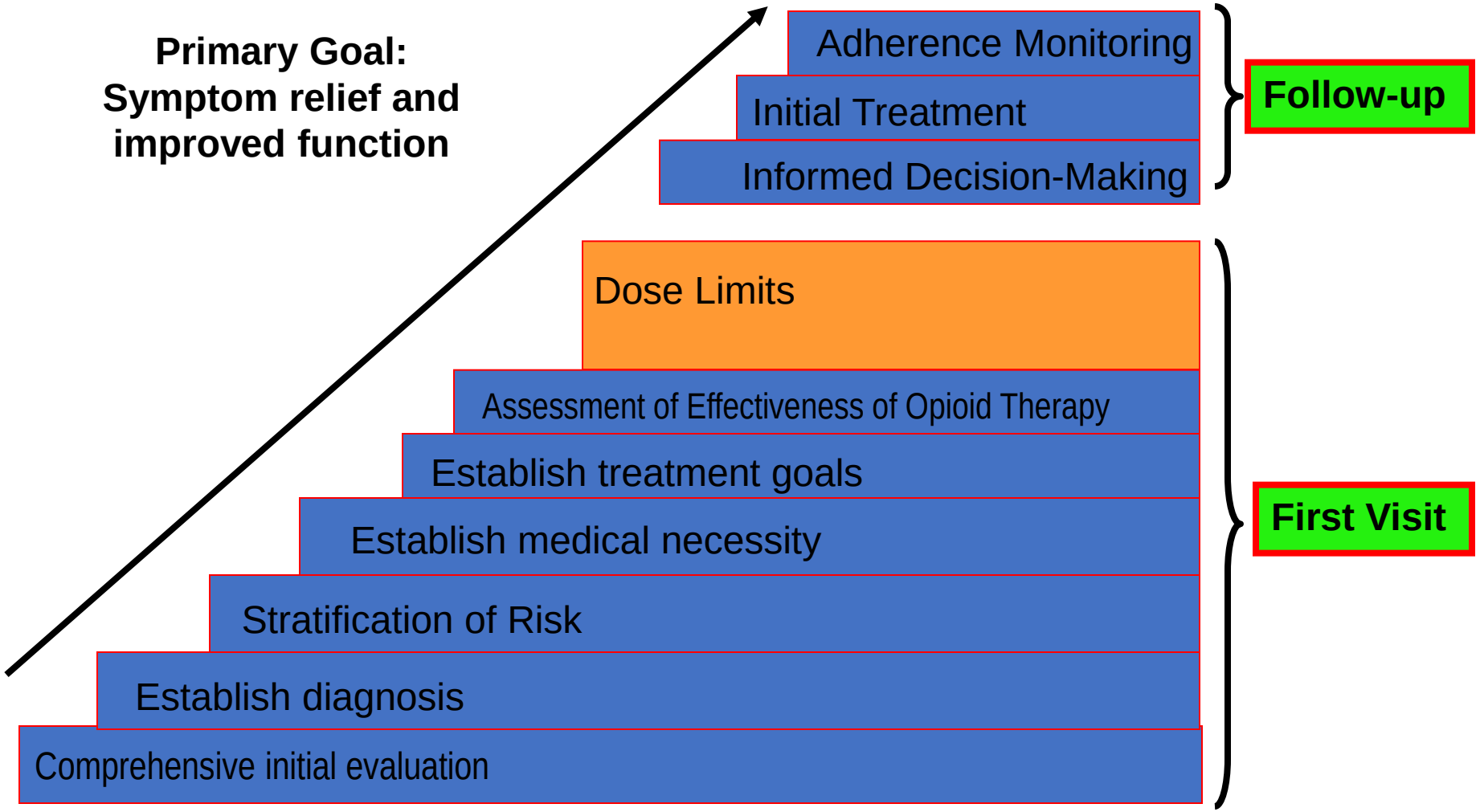
- Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data
- If prescribing opioids for chronic pain, clinicians should use urine drug testing before and periodically during opioid therapy to assess for prescribed medications and other controlled prescription and illicit drugs
- Clinicians should offer or arrange evidence-based treatment for patients with opioid use disorder

Determining when to use opioid medications:

- Physicians should look to opioids to treat chronic pain after considering non-pharmacologic therapy and non-opioid pharmacologic therapy
- Physicians and patients should establish treatment goals for opioid therapy regarding pain and function
- Patients and providers should regularly discuss the risks, benefits and management of opioid therapy as the treatment is being administered
- Providers should not prescribe opioids unless it is determined that the potential benefits outweigh the potential harms

Algorithm for Opioid Therapy in Chronic Pain

10 Step Risk Management Plan



American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance. Pain Physician 2017; 20:S3-S92

Risk Stratification

	Low Risk	Medium risk	High Risk
Body regions	Involvement of less than 3 regions	Involvement of more than 3 regions	Involvement of more than 3 regions
Physical pathology	Objective signs and reliable symptoms confirmed by radiological evaluation, physical examination, or diagnostic interventions	Significant pain problems with objective signs and symptoms confirmed by radiological evaluation, physical examination, or diagnostic interventions	Widespread pain without objective signs and symptoms, radiologic or electro-diagnostic evaluations
Age	Greater than 45 years	Less than 45 years	Less than 45 years
Smoking	None or mild	Moderate	Heavy
Coexisting Medical Disorders	None or mild	Moderate : • Pulmonary issues	Multiple co-exiting problems: • Sleep Apnea Syndrome
Psychological Comorbidities	None or mild	Moderate	Major or Multiple : • Bipolar or personality disorders

Risk Stratification

	Low Risk	Medium risk	High Risk
Personal or family history of alcoholism or substance abuse	None or well defined	Moderate with well controlled Abnormal History	Uncontrolled history of misuse, abuse, addiction, diversion, dependency, tolerance alcoholism and aberrant drug-related behavior
Other Risk Factors	None	>65 years	HIV related pain
Participate in Rehabilitation	Well-motivated with willingness to participate in multimodal therapy and functioning at normal levels	motivated with willingness to participate in multimodal therapy and attempting to at function normal levels	Not motivated with unwillingness to participate in multimodal therapy and not attempting or function normal levels
Pain Acceptance	High level	Moderate level	Low level
Coping Strategies	High level	Moderate level	Low level

Dose Limitation

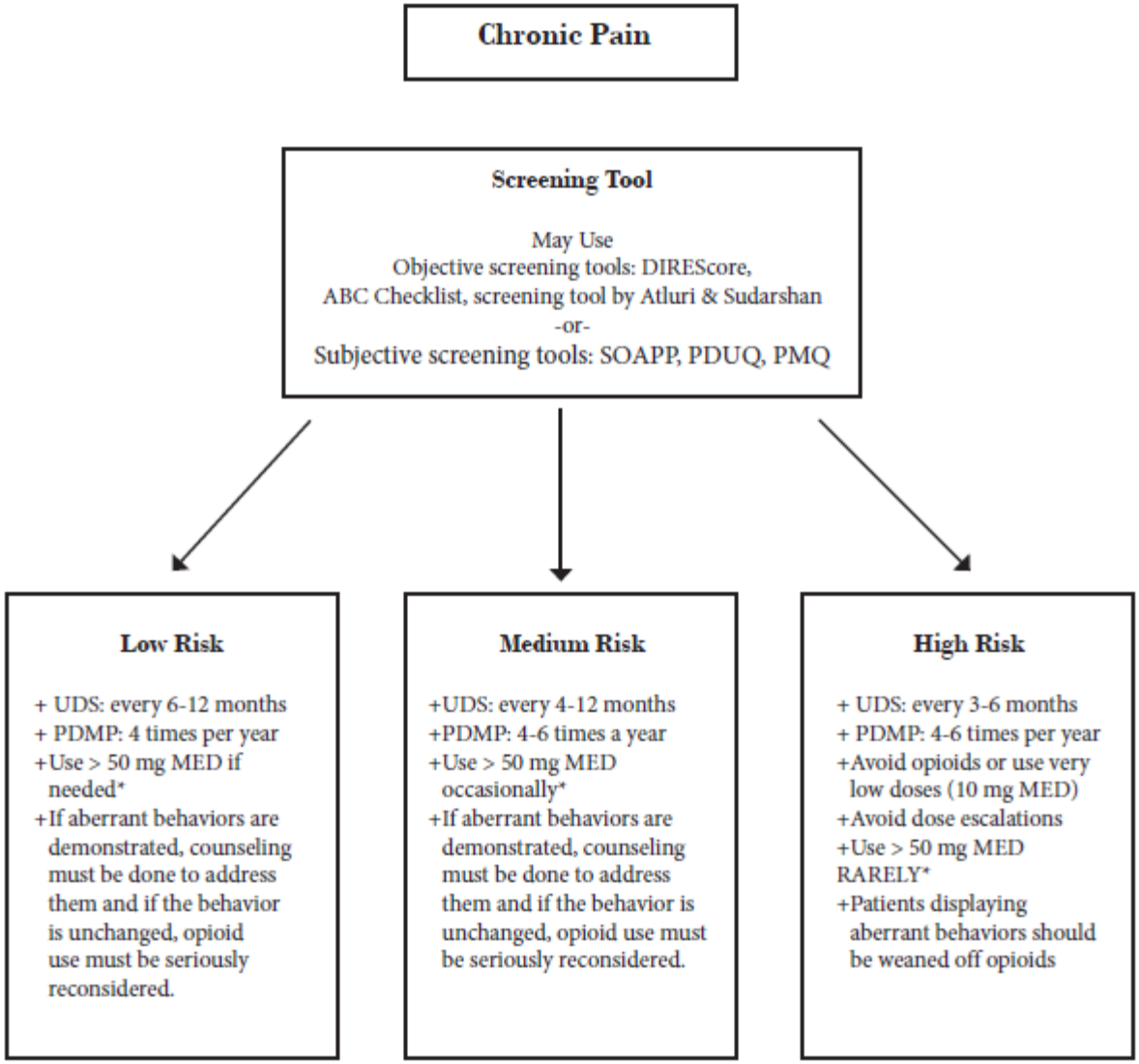
- Low dose – 40 mg of morphine equivalent dose
- Medium dose – 41-90 mg of morphine equivalent dose
- High dose – >90 mg of morphine equivalent dose

Morphine equianalgesic doses of opioids.

Opioid	Approximate Equianalgesic Dose (oral & transdermal) *	To convert to oral morphine equivalent multiply by:	To convert from oral morphine multiply by:
Morphine (reference)	**30 mg**	1.0	1.0
Codeine	200 mg	0.15	6.67
Hydrocodone	30 mg	1.0	1.0
Hydromorphone	7.5 mg	4.0	0.25
Methadone	Chronic: 4 mg	7.5	0.133
Oxycodone	20 mg	1.5	0.667
Oxymorphone	10 mg	3.0	0.337

*Adapted from VA 2003 & FDA labeling

Risk stratification and adherence monitoring

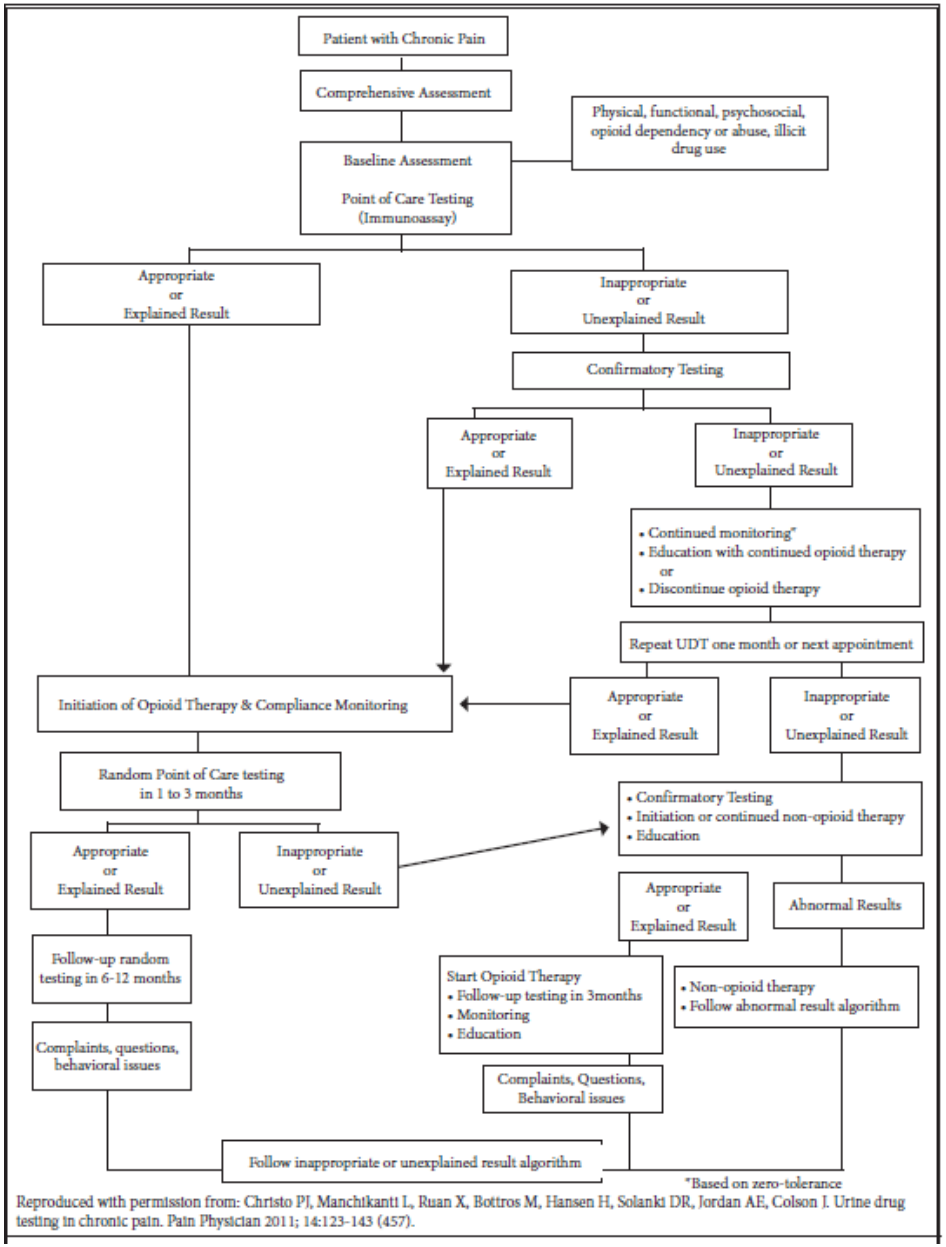


*MED – Morphine Equivalent Dose

Reproduced with permission from: Atluri SL, Akbik H, Sudarshan G. Prevention of opioid abuse in chronic non-cancer pain: An algorithmic, evidence based approach. Pain Physician 2012; 15:ES177-ES189 (642).

American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance. Pain Physician 2017; 20:S3-S99

Guidance to opioid therapy.



Reproduced with permission from: Christo PJ, Manchikanti L, Ruan X, Bottros M, Hansen H, Solanki DR, Jordan AE, Colson J. Urine drug testing in chronic pain. Pain Physician 2011; 14:123-143 (457).

American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance. Pain Physician 2017; 20:S3-S99

Strategy is Mandatory

- No convincing functional benefit despite:
  - Dose adjustment
  - Side-effect management
  - Opioid rotation
- Poor SE profile at analgesic dose
- Persistent compliance problems despite
  - Treatment agreement
  - Limits
- Comorbid condition that increases risk of harm (e.g., sleep apnea)

Pujol LM. *The PainEDU.org Manual. A Pocket Guide to Pain Management.* Newton, MA: Inflexxion, Inc.; 2007:165-182.

SE-side effect

Conclusion:

Opioid therapy for chronic non-cancer pain should be provided only: to patients with proven medical necessity and stability with improvement in pain and function, independently or in conjunction with other modalities of treatments in low doses with appropriate adherence monitoring and understanding of adverse events.

The guidelines are based on the best available evidence and **do not constitute inflexible treatment** recommendations. Due to the changing body of evidence, this document is **not intended to be a "standard of care."**

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Trends in Opioid Analgesic Abuse and Mortality in the United States

Richard C. Dart, M.D., Ph.D., Hilary L. Surratt, Ph.D., Theodore J. Cicero, Ph.D., Mark W. Parrino, M.P.A., S. Geoff Severtson, Ph.D., Becki Bucher-Bartelson. Ph.D.. and Jody L. Green, Ph.D.

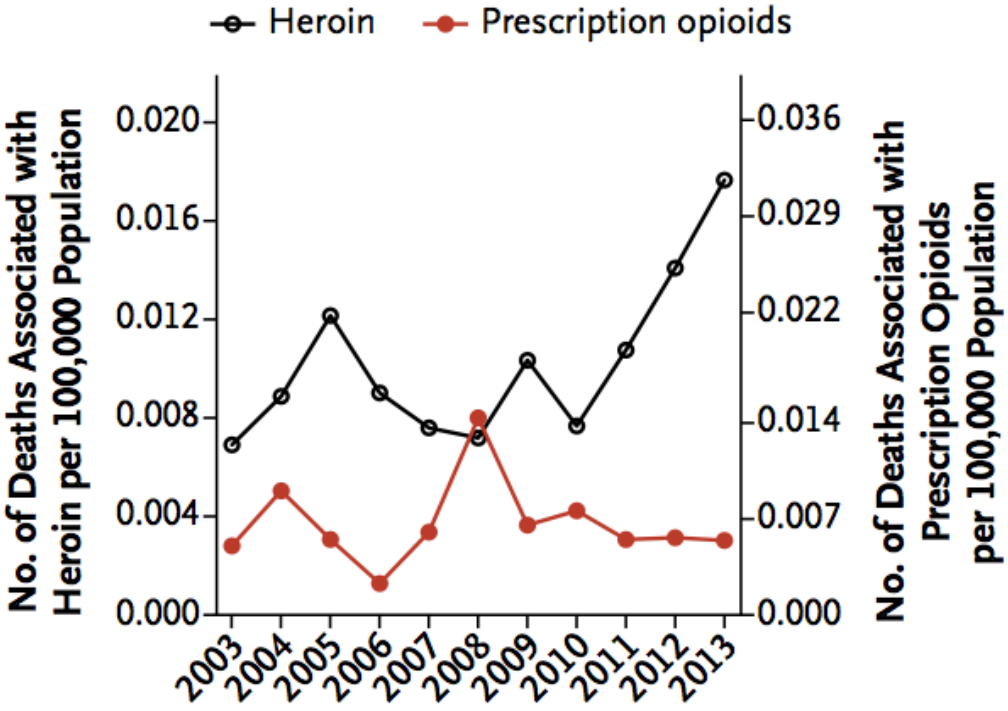
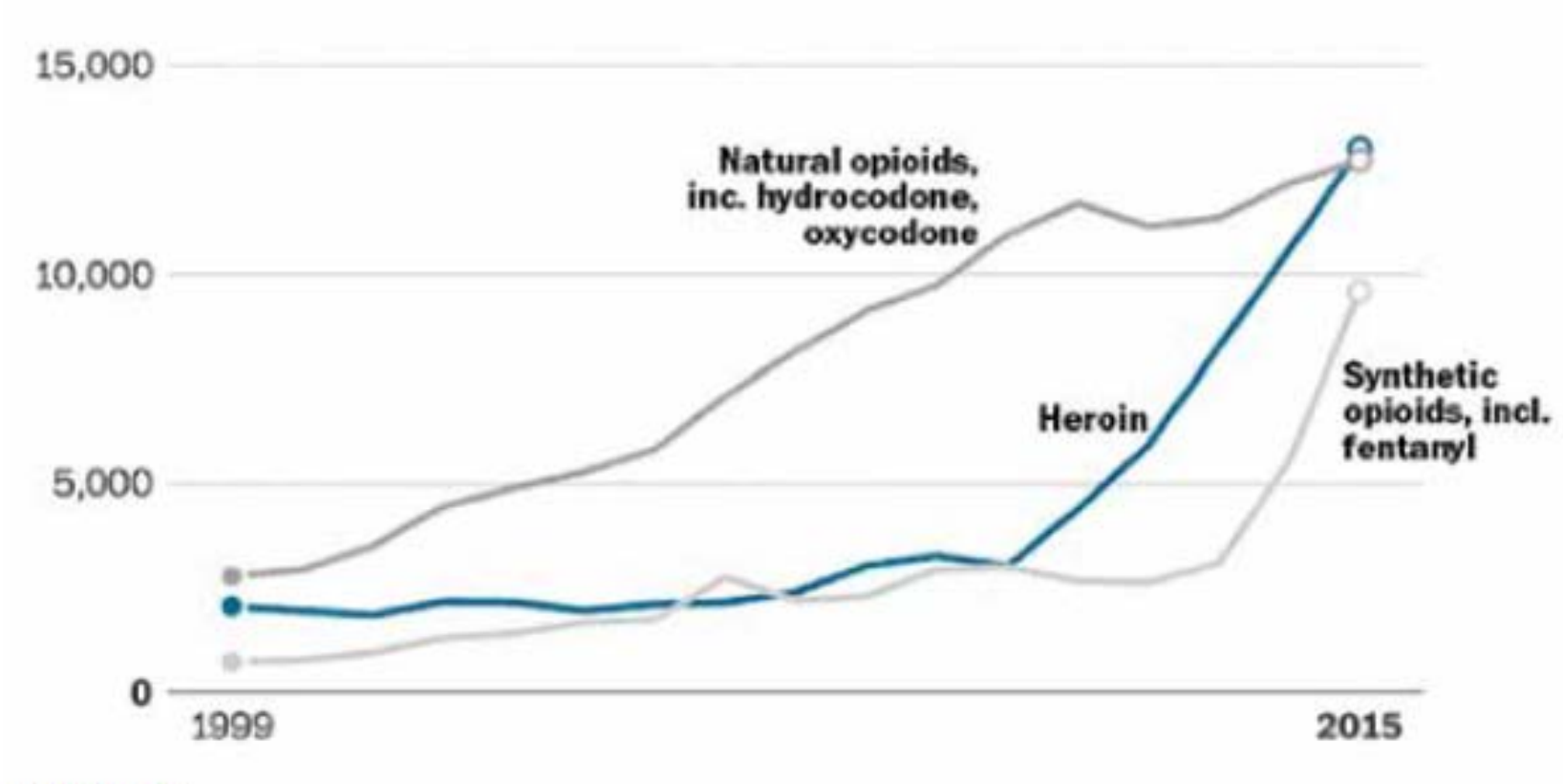


Figure 3. Rates of Death Associated with Heroin and Prescription Opioids, 2002–2013.

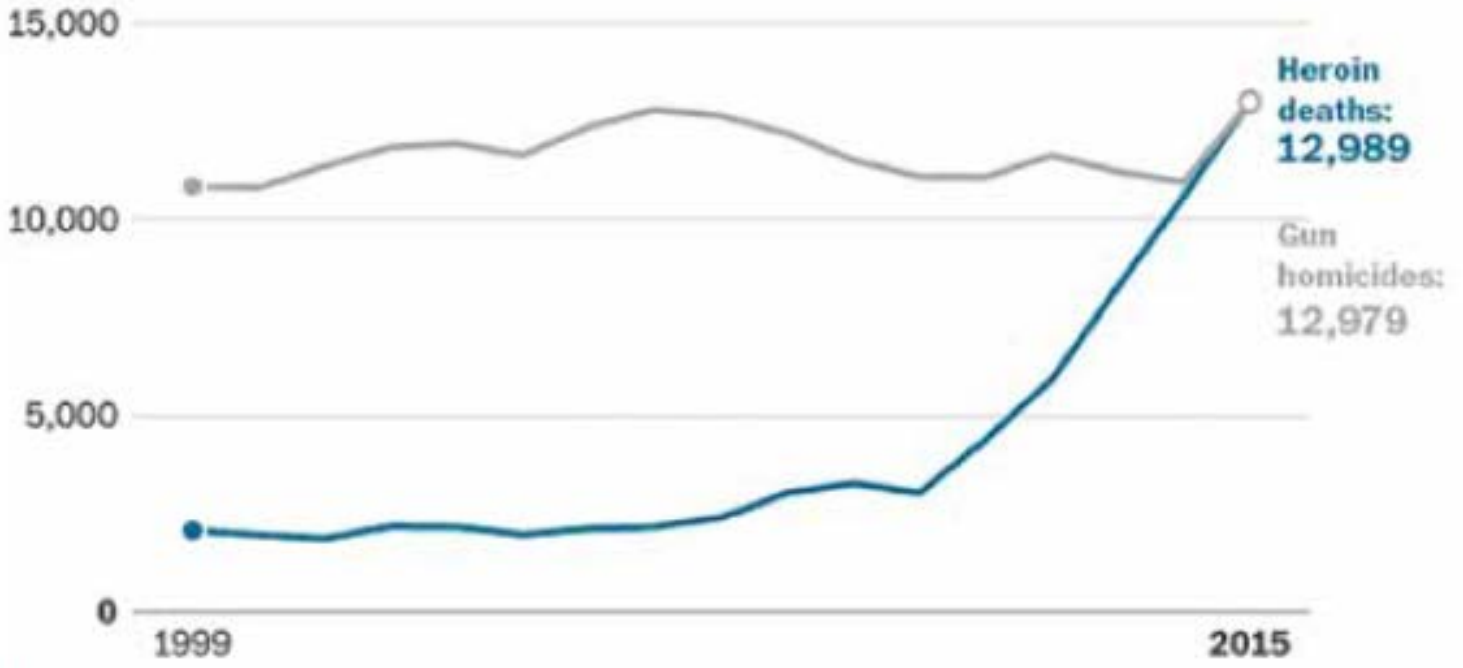
Heroin and fentanyl deaths rise sharply in 2015.



Source: CDC WONDER

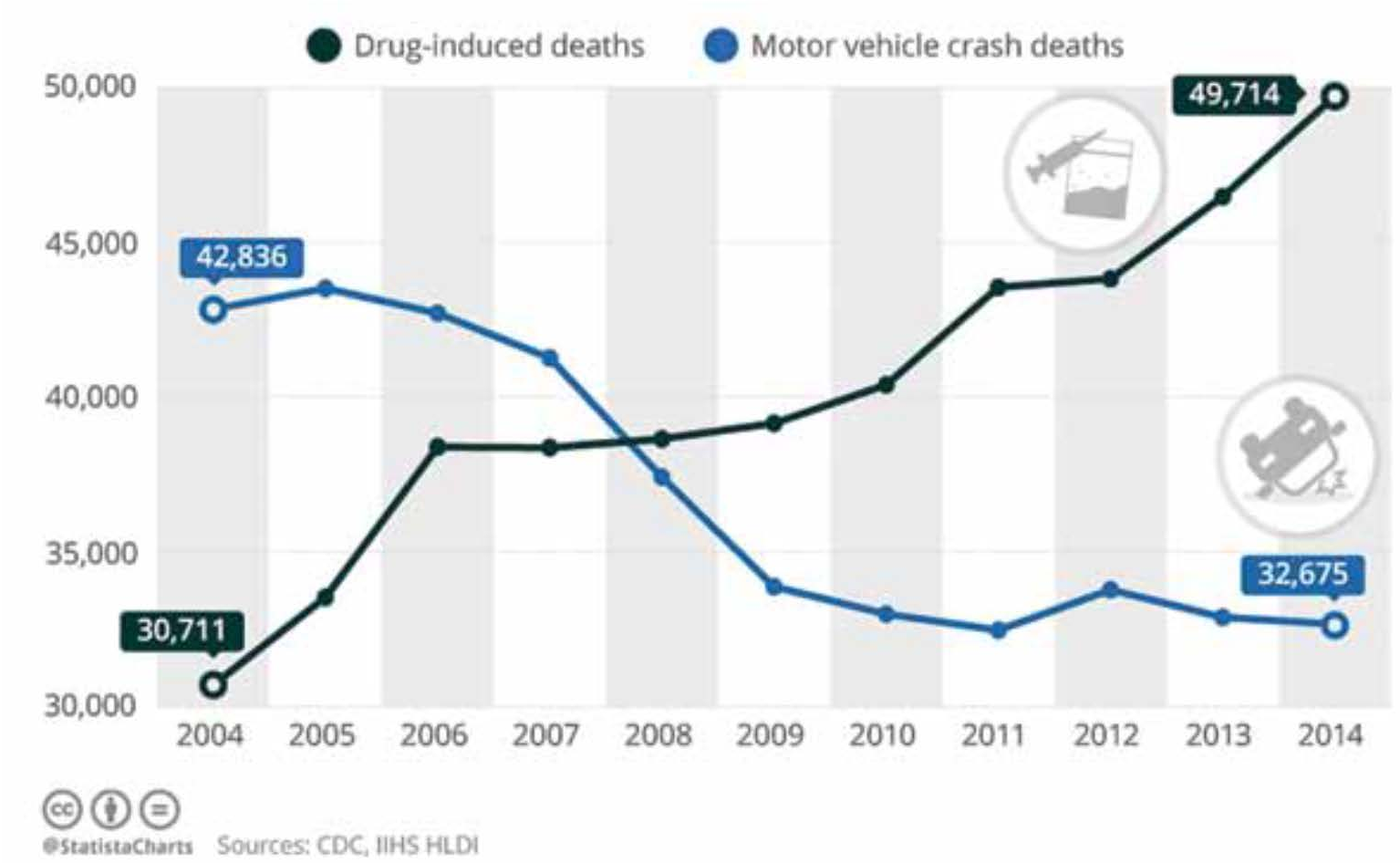
Source: Opioid Guidelines, Pain Physician 2017; 20:S3-S92

Heroin deaths surpass gun homicides in 2015.



Source: CDC WONDER

Source: Opioid Guidelines, Pain Physician 2017; 20:S3-S92


Drug-induced deaths
Motor vehicle crash deaths
50,000
45,000
40,000
35,000
30,000
42,836
30,711
49,714
32,675
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
@StatistaCharts
Sources: CDC, IIHS HLDI

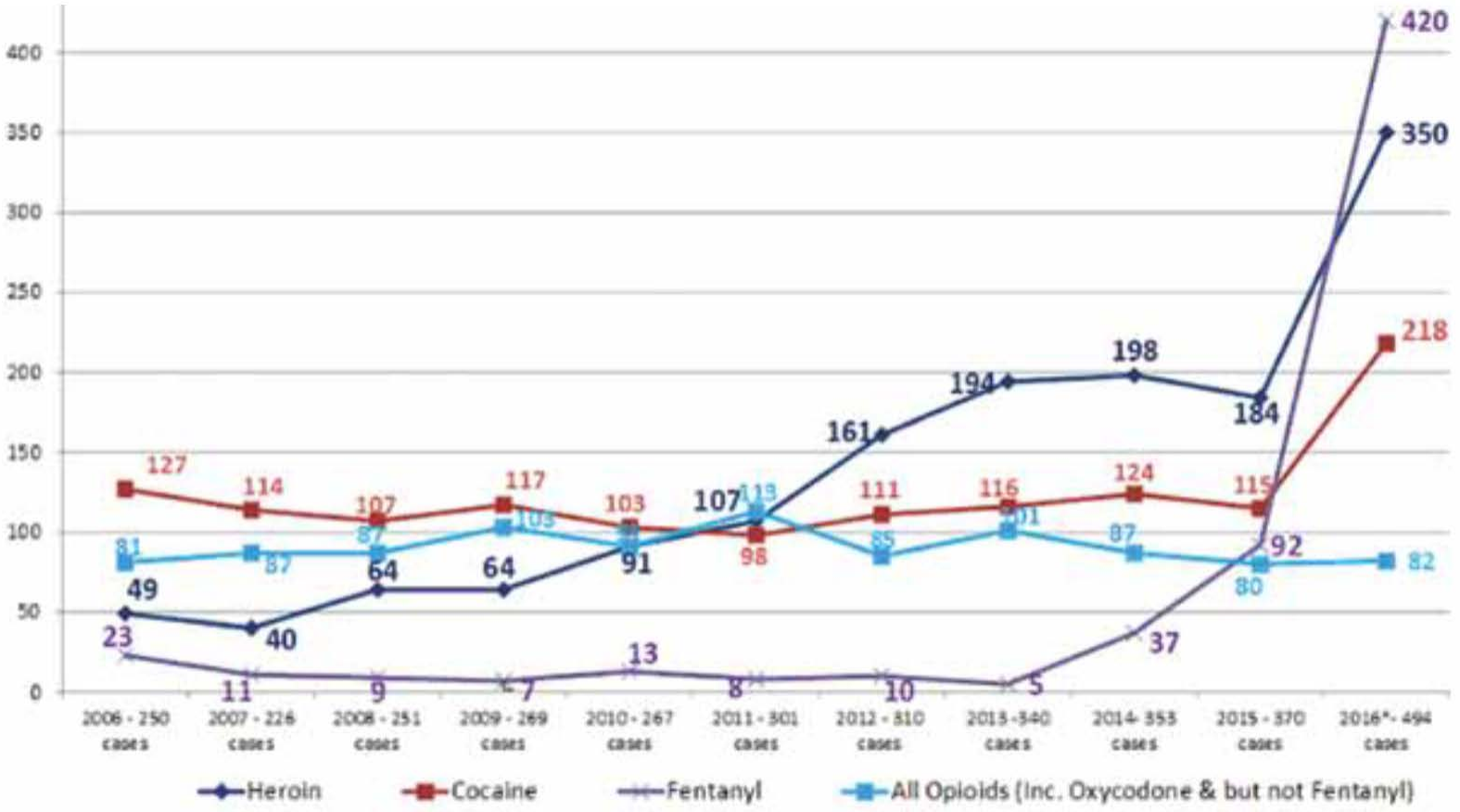
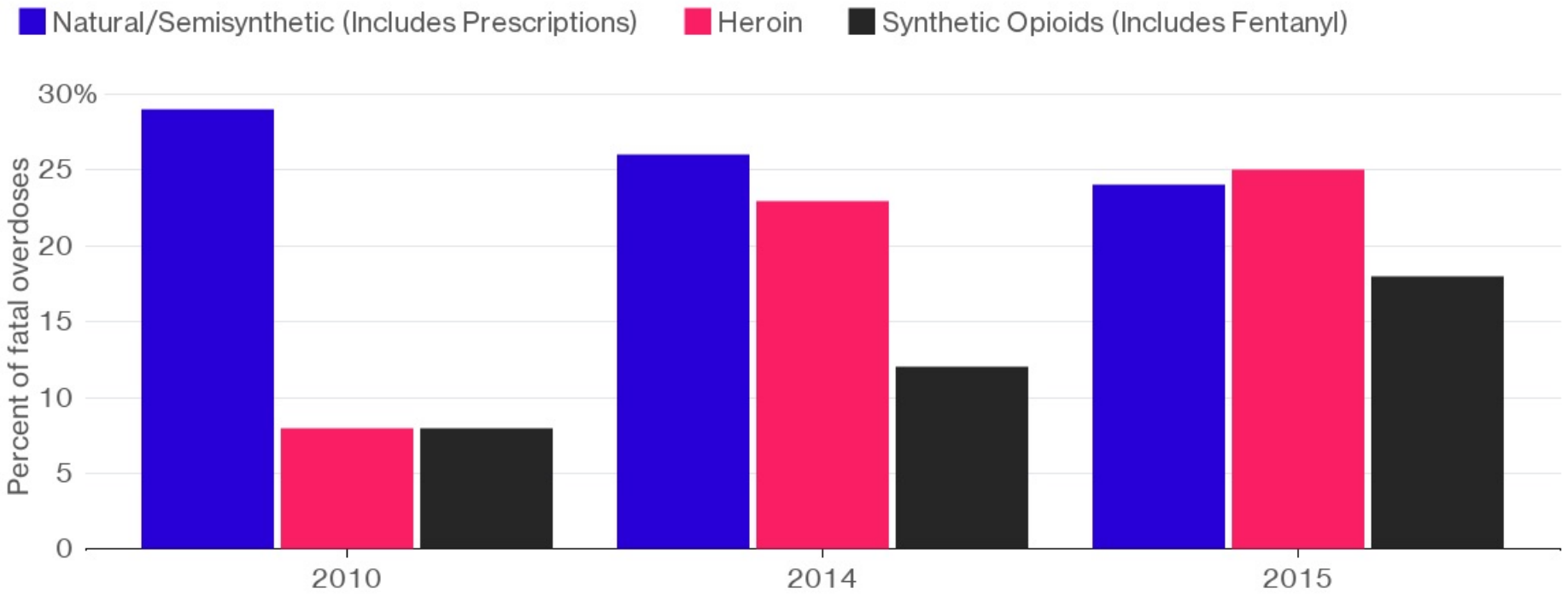


Fig. 8. *Cuyahoga County overdose deaths 2006 – 2016* from most common drugs (*projected based on ruled cases as of August 31).*

The Pill-to-Heroin Shift

Prescription opioids, once the top drug involved in overdose, have handed off to heroin



Source: CDC data

Bloomberg

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least 3 other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...

ALCOHOL

are **2x**

MARIJUANA

are **3x**

COCAINE

are **15x**

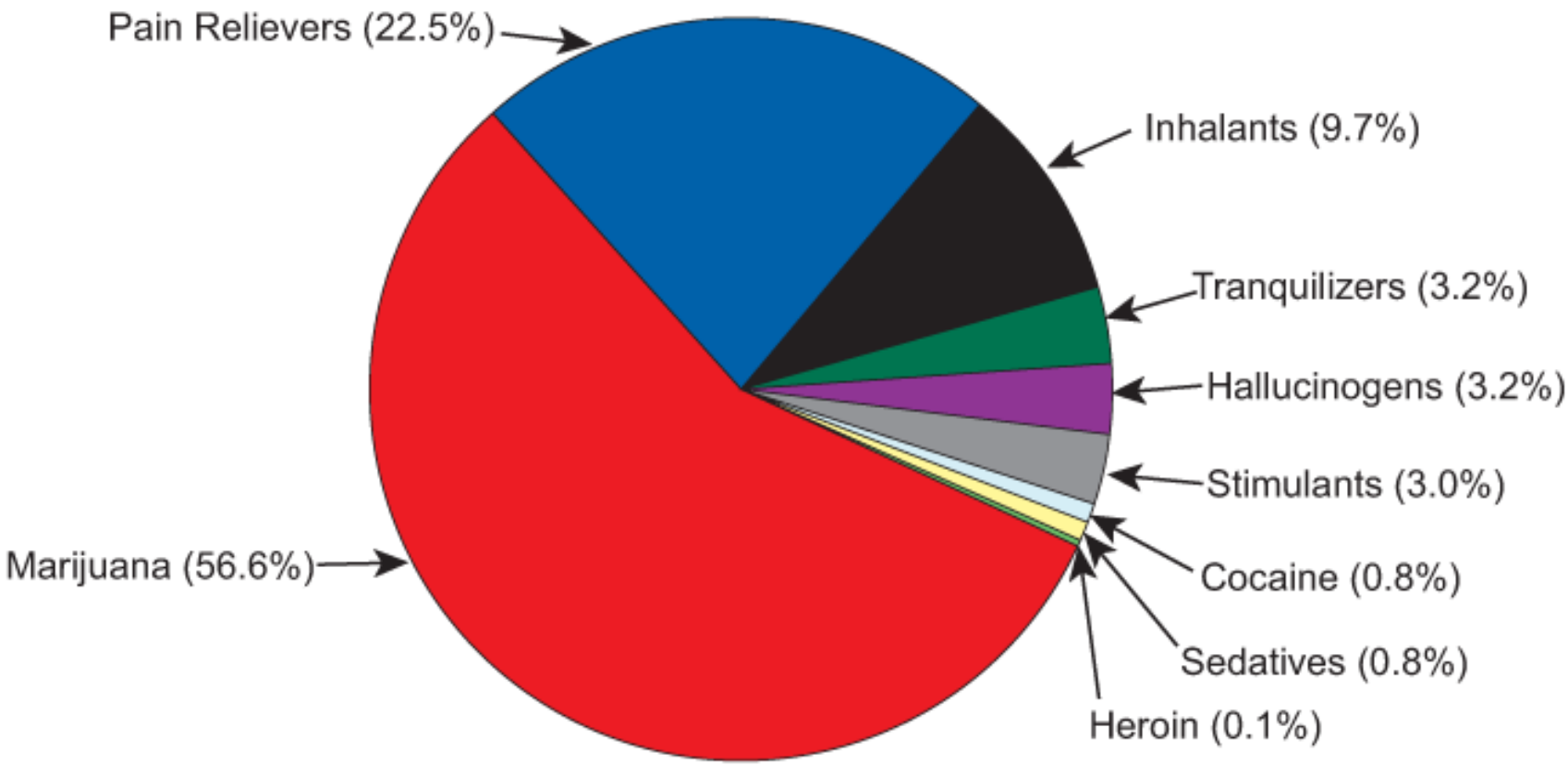
Rx OPIOID PAINKILLERS

are **40x**

...more likely to be addicted to heroin.

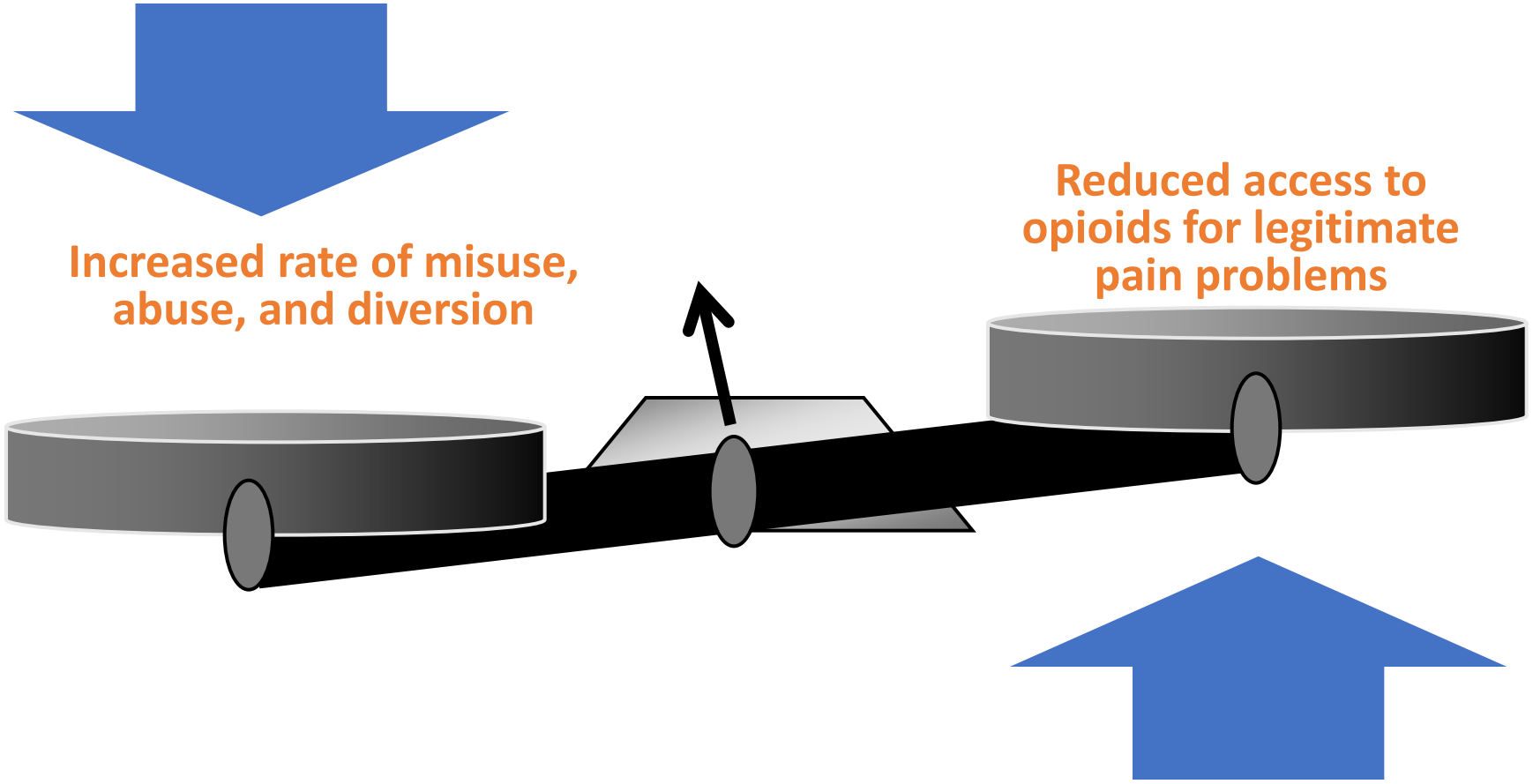
CDC Vitalsigns

Specific Drug Used When Initiating Illicit Drug Use among Past Year Initiates of Illicit Drugs Aged 12 or Older



2.9 Million Initiates of Illicit Drugs

Need to balance access to pain medications with abuse prevention



Kuehn BM. *JAMA*. 2007;297(3):249-251.

Thanks!

RBENYAMIN@millenniumpaincenter.com