

# ***The Opioid Crisis and the Management of Orofacial Pain***

## **Course Material**

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Indiana State  
Department of Health

# ***Outline***

**Introduction**

**Miller**

**Objectives**

**Mackie**

**Definitions**

**Mackie**

**Data (Mortality, Morbidity, and SUD)**

**Mackie**

**Risk Factors**

**Mackie**

**Responses**

**Mackie**

**Managing Pain (Considerations)**

**Mackie**

**Lessons for Dentists**

**Miller & Berman**

**Cases Studies**

**Mackie & Miller & Berman**

# ***Introduction***

*This course will present information about the opioid crisis and how this crisis impacts the management of orofacial pain by oral health care providers.*

# ***Introduction (cont.)***

- *Many resources are becoming available on guidelines for prescribing medications for the management of acute and chronic pain.*
- *These resources are readily available online, some of which may be mentioned in this course.*
- *This course is not designed to recapitulate these guidelines, but more to give an overview of the opioid epidemic and what a dentist needs to consider before prescribing medication for the pain management of patients*

## ***Introduction (cont.)***

- *At the end of the material by Dr. MacKie, Drs. Miller and Berman added a “lessons learned” section that summarizes some of the main points of this material*
- *Finally, Drs. MacKie, Miller, and Berman prepared hypothetical cases to illustrate some of the issues that are involved in pain management of patients, given the current opioid epidemic*

# ***Objectives***

- Review **DEFINITIONS** pertaining to the opioid crisis (epidemic)
- Review **DATA** about mortality and morbidity associated with the opioid crisis and data on substance use disorders (SUD) and the opioid use disorder (OUD)
- Review **RISK FACTORS** for SUD and OUD, including demographic factors associated with these disorders
- Review **RESPONSES** to this crisis by health care providers, legislatures, medical and dental boards, and organizations
- Review **CONSIDERATIONS FOR MANAGING PAIN** in the context of the current opioid crisis

# ***Definitions***

- ***Addiction***
  - *v. Dependence*
  - *v. Tolerance*
- ***Substance Use Disorder (SUD)***
  - *Opioid Use Disorder (OUD)*



# What is Drug Addiction?

- **Addiction is a chronic relapsing brain disease**
- **Characterized by compulsive drug seeking and use, despite harmful consequences**
- **Drugs of abuse change the structure and function of the brain**
- **These brain changes can be long-lasting, and can lead to harmful behaviors**



# Addiction

**Neurobehavioral condition with genetic and environmental factors**

- Chronic**
- Craving**
- Compulsive**
- Continues despite harm**



# **Addiction**

**Neurobehavioral syndrome with genetic and environmental influences that result in psychological dependence for psychic effects. Chronic, Craving, Compulsive and Continuous despite harm**

# **Dependence**

**Neuro-adaptation characterized by withdrawal syndrome if substance is stopped or lowered abruptly**

# Tolerance

Physiologic state resulting from regular use of drug in which the dose must be increased to achieve the same clinical response

\* Duration then magnitude \*

## Pseudo-addiction (totally discredited notion)

Behavior pattern exhibited “drug seeking” by patient who is receiving inadequate pain management/too little opioids.

# What is a Substance Use Disorder?

- **Problematic pattern leading to clinically significant impairment or distress, including at least 2 of the following and occurring within 12 months:**
  - **Larger amounts than and longer than intended**
  - **Persistent desire or unsuccessful efforts to cut/control use**
  - **Seeking time and energies increases**
  - **Craving/desire for substance**
  - **Use associated with failure to fulfill roles, work, interpersonal/social, family, school**
  - **Giving up important activities due to use**
  - **Hazardous situations related to use**

# Substance Use Disorder DSM-V

Maladaptive pattern leading to clinically significant impairment or distress within a year including two or more of:

1. Tolerance\*\* \*\* = not a criteria when on Rx opioids
2. Withdrawal signs\*\*
3. Substance taken in larger amounts/longer period of time than intended
4. Unsuccessful efforts to quit/cut back
5. Energy, time and effort to obtain, use or recover from substance
6. Strong desire/craving for substance
7. Use interferes with major role obligations: work/school/home
8. Continues despite impact on social and interpersonal relationships
9. Used in situations where it may be physically hazardous
10. Social, occupational, recreational activities reduced or eliminated
11. Use despite knowledge of medical or psych, problem resulting from use

Motivational  
Injury



# ***Data***

***Mortality***

***Morbidity***

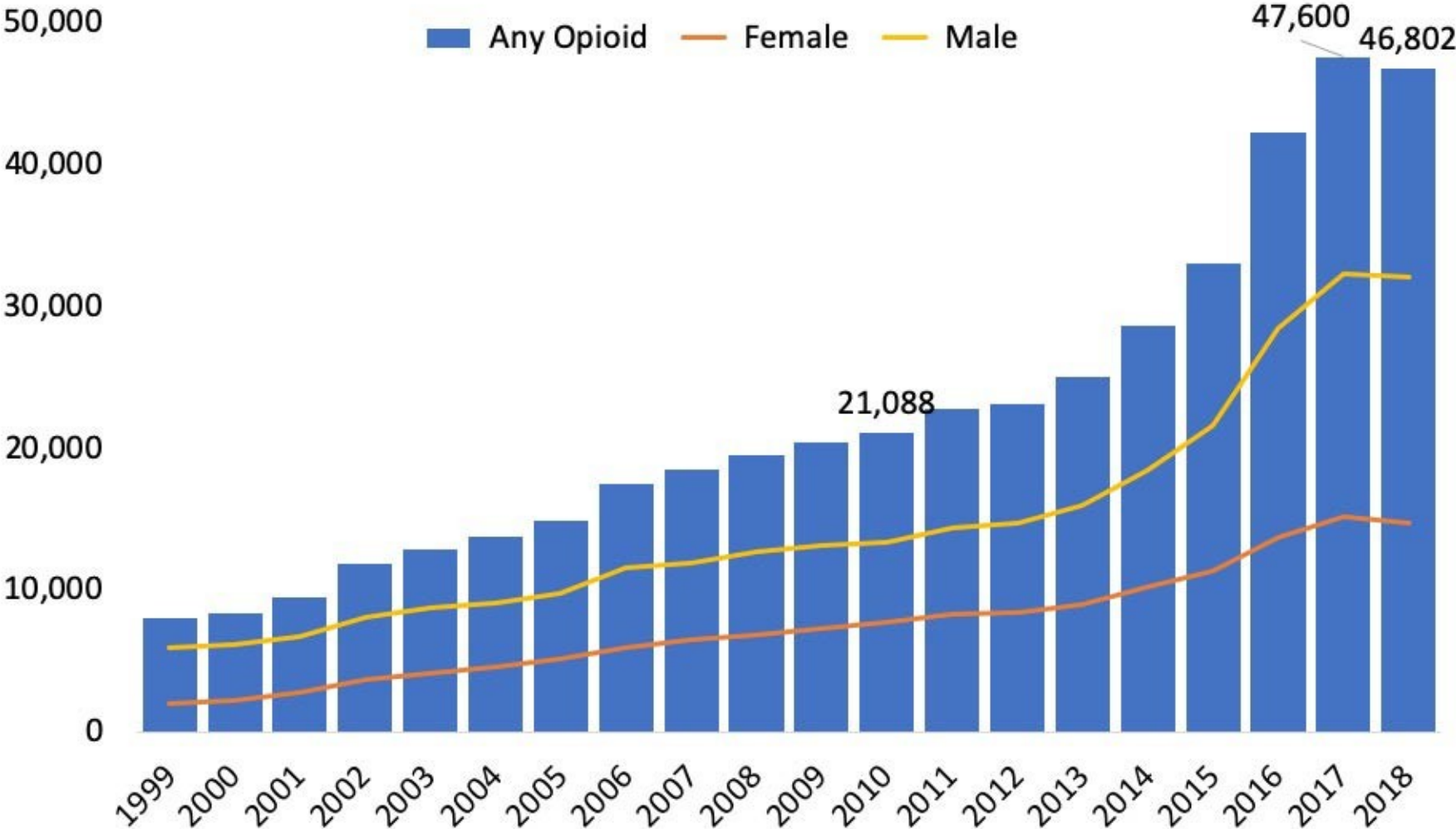


# ***Data***

***Mortality***

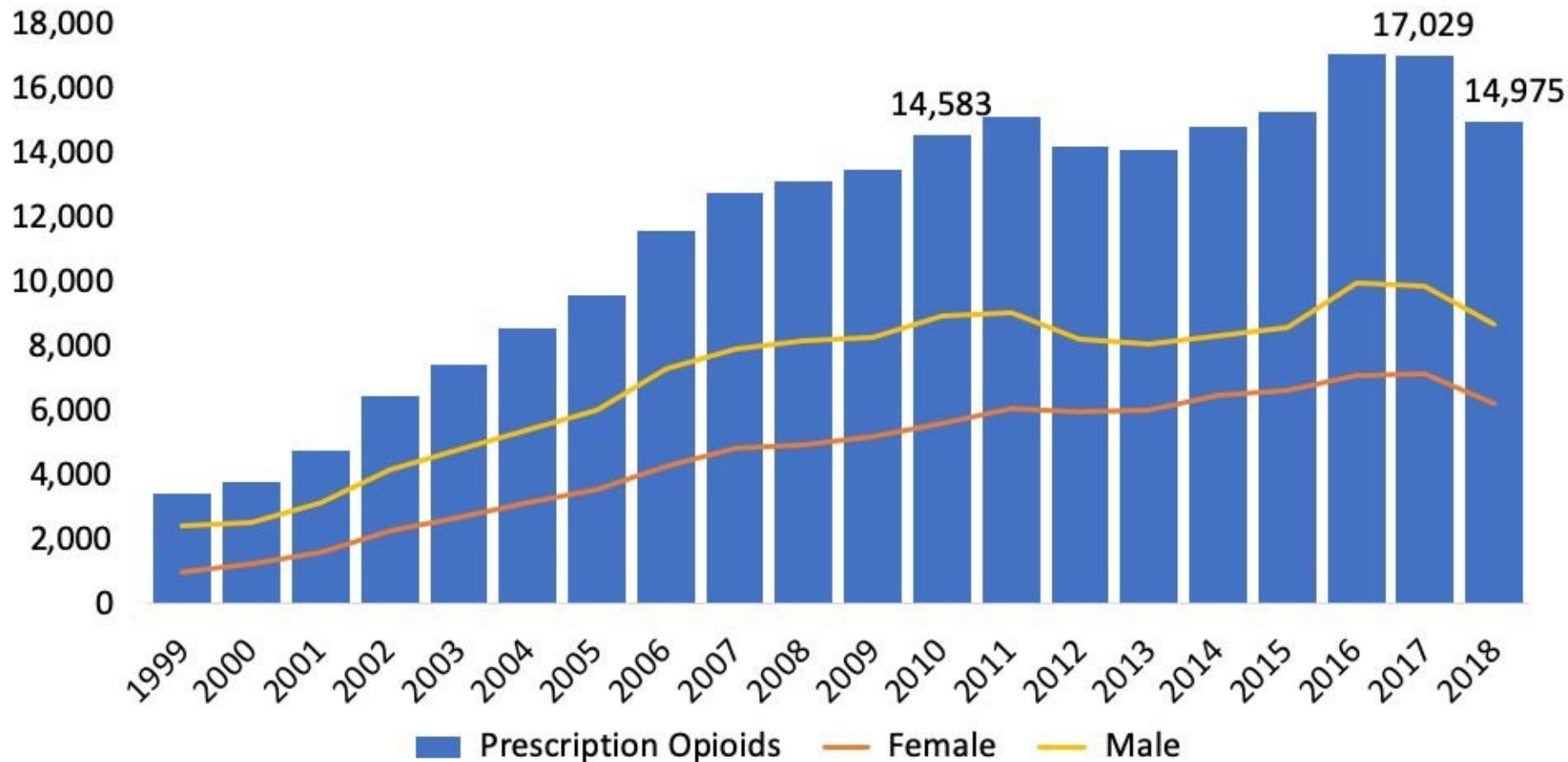
***Deaths from drug overdose***

# Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2018



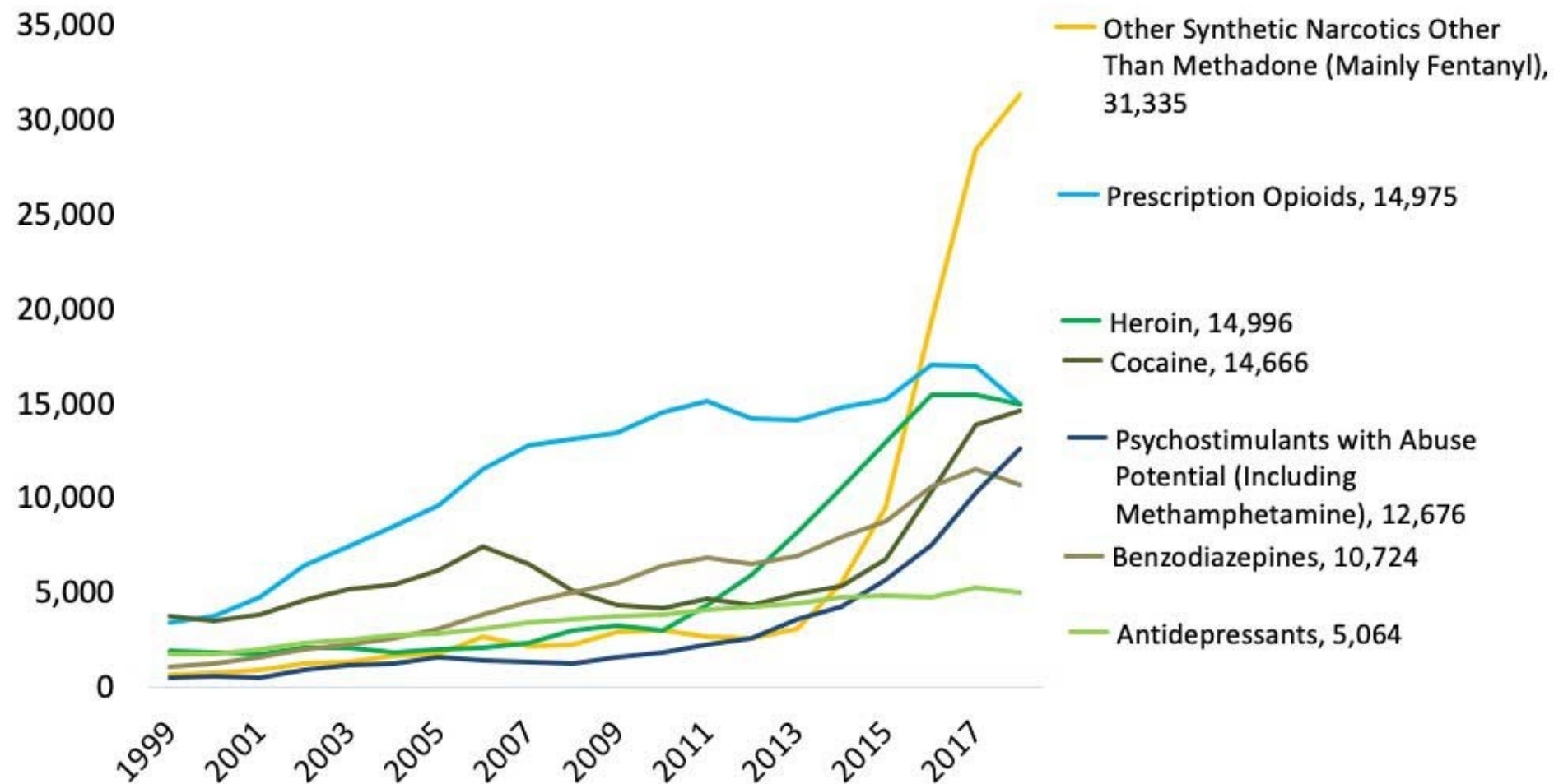
Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019

# Figure 4. National Drug Overdose Deaths Involving Prescription Opioids, Number Among All Ages, 1999-2018

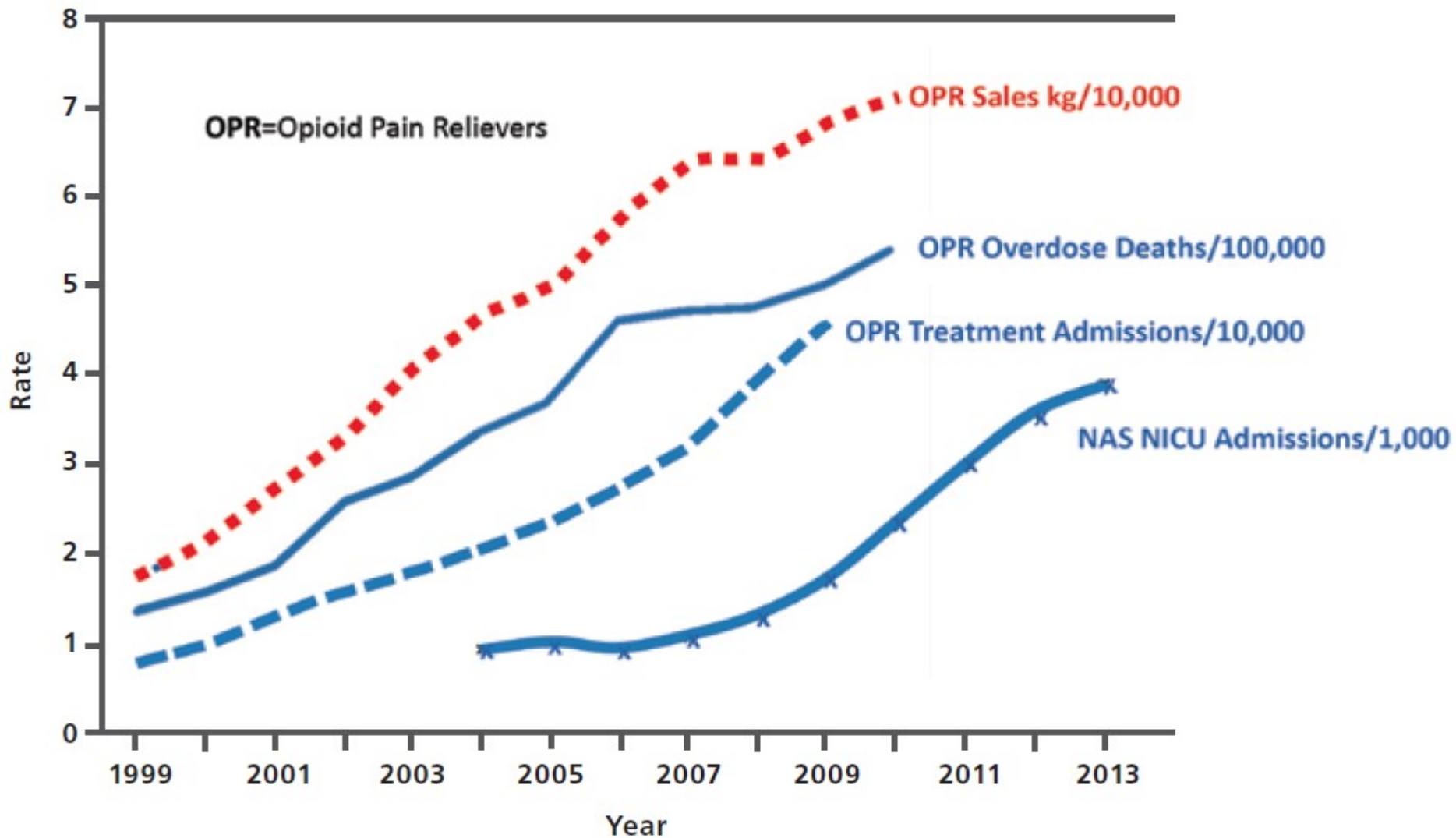


Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019

# Figure 2. National Drug Overdose Deaths Number Among All Ages, 1999-2018



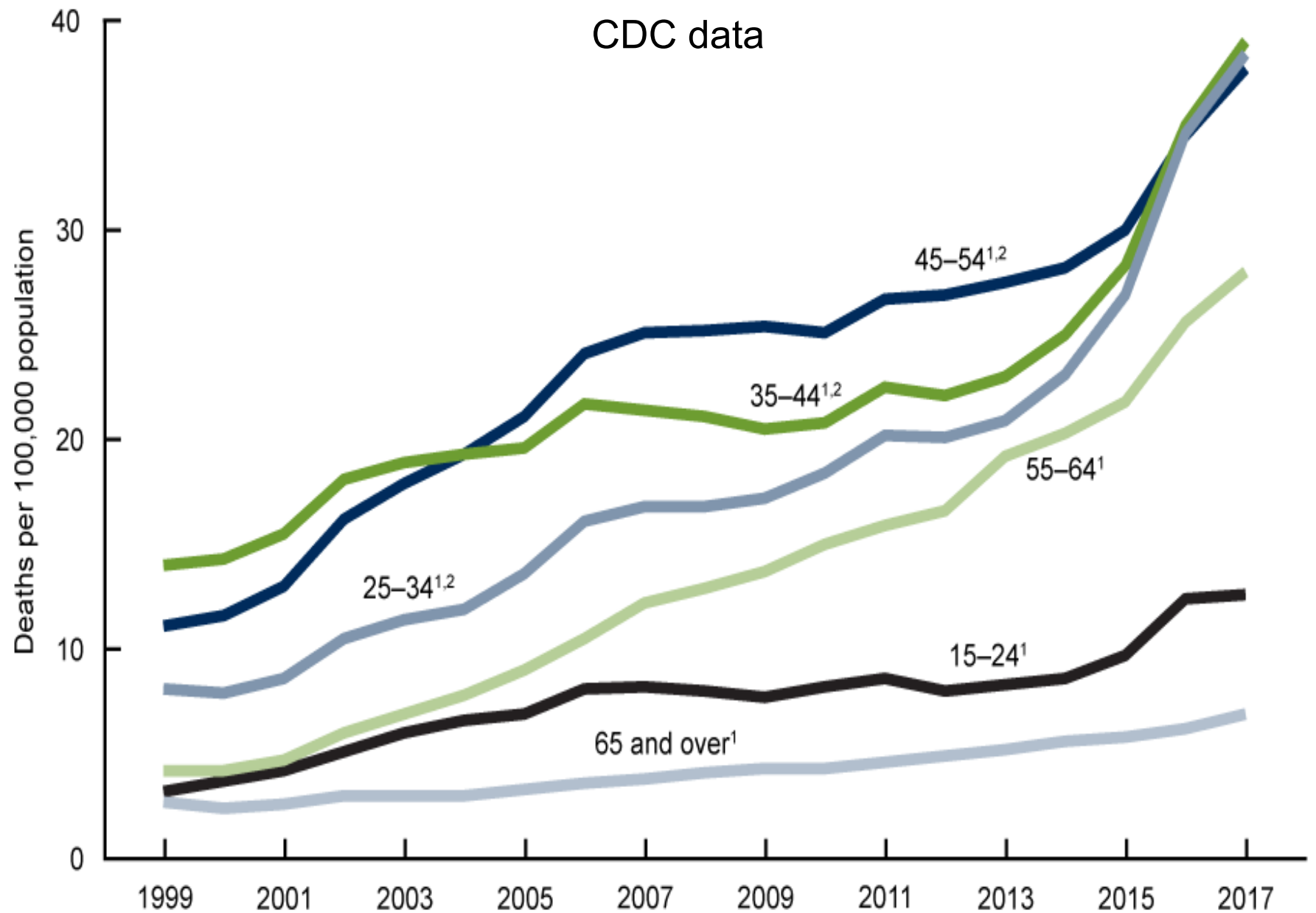
Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2018 on CDC WONDER Online Database, released January, 2019



# Iatrogenic Opioid Epidemic



Figure 2. Drug overdose death rates, by selected age group: United States, 1999–2017



# Years of Life Lost (YLL) From Opioid-Related Deaths in the United States in 2016

| Sex and Age | US Population, No. | Opioid-Related Deaths, No. | Rate of Opioid-Related Deaths, No./1 000 000 Population | YLL, No.  | YLL, No./1000 Population |
|-------------|--------------------|----------------------------|---|-----------|--------------------------|
| Overall     |                    |                            |   |           |                          |
| 0-14 y      | 61 037 347         | 83                         | 1.4   | 6180      | 0.1                      |
| 15-24 y     | 43 612 557         | 4027                       | 92.3  | 230 694   | 5.3                      |
| 25-34 y     | 44 864 505         | 11 552                     | 257.5   | 576 676   | 12.9                     |
| 35-44 y     | 40 577 537         | 9747                       | 240.2   | 400 611   | 9.9                      |
| 45-54 y     | 42 864 368         | 9074                       | 211.7   | 290 153   | 6.8                      |
| 55-64 y     | 41 618 831         | 6321                       | 151.9   | 154 065   | 3.7                      |
| ≥65 y       | 49 420 383         | 1441                       | 29.2  | 22 979    | 0.5                      |
| Total       | 323 995 528        | 42 245                     | 130.4   | 1 681 359 | 5.2                      |



# ***Overdoses in Children***

## **Pediatric Opioid Rx Overdoses: 2001-2008**

- Emergency department visits for opioid overdose rose 101%
- Admissions related to Rx opioid overdoses rose 86%

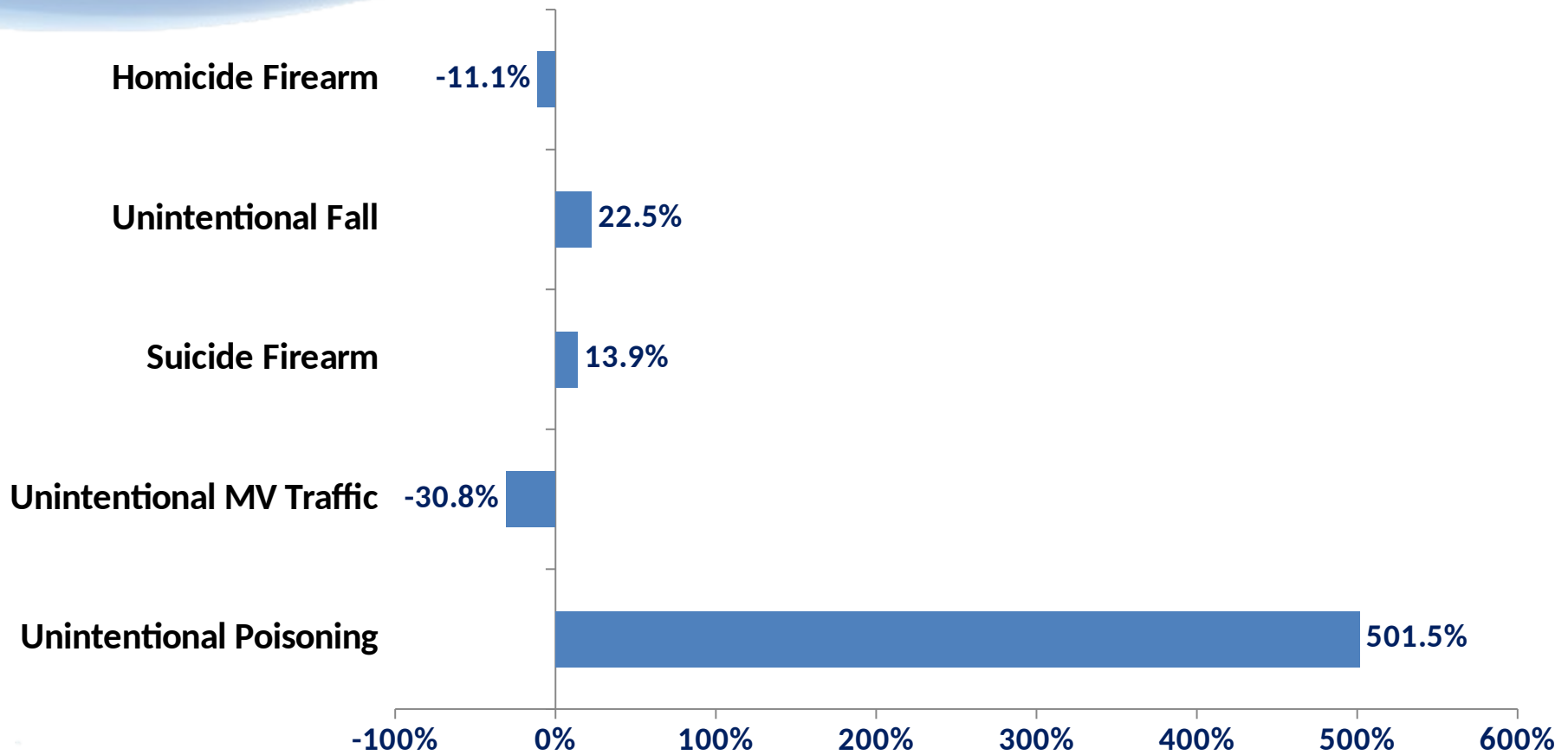
J Pediatr 2012;160:265-70)

# *Data*

***INDIANA***

***Deaths from drug overdose***

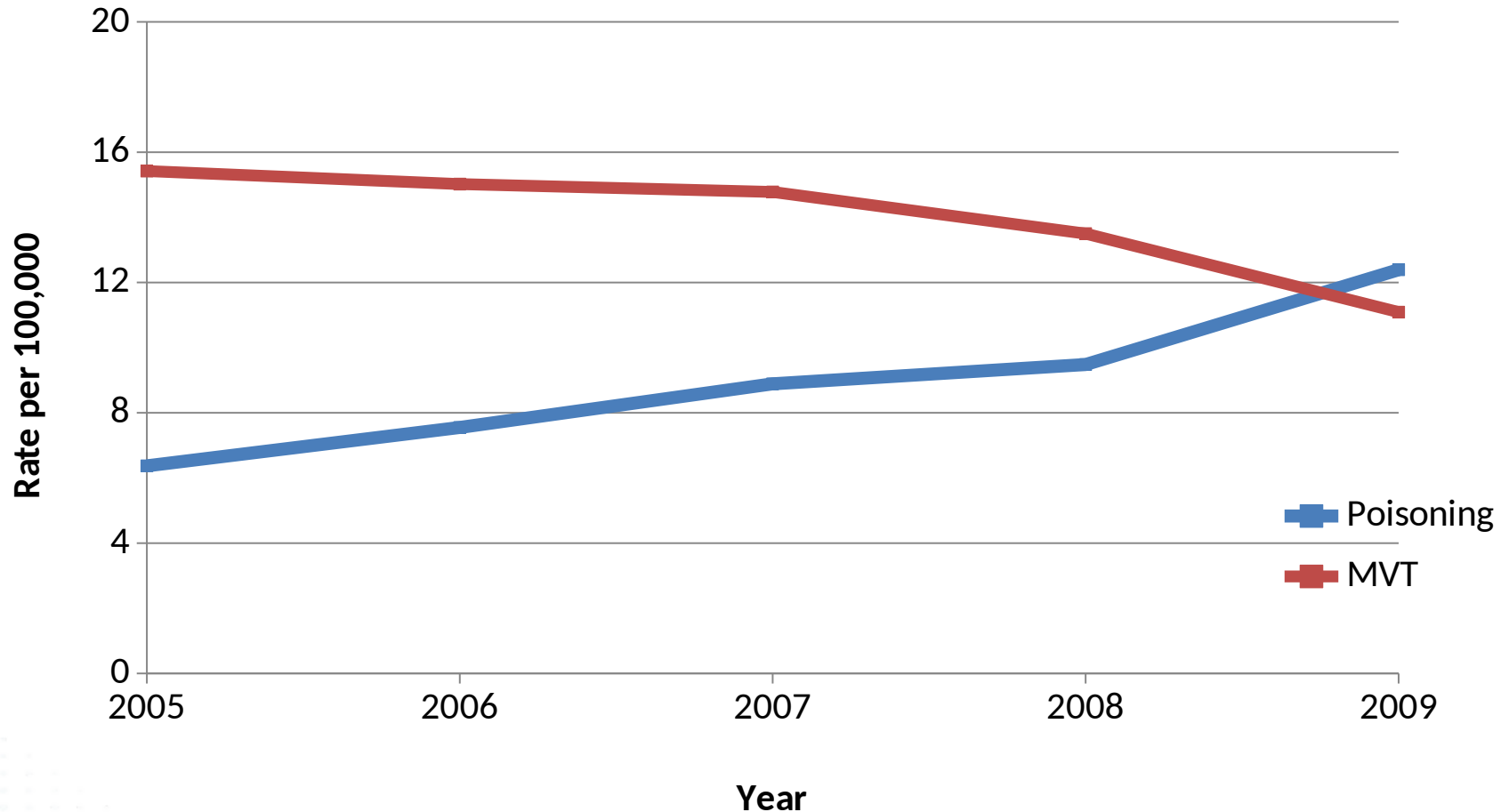
# Percent Change in Leading Causes of Injury Death\* — *Indiana*, 1999–2009



\*Age-adjusted rates

Source: WISQARS

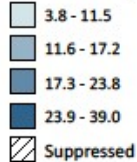
# Unintentional Poisoning and Motor Vehicle Traffic Death Rates, Age-Adjusted, *Indiana*, 2005 - 2009



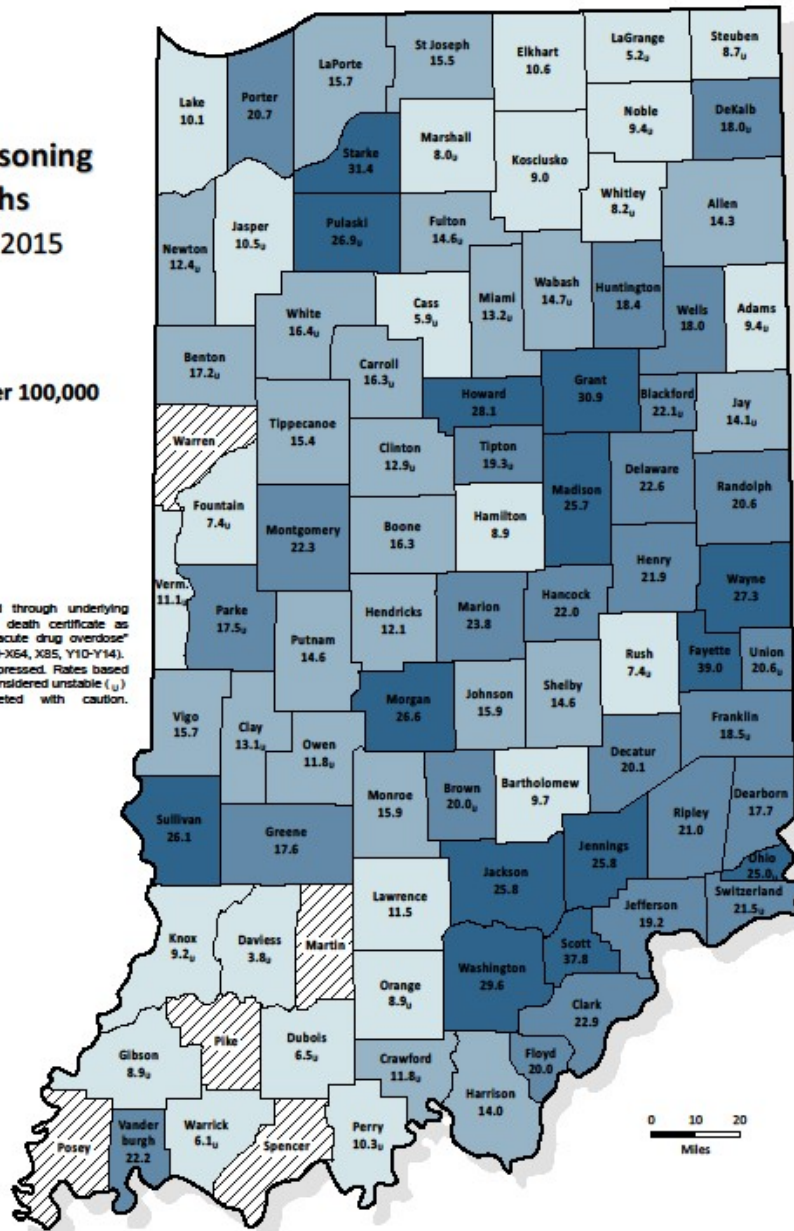
Source: Centers for Disease Control and Prevention, WISQARS Database

## Drug Poisoning Deaths 2012 to 2015

### Crude Rate per 100,000



Overdose deaths identified through underlying cause of death coded on death certificate as drug overdose fatality or "acute drug overdose" (ICD-10 codes X40-X44, X60-X64, X85, Y10-Y14). Counts less than 5 are suppressed. Rates based on counts less than 20 are considered unstable (u) and should be interpreted with caution.



Map Author: ISDH ERC PHG, January 2017

Data Source: ISDH ERC Data Analysis Team, Division of Trauma and Injury Prevention

## DEATH CERTIFICATES

### Overdose as cause of death (Jan 2017)

- **GREATER THAN 60%** of all recent deaths in IN are opioid related
- **13 or more counties** had the highest rate ( 24-39 per 100,000 )

# 2018 Opioid Deaths in Indiana

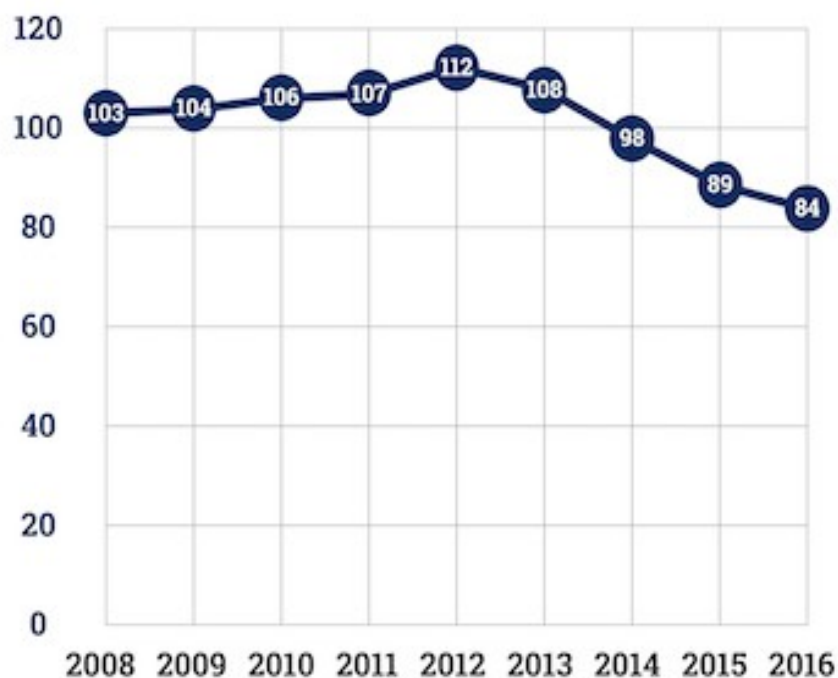
| Location | 0-24 | 25-34 | 35-44 | 45-54 | 55+ |
|----------|------|-------|-------|-------|-----|
| Indiana  | 103  | 328   | 295   | 197   | 181 |

<https://www.kff.org/other/state>

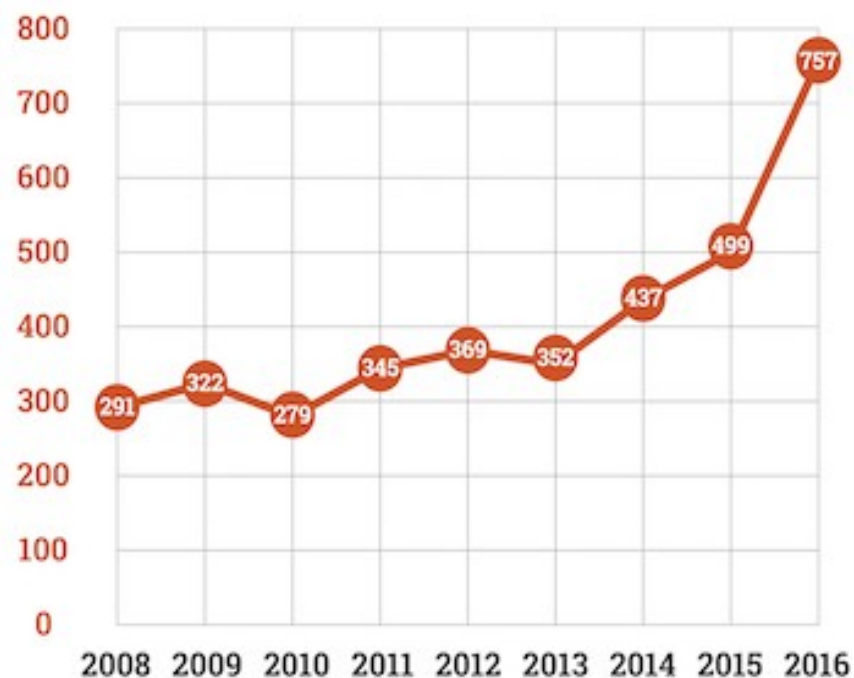


# The Opioid Epidemic in Indiana

## Prescriptions per 100 Residents



## Opioid Deaths



Source: Centers for Disease Control and Prevention, as calculated by Indiana Management Performance Hub



# ***Opioicentric Pain Care: Medicine's Greek Tragedy***



***Good intentions gone astray***

# Opiophilia: Morbidia & Mortalicus



# The Cast and Stage

|                   |   |
|-------------------|---|
| <i>The Chorus</i> | Providers, Advocacy, Patients                 |
| <i>Hero</i>       | Dr. A. Skip Aleze                             |
| <i>Heroin</i>     | Ann O. Dyne                                   |
| <i>Titans</i>     | Big Pharma, Medicalization,<br>Pain “Experts” |
| <i>The Plague</i> | Iatrogenic Opioid Epidemic                    |
| <i>Period</i>     | 1992 - ??                                     |

# *Ann - A tragic case*

17 drinking and weed

17-19 aches and pains from motor vehicle accident  
and soccer

- Soma and Vicodin from Dr. Skip Aleze
- Percocet from friend and college MD

## **Why did she keep getting refills?**



**HOMETOWN CLINIC**

John Doe, M.D.

Family Practice

1234 Your Address

YourCity, GA 98765

(987) 654-3210

Fax (987) 654-3211



Lic. #: A12345

DEA #: AA7654321

NPI #: 789456123

110922A12345 #00001

Name Ann O. Dyne DOB 6/06/84  
 Address 123 Diversion Way Date 1/16/03 MF



Vicodin 5 mg

Sig.- 1-2 po each 6 hrs prn pain

Disp.- 84

Refill NR 1 2 3 4 5 Void After \_\_\_\_\_  Spanish

Do Not Substitute-Dispense As Written

Skip Aleze, MD

Signature



# Ann - More Meds, Less Help

17 Drinking and weed

17-19 Aches and pains from MVA and soccer

- Soma and Vicodin from Dr. Skip Aleze
- **Percocet** from friend and college MD

21 Fatigue, pain and dysfunction

- Anxiety worse & leave of absence
- Xanax added to mix by Dr. Holly Trinity

22 Unintended pregnancy

- Dr. Skip delivers her daughter, Sophia

Note: This combination of drugs would have a euphoric effect which is desirable by drug abusers

# *Ann and Sophia – New Beginnings...*

- Sophia in Hospital 6 days, crying, not eating
- Ann and Sophia move home with her mom





# Ann - Hibernation then Relapse

- Counseling helps Ann adjust to life
- Age 25 - Stable Job, good daycare and new boyfriend
  - Xanax ( 2-4/wk) & just social Etoh
- Fell while being “social”, fractured wrist
  - Norco from ED and post-op Percocet
- Hibernation Ended

**\*\* Iatrogenic Relapse \*\***



# Ann - Guided further down the wrong path

- 2008-2011 Ann remained on opioids and **Xanax**
- Saw Dr. Skip Aleze and others
  - Norco 10 mg 4-5/day, Xanax 1 prn #90/mo
- 2010- Sales Rep. showed him convenience,
  - *point of care (poc)* Urines --\$ and benefit to urine toxicology done in office
  - Dr. Aleze began *poc* Urine Drug Monitoring (UDM) in 2010
- 2011 he sent urine for confirmation to Ameritox
  - Morphine, hydrocodone & alprazolam

What does this likely mean?

# Athens, Indiana



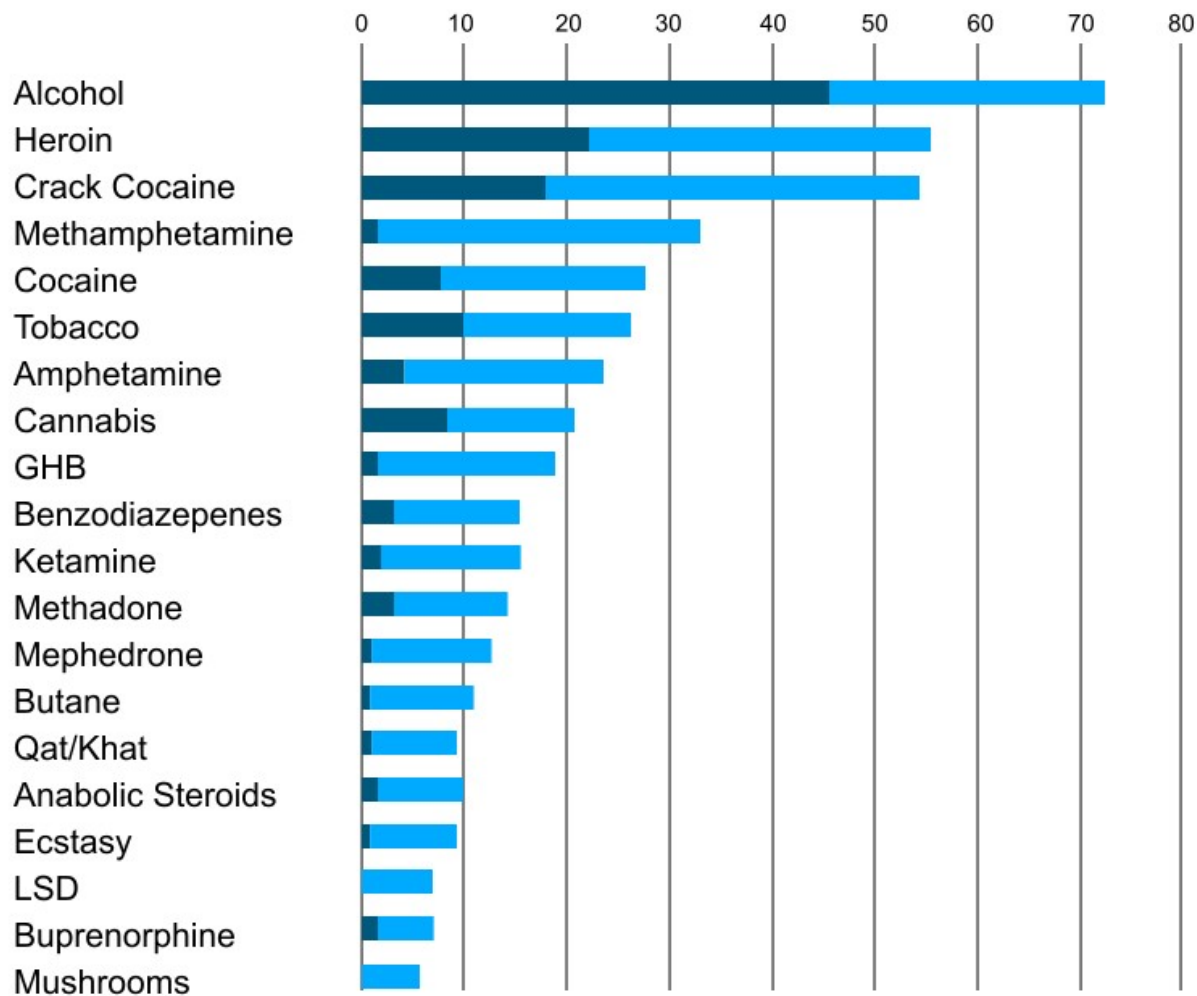
# *Data*

## *Morbidity with SUD / OUD*

# Harm Caused by Drugs

■ Harm to others  
■ Harm to users

\*With a maximum possible harm rating of 100



# We treat, but do we help?

Aggressive use of opioids and interventional technologies has been brought to bear between 1997 and 2005 (~ 65 % increase in expenditures) without evidence of improvement in self-assessed health status and pain. Many outcomes were worse.

JAMA 2008; 299(6):656-664

# Points to Note

- Pain care and opioid use did not seem to help people have less pain or improvements
- Practices were not evidence based
- Opioid Rx 112/100 Hoosiers in 2012
- “Pseudo-addiction” was introduced and drove increases in use. There is NO evidence that pseudo-addiction is real.
- Many teenagers take opioids illicitly

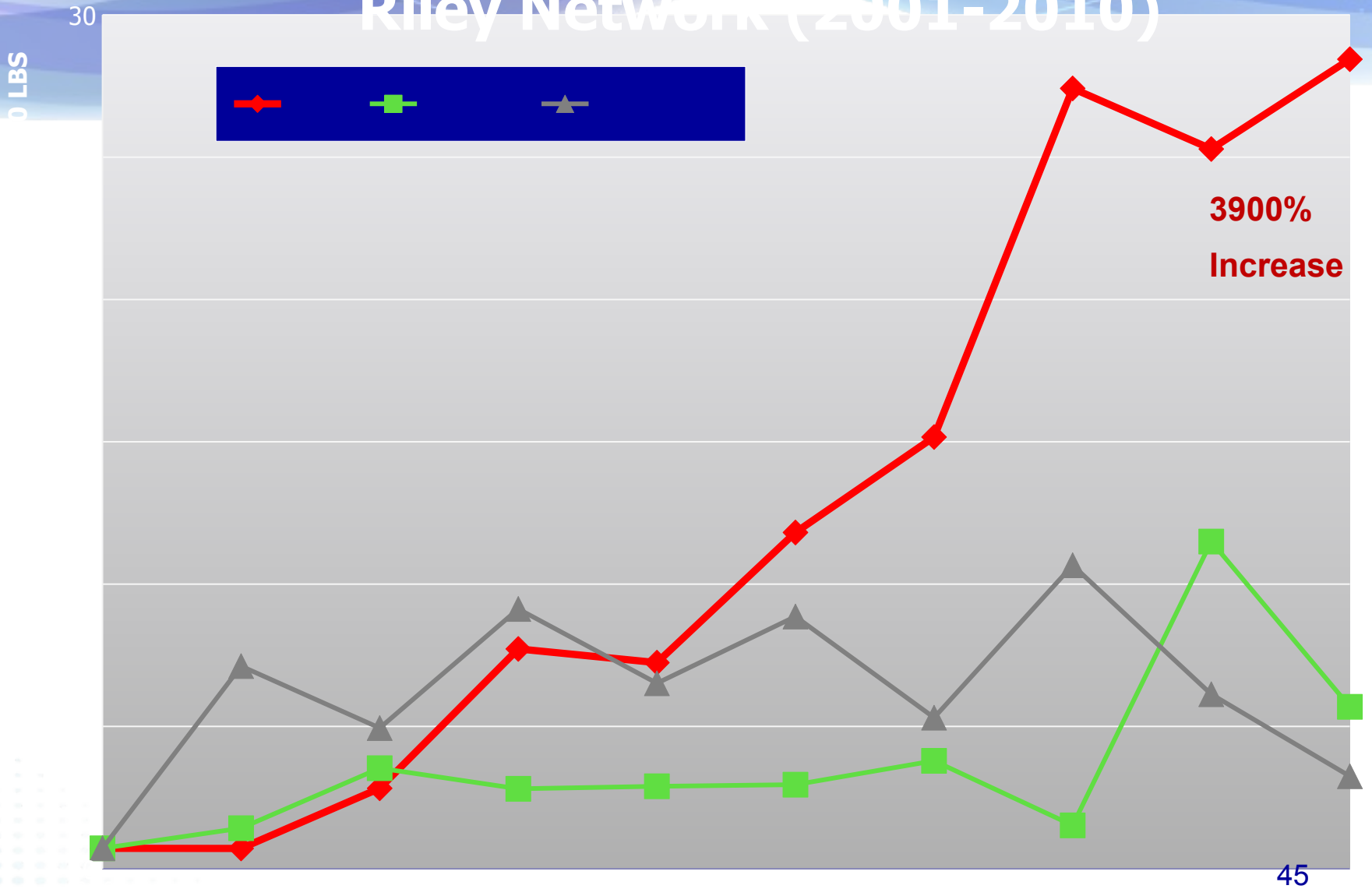


# Data

***Morbidity  
with SUD / OUD***

**Harm to  
Neonate**

# Neonatal Opiate Withdrawal Riley Network (2001-2010)



**Human epidemiological studies have reported an association between opioid use during pregnancy and an increased risk of neural tube defects and other birth defects. The opioid system is implicated in bonding between mother and infant—for example, mice that lack the gene coding for the mu opioid receptor, the main target of opioid analgesics and heroin, show deficits in attachment toward their mothers. Opioid use during pregnancy could theoretically disrupt attachment between women and their babies Cognitive impairments have also been reported in children and young people born to women who misused opioids during pregnancy, although the relative contributions of other drugs or lifestyle factors to such deficits are unclear. **BMJ 2016; 352****

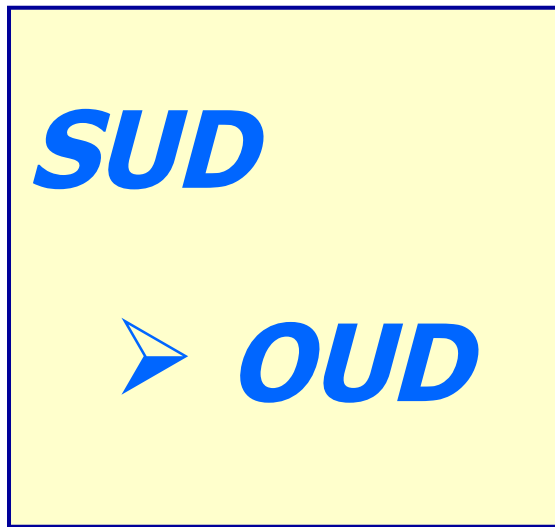
**Much remains to learn on this. Opinions vary.**

# Perspective and Wisdom

**“The possibility that health care might cause net harm is increasingly important given the sheer magnitude of the modern health care enterprise...these issues will likely challenge assumptions about the value of many current health care practices.”**

JAMA 2009; Vol 302.(1):89-91

# ***Data***



**Prevalence  
(Burden)**

# Prescription Drug Misuse

- **USA <5%** of world population
- consumes **99%** global hydrocodone
- consumes **>80%** global opioid



Source: NSDUH 2009

Note: These statistics raise “safety issues” related to prescribing controlled substances:

1. What we wish to prescribe, based on our assessment
2. What the patient may be receiving from other MDs and dentists
3. What the patient may be using illicitly

# Number of Americans on Long-term Opioids

# 10 Million

Opioid overdose deaths rose 28 percent in 2016, to 42,000 men, women and children

Ann Intern Med 2017; 167:181–191



# NSDUH (SAMSHA) Data 2015

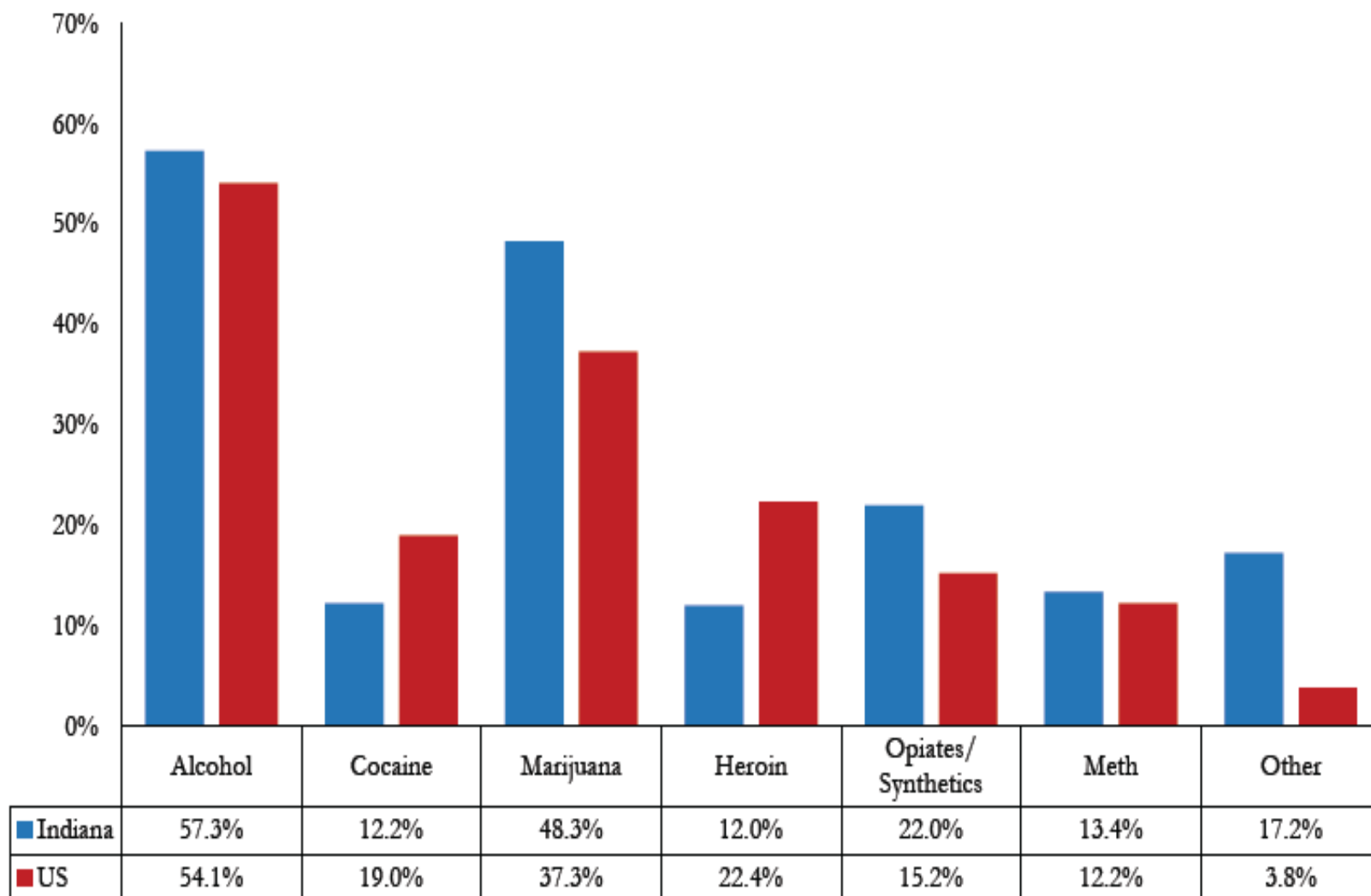
- **National survey of 51,200 people from 50 states and D.C. in 2015**
- **Survey results indicated that 38% of U.S. population used an opioid in 2015 (i.e. approx. 91.8 million people)**
- **Among Adults with opioid Rx**
  - 12.5% reported misuse
  - Among these 12.5%, 16.7% indicated they had a OUD
- **Of all adults who reported misusing opioids**
  - 40% with a Rx, and 60% without an Rx
  - Among the 60%, 41% obtained opioids illicitly for free from friends and family
- **Among adults who misused opioids 63% reported relief of pain as motivation**

# Lifetime Prevalence of SUD

- **12-15% of Americans**
- **30% of children of alcoholics**
- **28-33% of people on chronic opioids**

J Addictive Dis 2011; 30:185-194

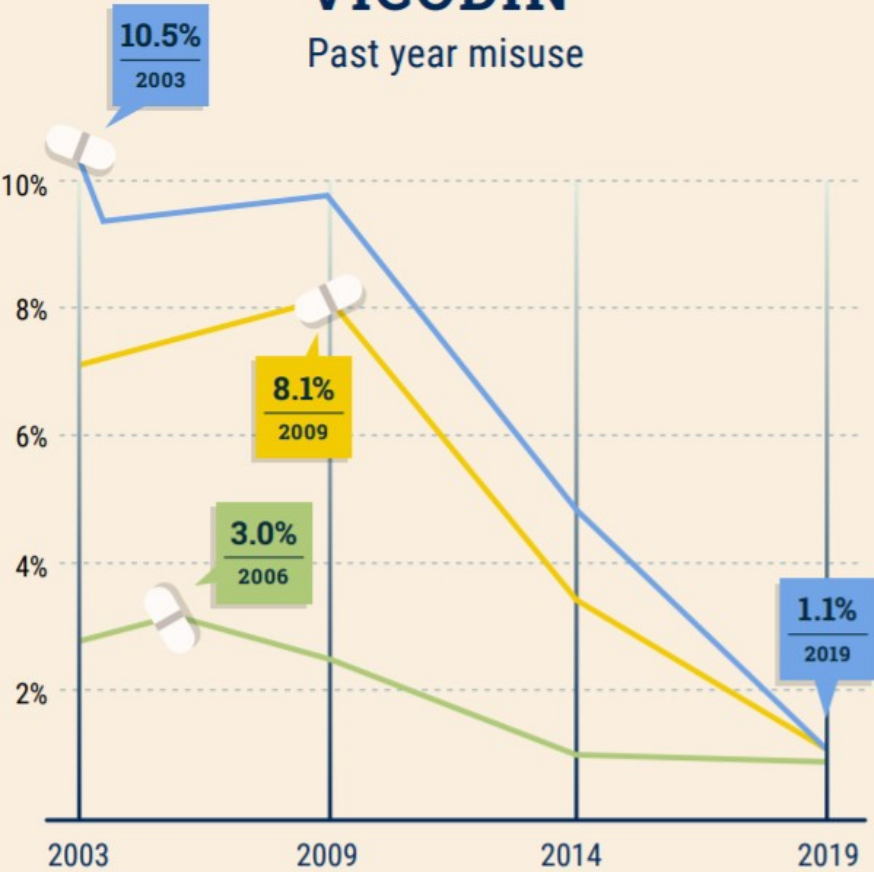
Figure 4. Percentage of Treatment Admission with Reported Use of Substances (TEDS-A, 2013)



Note: Reported use of various substances by individuals admitted for treatment to hospitals (Indiana vs. U.S.)

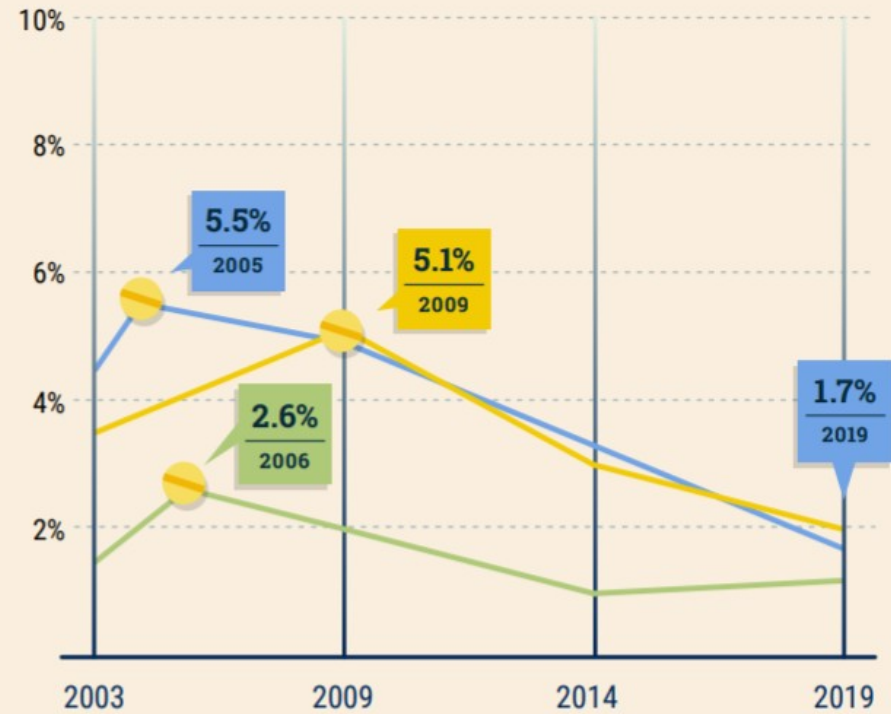
# VICODIN®

Past year misuse



# OXYCONTIN®

Past year misuse



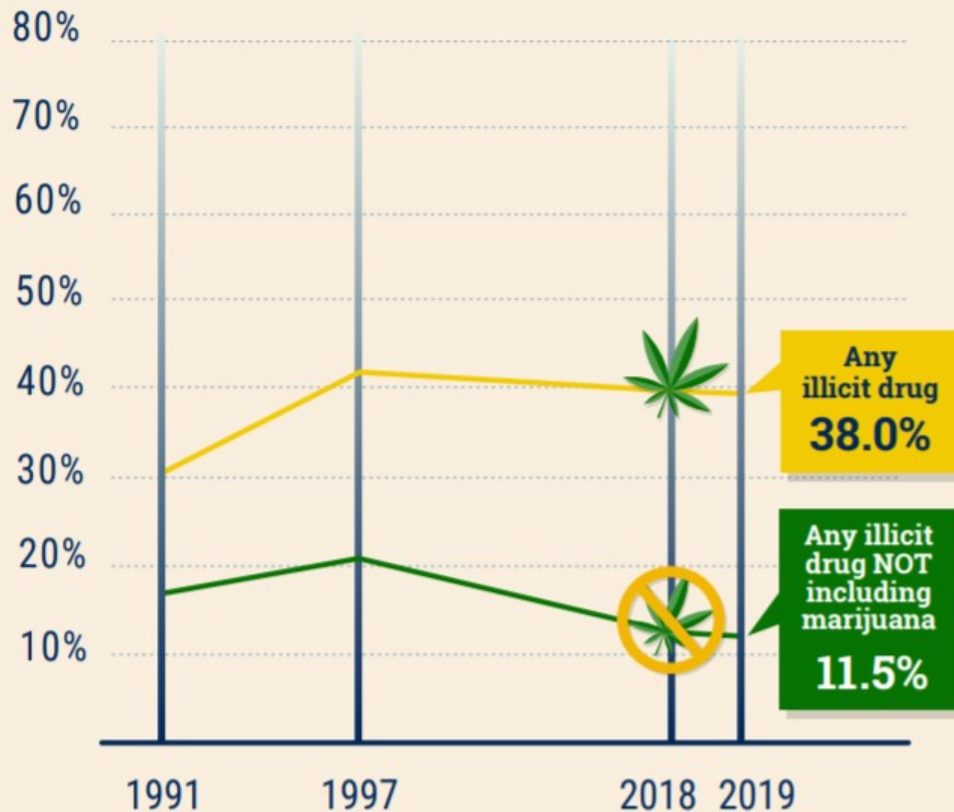
8th graders

10th graders

12th graders

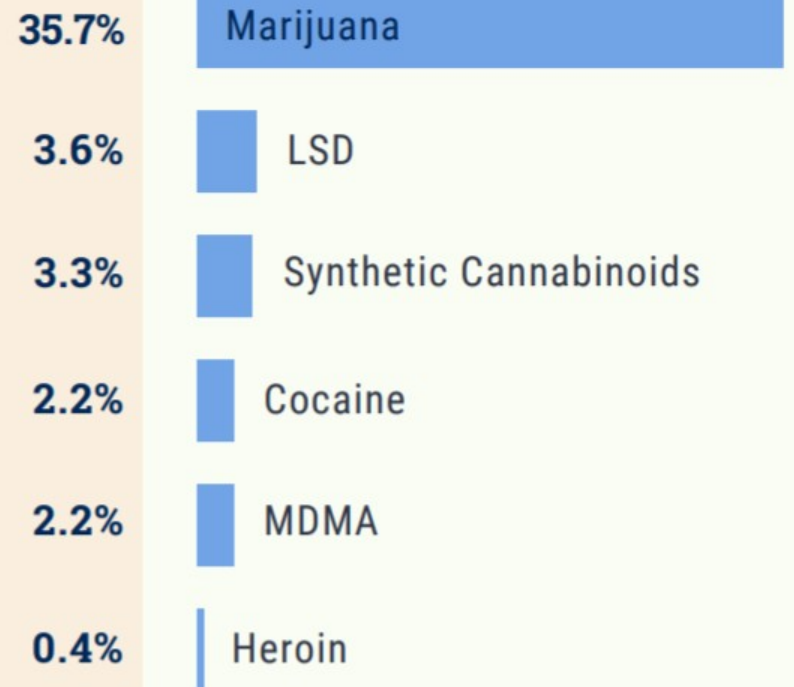
## ILLCIT DRUG USE STEADY

Past year use among 12th graders



## PAST YEAR ILLICIT DRUG USE

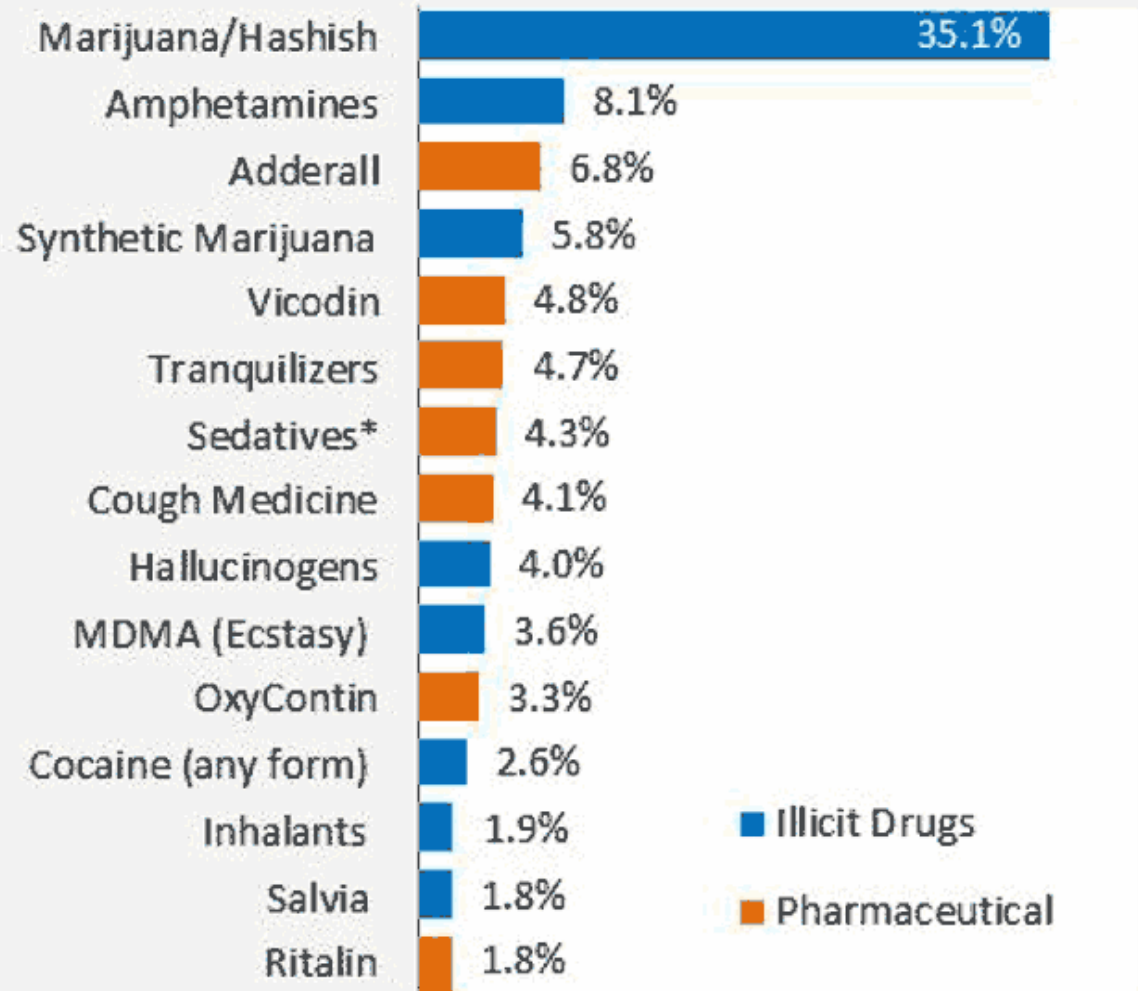
Past year use among 12th graders





# SUD in 12<sup>th</sup> Graders

## Past-Year Use of Various Drugs by 12th Graders (Percent)

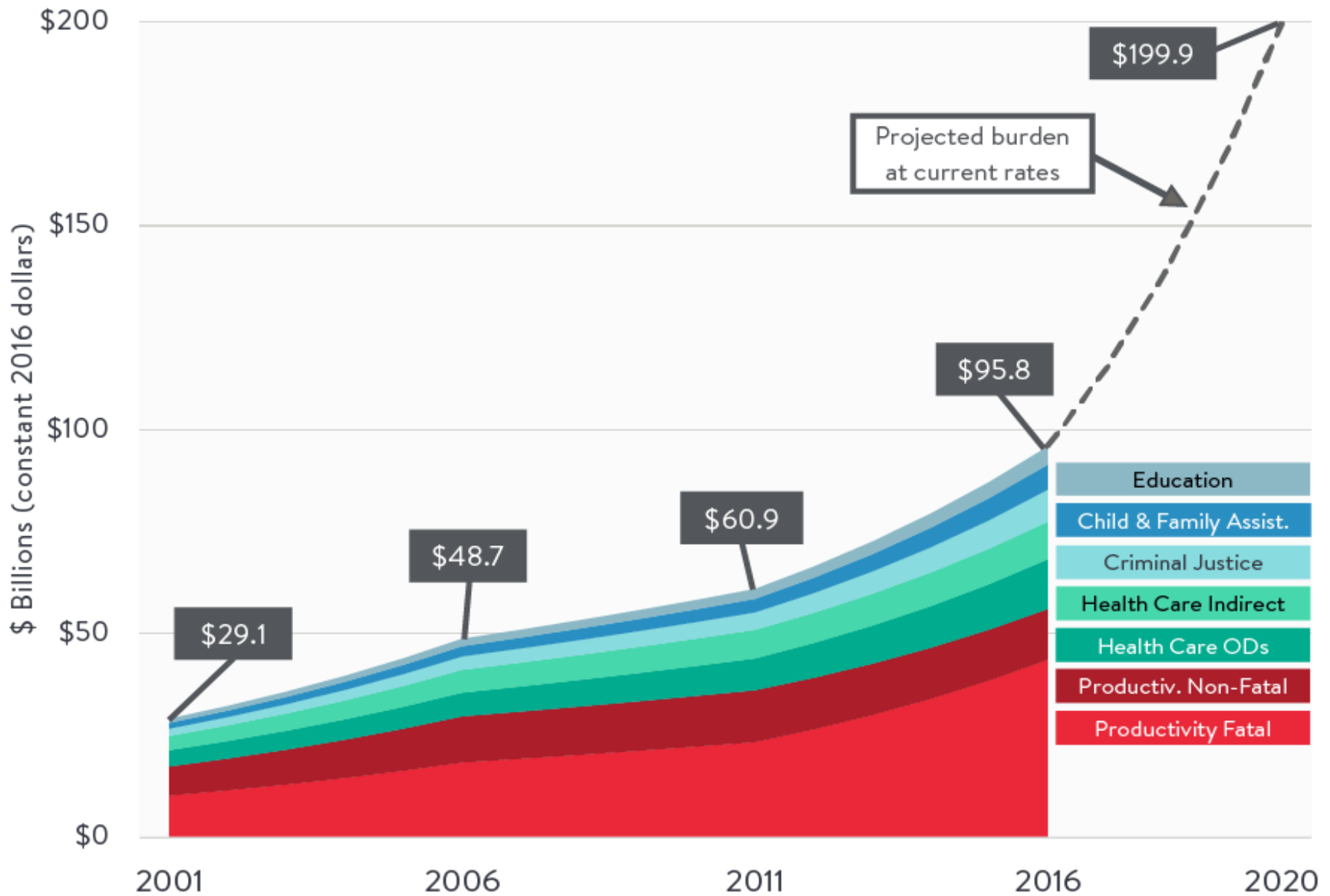




# Cost of Opioid Prescriptions in US

- **2006 estimated total cost nonmedical use prescription opioids was \$53.4 billion**
- **\$42 billion (79%) to lost productivity**
- **\$8.2 billion (15 %) to criminal justice costs**
- **\$2.2 billion (4%) to drug abuse treatment**
- **CDC's estimate for 2009 is \$ 72 billion**

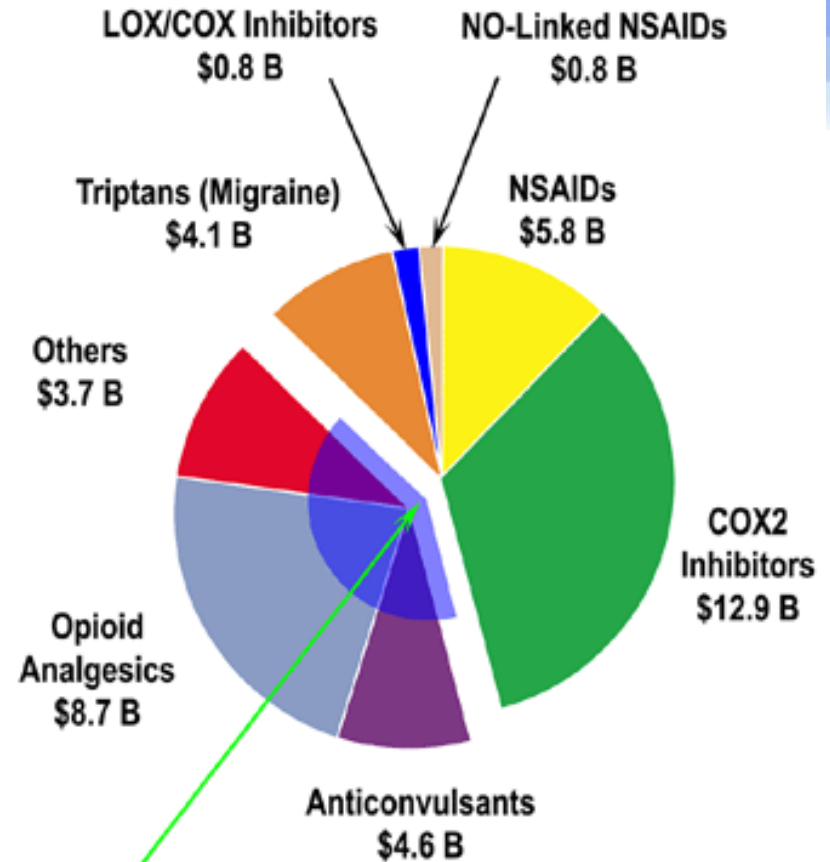
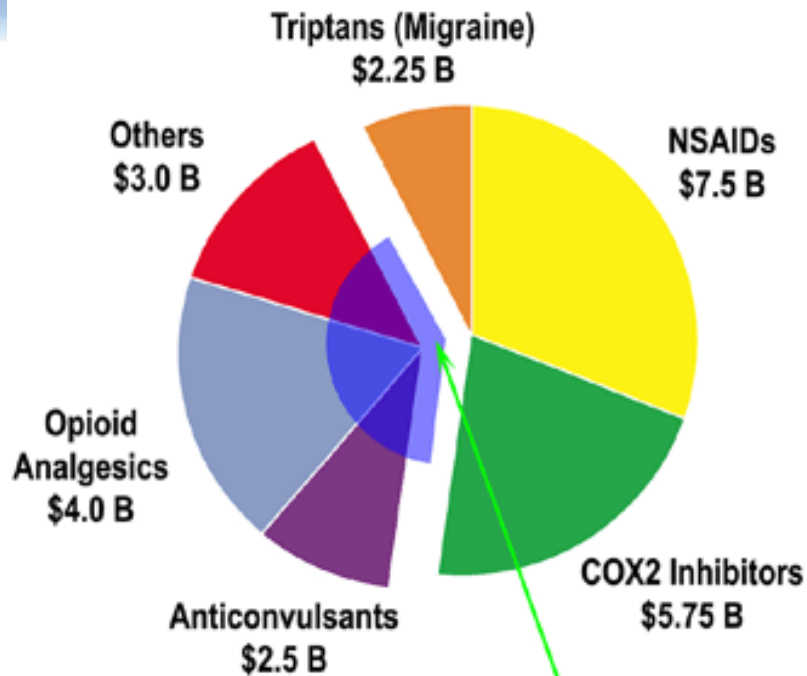
# Costs of the Opioid Epidemic by Year and Type



\* Data between labeled estimates interpolated using constant growth rates

2001 (US \$ 25 billion)

2010 (US \$ 41.5 billion)



**Chronic Pain Market  
(CGX-1160 Opportunity)**

# Points to Note

- **Addiction, morbidity and morality data were not seriously addressed until 2012-2013**  
Ignoring harm, OD is dose related
- **Rx opioid use clearly hurting our economy by 2006**
- **Chronic strong opioid use associated with lower quality of life scores, all 8 domains in SF-36**
- **Neonatal Abstinence Syndrome rose > 1000 fold in Indiana over a decade**
- **National Organizations attention and regulations arrived too late**
- **Over 200,000 die from Rx opioid related death in under a decade**

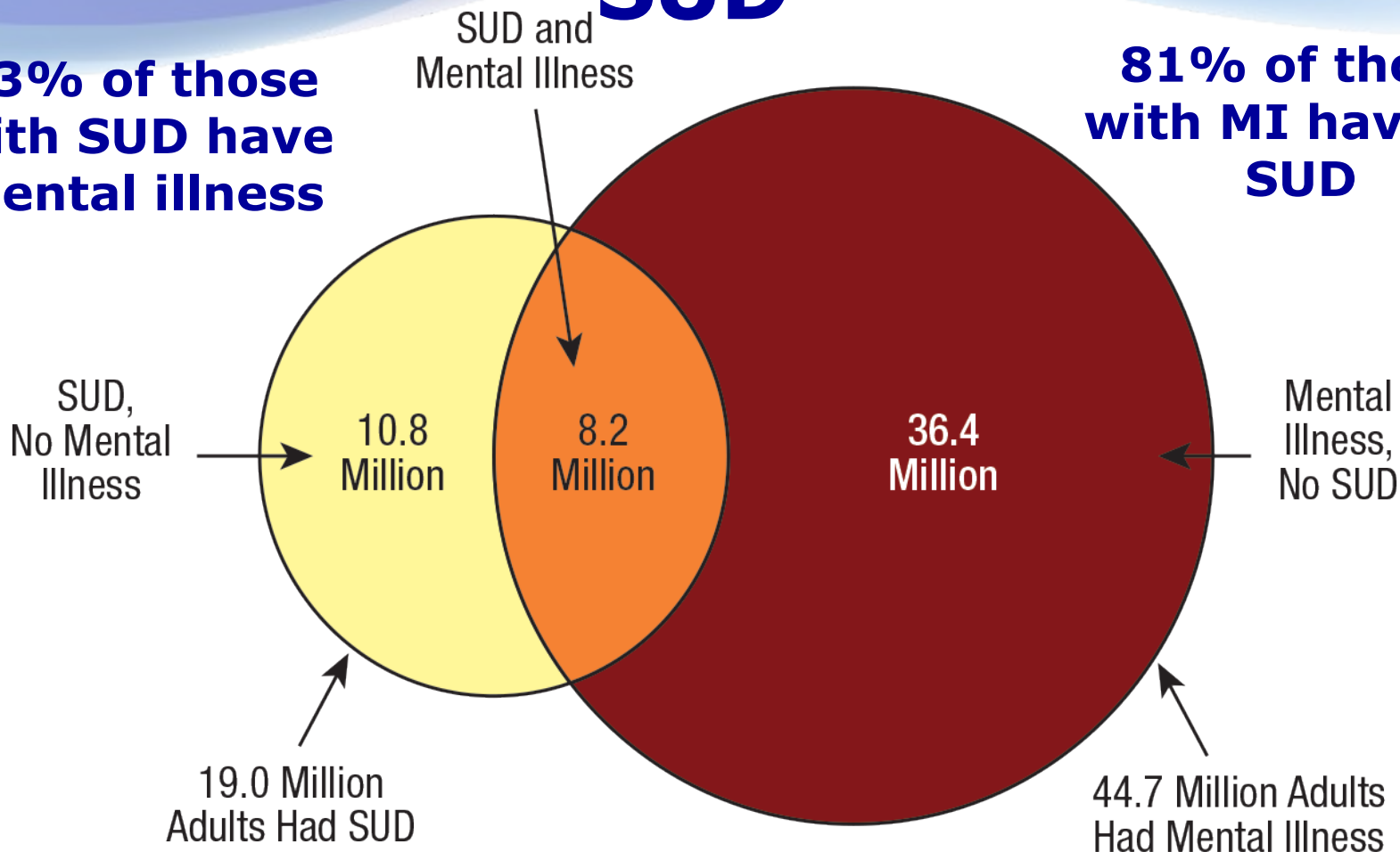
# ***Risk Factors for***

- ***Substance Use Disorders  
(SUD)***
  - ***Opioid Use Disorder (OUD)***
- ***Addiction***
- ***Death from Overdose***

# Overlap of Mental Illness and SUD

**43% of those with SUD have mental illness**

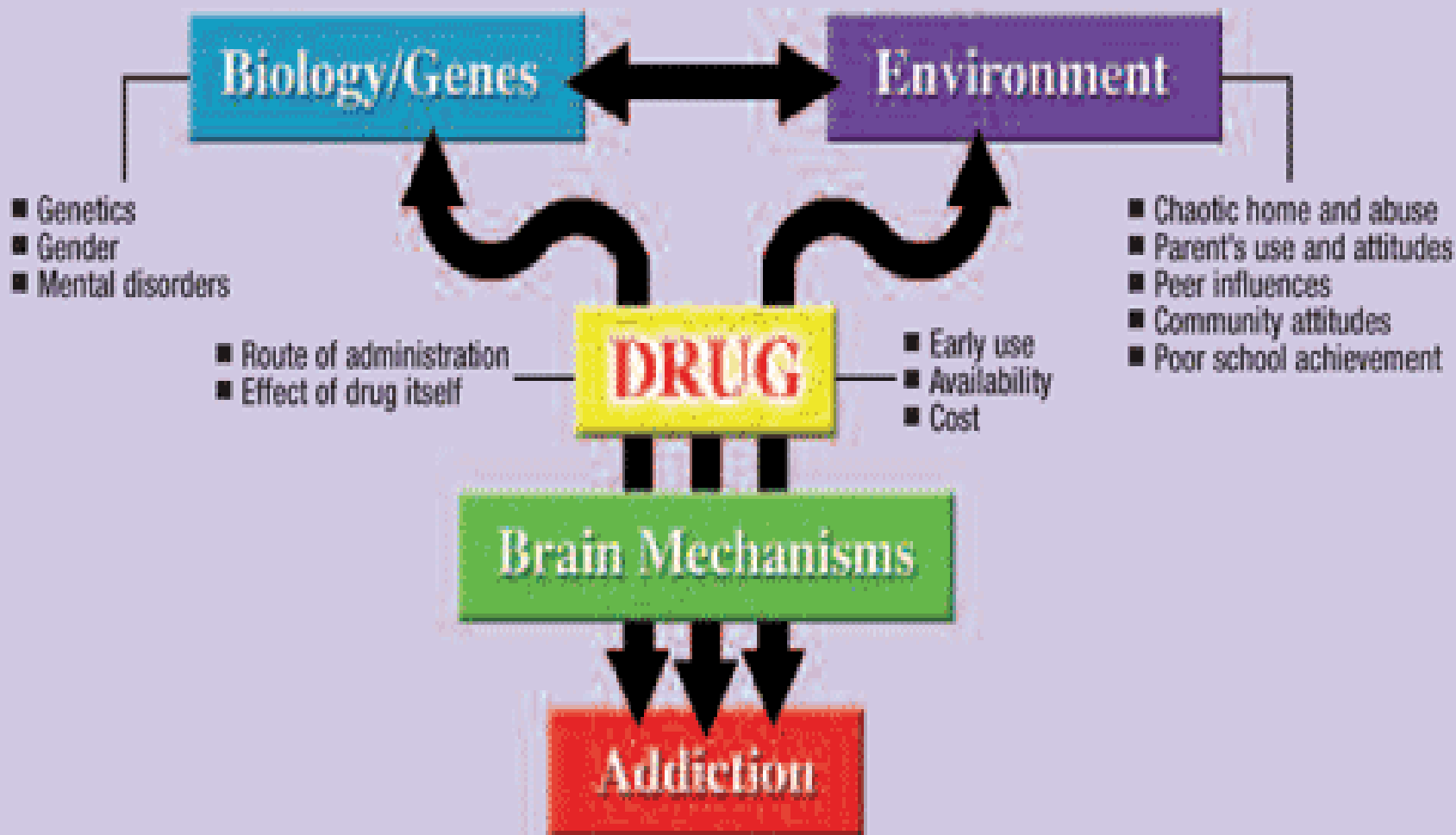
**81% of those with MI have no SUD**



**2016 NSDUH**



# RISK FACTORS



# ***Risk Factors***

***"Feel Good"***

# Why folk try exogenous chemicals

- **To feel good and to have “novel”**
  - **Feelings, sensations, experiences and to share**
  - **Positive re-enforcement**
- **To feel less/less bad**
  - **Anxiety, worries, fears, depression, hopelessness**
  - **Negative re-enforcement**



***Risk Factors***

***Alleviate Pain***

# What is Pain

- **An unpleasant sensory and emotional experience associated with actual or *potential* tissue damage, or *described* in terms of such damage**

# Pain: Big Take Home Point

Pain is a *Perceptual Experience* formed in the brain

- Similar to other experiences with flexible biological associations:
  - Hunger, tickle, itch, urinary urgency and orgasm
- A complex experience embracing physical, mental, social, and behavioral processes, compromising the life of many individuals
  - *SSI Commission For Evaluation of Pain*

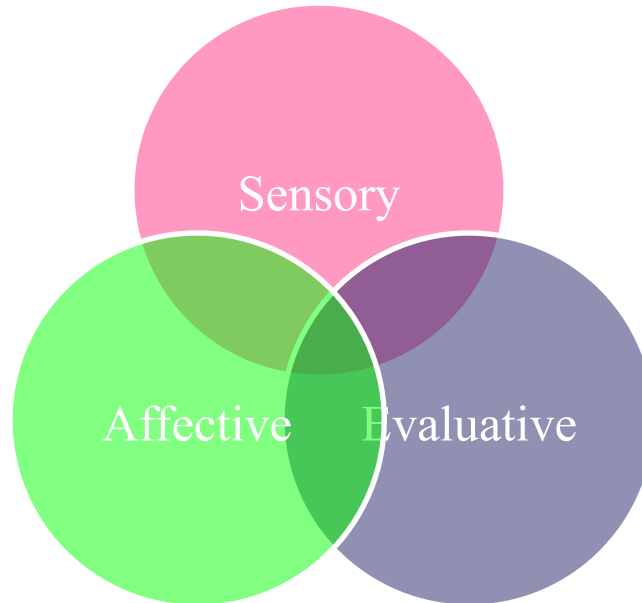


# Increase in opioid medications to manage pain

- Growing public awareness of the right to pain relief
- Joint Commission Standards – 2000
  - New pain standards
- Liberalization of laws governing *opioid prescribing*
- Aggressive marketing of *long-acting opioids* by the pharmaceutical industry

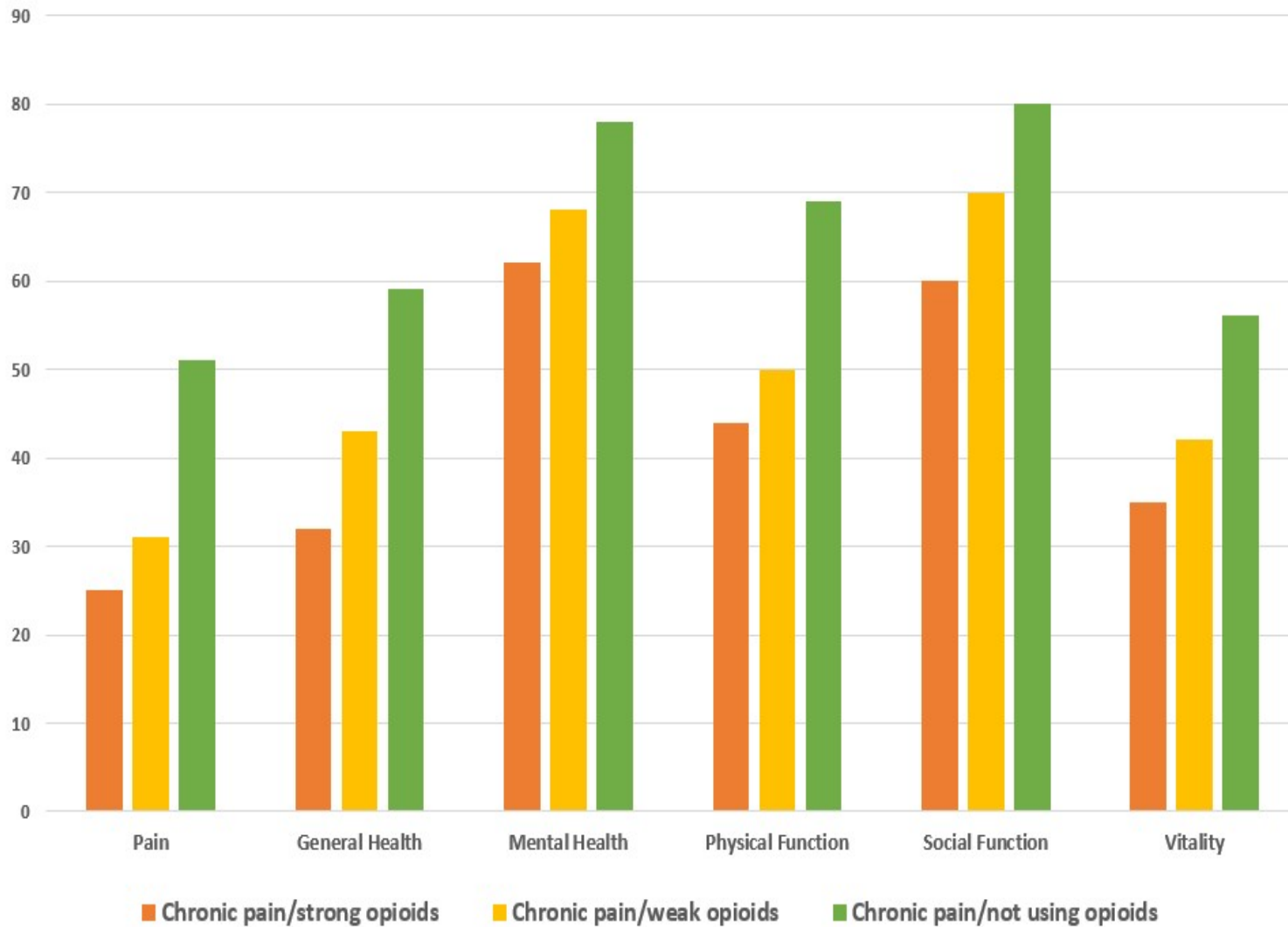


# Chronic Pain



Chronic pain is more complex than acute pain and can be difficult to manage

## Quality of Life Scores According to Chronic Pain Status and the use of Opioids

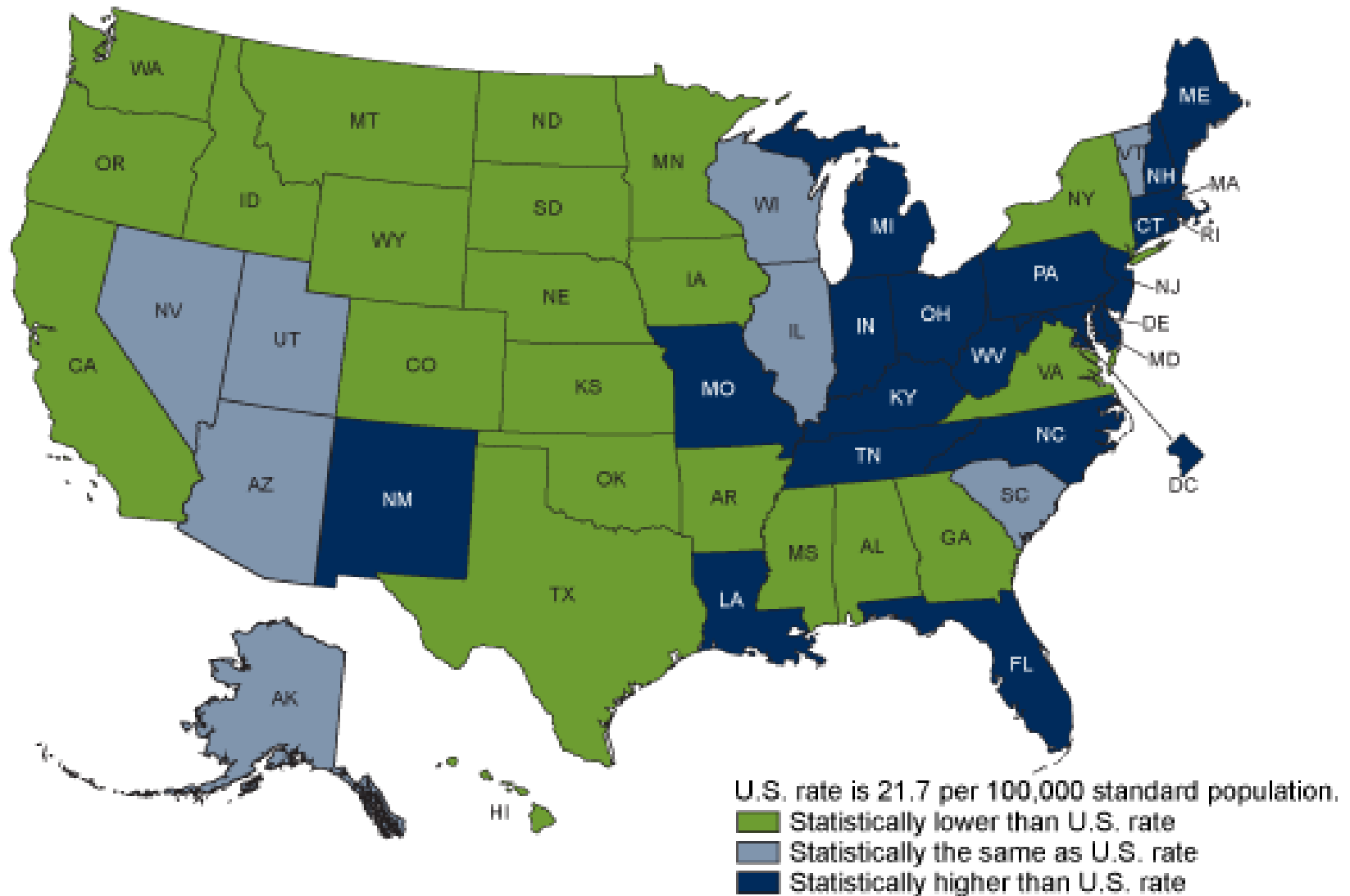


# Predictors of Opioid Misuse in Patients with Chronic Pain

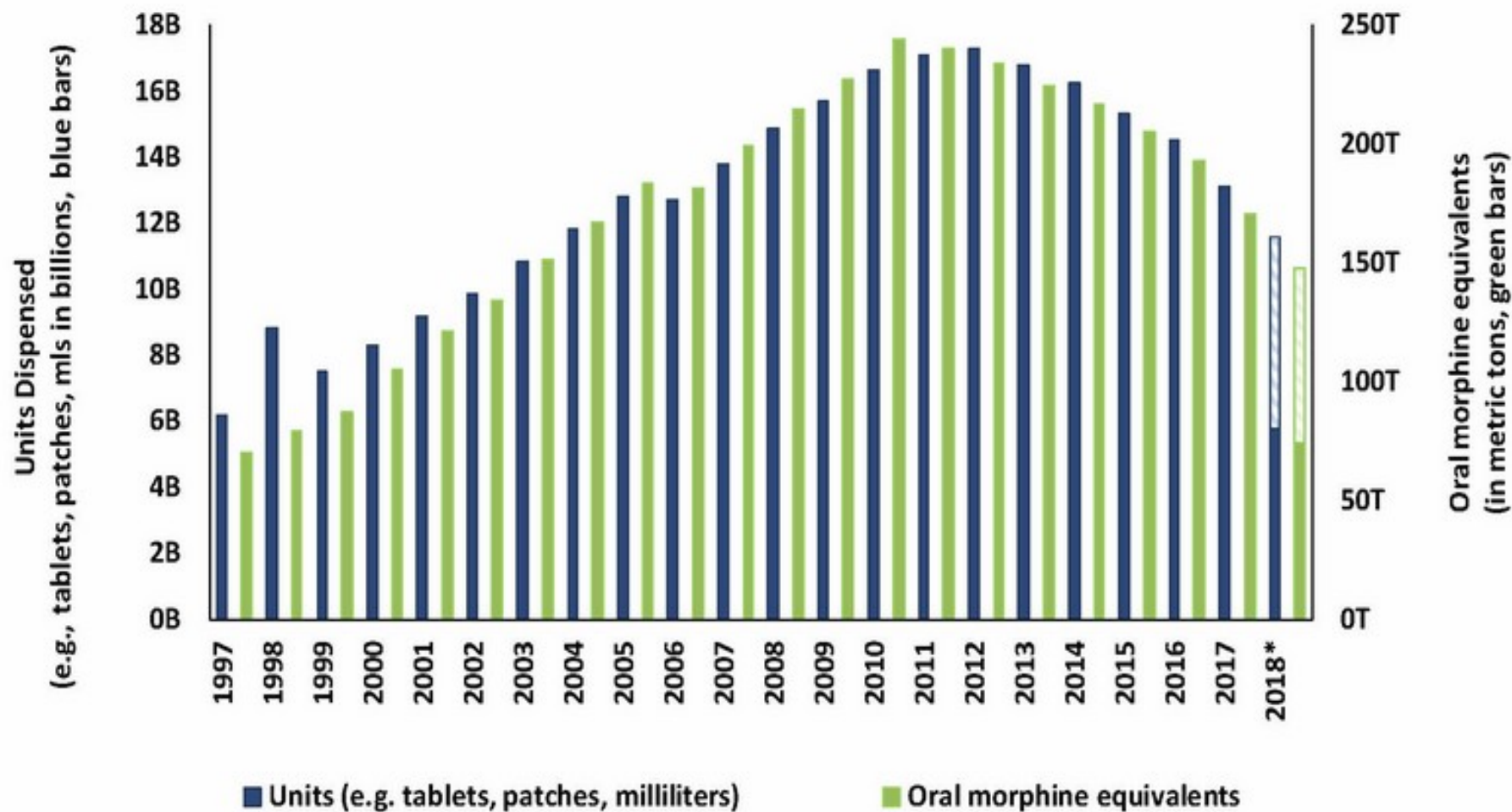
- **196 patients in Academic Chronic Pain Venue (Int. Med)**
- **Monitored for 12 months**
- **Misuse criteria**
  1. **- UTS**
  2. **+ UTS ( too much)**
  3. **Multiple providers**
  4. **Diversion**
  5. **Rx forgery**
  6. **Stimulants**

**74% participants were depressed on screening**

# Age-adjusted drug overdose death rates, by state: United States, 2017



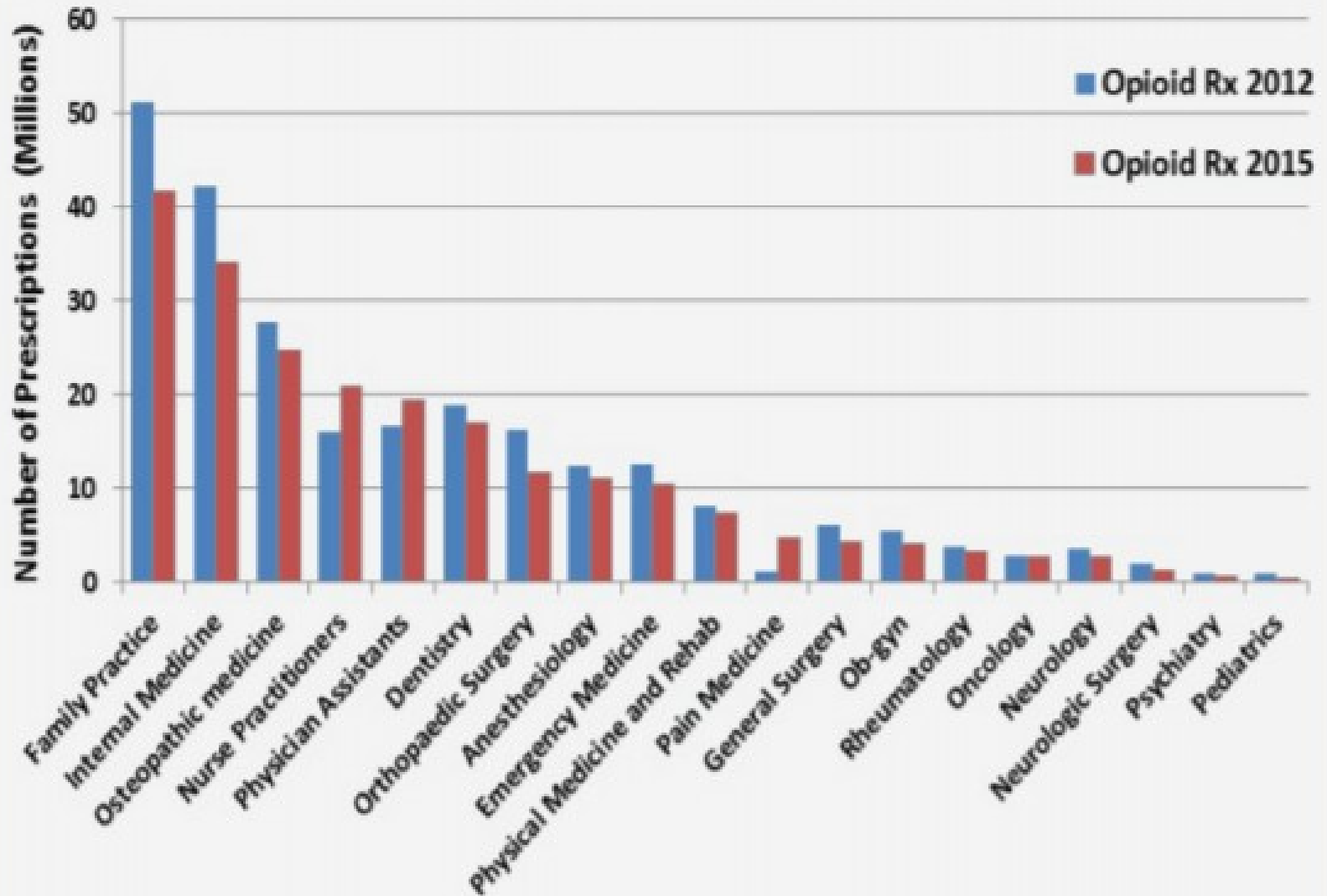
# Prescription Opioid Analgesics



SOURCE: FDA AND IQVIA



## National Opioid Prescribing by Specialty



Source: IMS Health

# Percentage of patients seeing multiple doctors

(Patients w/ Hx overdose vs. Patients w/o Hx overdose)

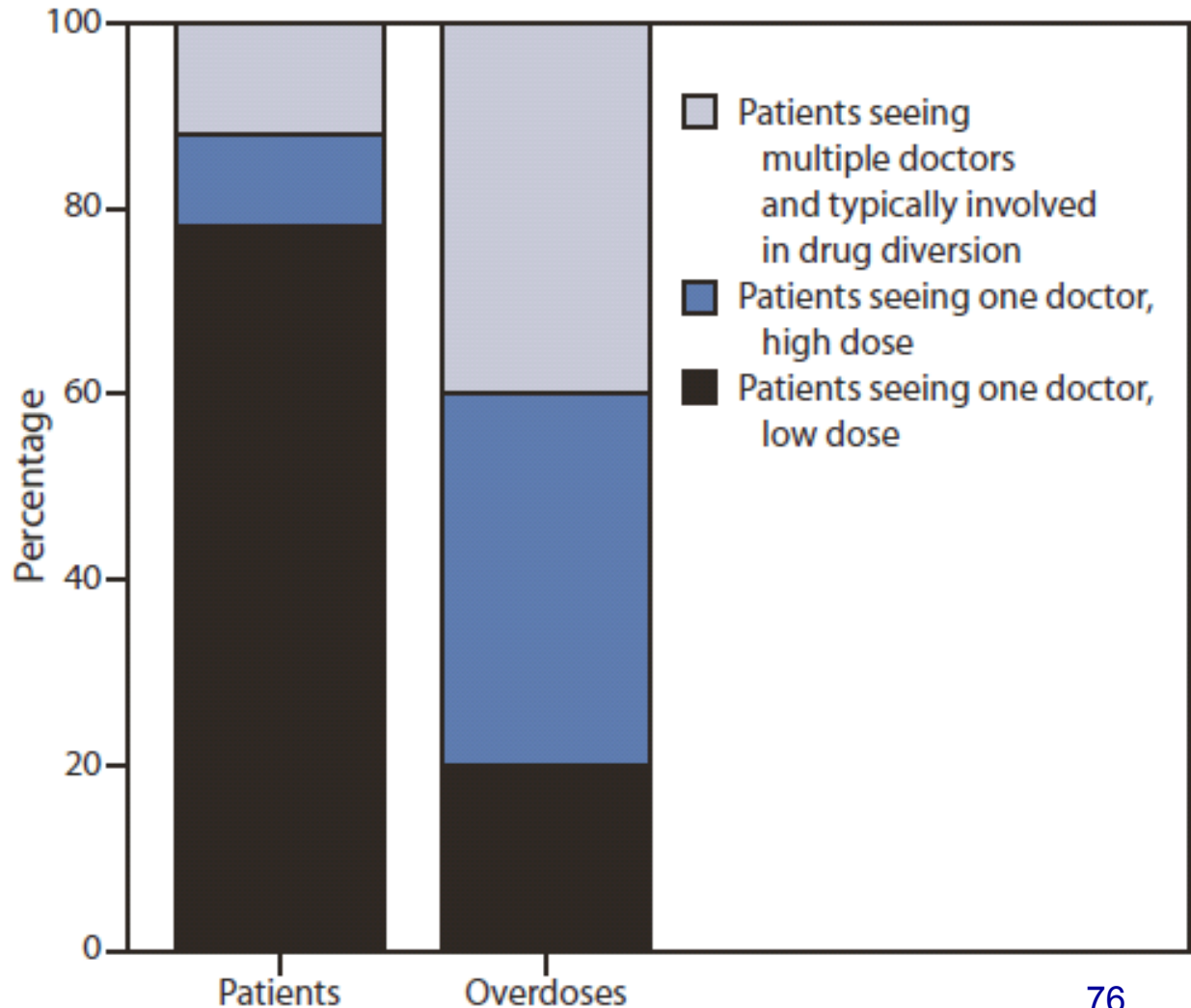
## NOTICE

### Patients with overdoses

- saw multiple doctors, and
- got higher dose prescriptions

*more frequently*

than patients without overdoses



# Points of Note

- **Experts over-stated opioid safety**
- **Pharma mislead providers and consumers**
- **Providers felt compelled to increase opioid use despite no solid evidence for chronic pain**
- **CMS and Joint Commission forced “standards” without evidence**
  - **Pain as 5<sup>th</sup> Vital Sign and survey questions**
- **Providers wrote for ever increasing amounts of opioids until 2013**

# AAN - Position paper

## **“Opioids for chronic non-cancer Pain”**

**"Whereas there is evidence for significant short-term pain relief, there is no substantial evidence for maintenance of pain relief or improved function over long periods of time without incurring serious risk of overdose, dependence, or addiction."**

A position paper of the American Academy of Neurology"  
Neurology 2014; 83(14):1277-84

# What is the Addiction Risk?

- **Published rates of abuse and/or addiction in chronic pain populations are 3-19%**
- **Suggests that known risk factors for abuse or addiction in the general population would be good predictors for future aberrant behavior as well**
  - **Past cocaine use, h/o alcohol or cannabis use<sup>1</sup>**
  - **Lifetime history of substance use disorder<sup>2</sup>**
  - **Family history of substance abuse, a history of legal problems and drug and alcohol abuse<sup>3</sup>**
  - **Heavy tobacco use<sup>4</sup>**
  - **History of BAD and severe depression or anxiety<sup>4</sup>**

<sup>1</sup> Ives T et al. BMC Health Services Research 2006    <sup>2</sup> Reid MC et al JGIM 2002

<sup>3</sup> Michna E et al. JPSM 2004    <sup>4</sup> Akbik H et al. JPSM 2006



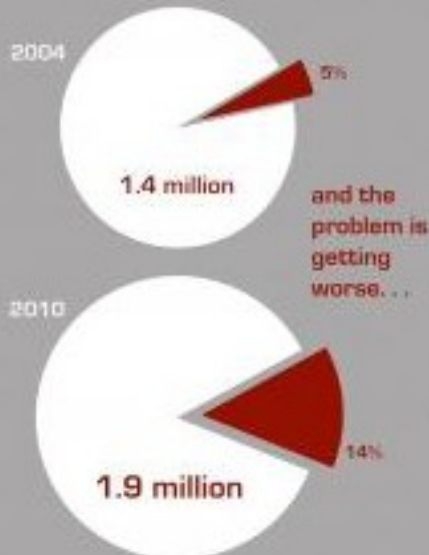
## ABUSE OF PRESCRIPTION PAIN MEDICATIONS RISKS HEROIN USE

In 2010 almost 1 in 20 adolescents and adults – 12 million people – used prescription pain medication when it was not prescribed for them or only for the feeling it caused<sup>1</sup>. While many believe these drugs are not dangerous because they can be prescribed by a doctor, abuse often leads to dependence. And eventually, for some, pain medication abuse leads to heroin.



PEOPLE WHO TAKE NON MEDICAL  
PRESCRIPTION PAIN RELIEVERS WILL TRY  
HEROIN WITHIN 10 YEARS<sup>2</sup>

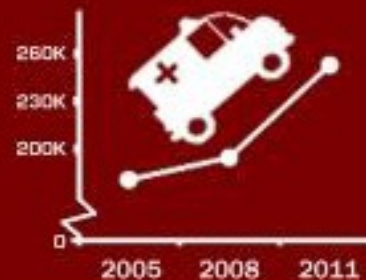
Number of People Who Abused or were  
Dependent on Pain Medications and  
Percentage of Them that Use Heroin<sup>3</sup>



Heroin users are **3X** as likely  
to be dependent

14% of non medical prescription  
pain reliever users are dependent.  
54% of heroin users are dependent.<sup>4</sup>

Heroin Emergency Room  
Admissions Are Increasing<sup>5</sup>





# 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

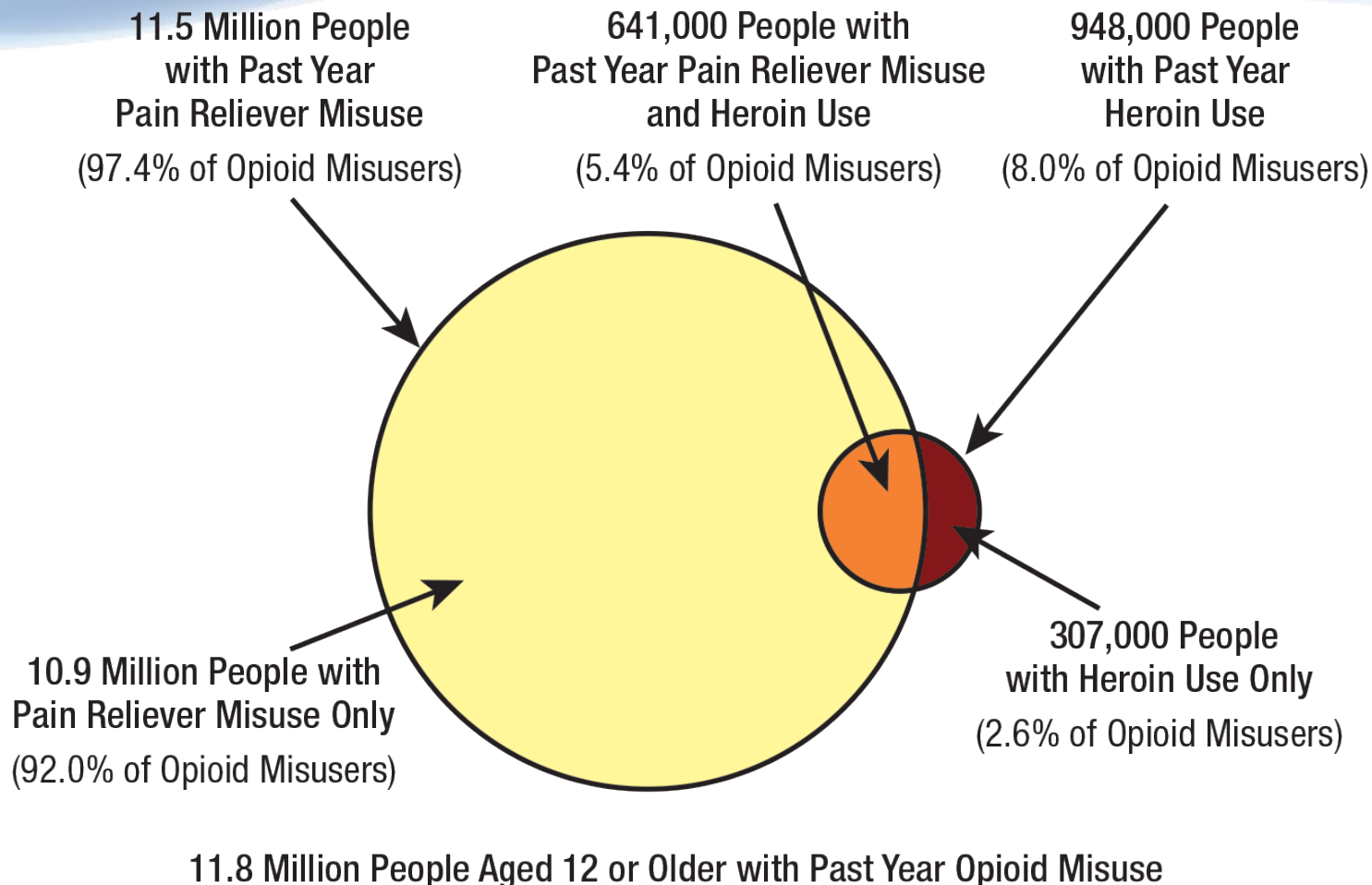
are

**40x**

**...more likely to be addicted to heroin.**

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

# Overlap of Pain Reliever Use and Heroin Use



# Select the true statements

- A. People suffer not because their discomfort is untreatable but because physicians are reluctant to prescribe morphine.**
- B. When patients take morphine for pain, addiction is rare.**
- C. Addiction seems to arise only in those who take it for psychological effects. e.g., euphoria or to relieve tension.**
- D. Patients who take morphine for pain do not develop the rapid tolerance that is often a sign of addiction.**

Ronald Melzack: Scientific American, 1990

# Select the true statements

- A. People suffer not because their discomfort is unbearable but because physicians are reluctant to use morphine.
- B. When patients take morphine for pain, addiction is rare.
- C. Addiction seems to occur only in those who take it for psychological reasons, e.g., euphoria or to relieve tension.
- D. Patients who take morphine for pain do not develop the rare tolerance that is often a sign of addiction.

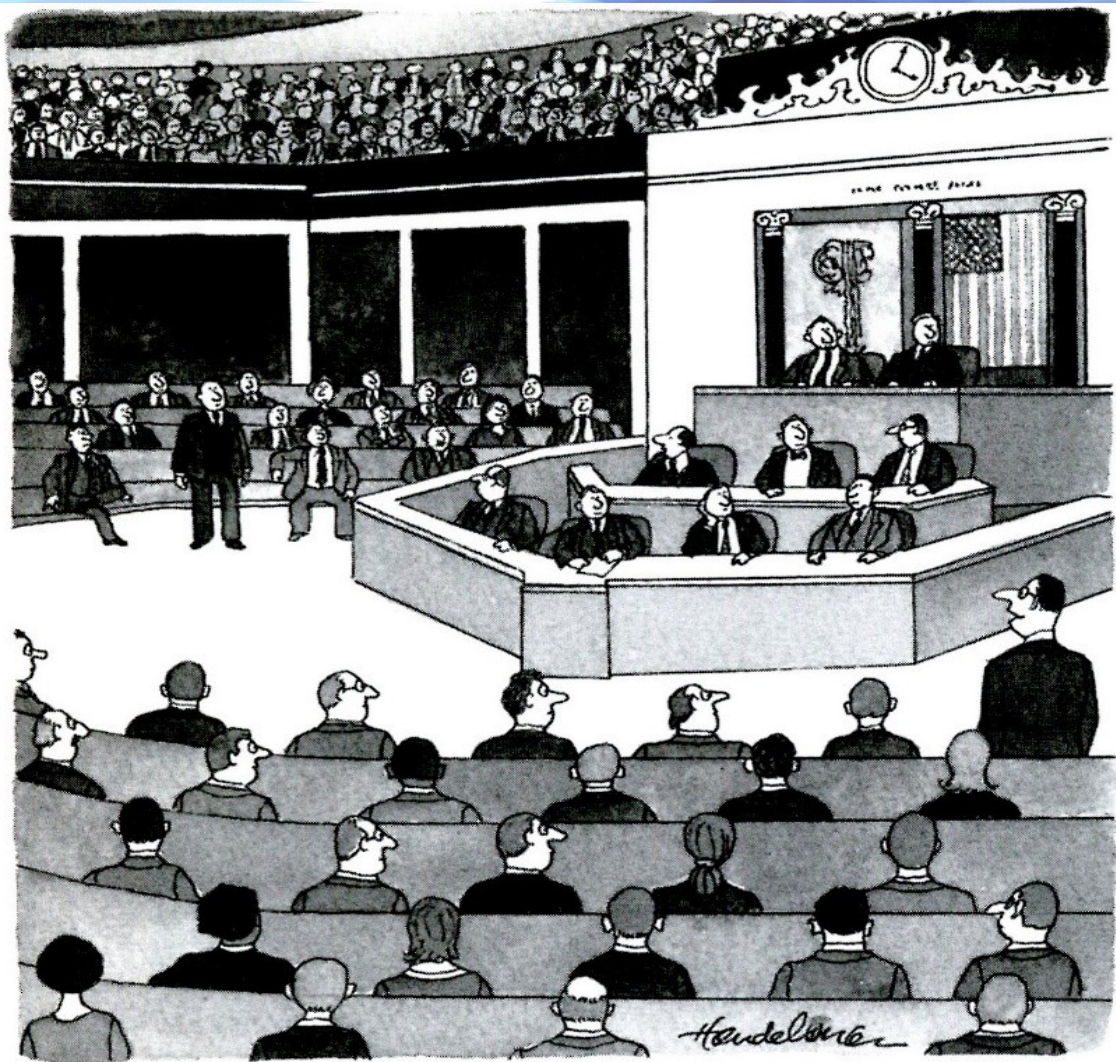
**Totally and Lethally Wrong**

Ronald Melzack: Scientific American, 1990

# Points to Note

- **Over 15 % of people using opioids with an Rx feel they have an OUD**
- **Most people who report using Rx opioids w/o an Rx report doing so to control pain**
- **40-60% of illicit Rx opioid use comes from friends or family**
- **Majority of nonmedical Rx opioid use that comes from a provider comes from a single provider**
- **Many current heroin users began with Rx opioids**
- **Polysubstance abuse is very common in those with SUDs**





## Pain Business Overshadows Health

"Mr. Speaker, will the gentleman from Big Imaging yield the floor to the gentleman from Big Opioid?"



# **“The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy”**

- **Unprecedented Marketing**
- **No studies support benefit over other opioids**
- **Can be crushed, injected, inhaled or swallowed**
- **Sales Reps trained “Risk of Addiction <1%”**
- **Original FDA Label- Risk of Abuse/Addiction**
- **Risk of Abuse consistently minimized**
  - \* Risk deemed “Very Rare” in 1996
- **2007 Purdue Pharma fined \$634M**
- **2009 OxyContin Sales \$3B**

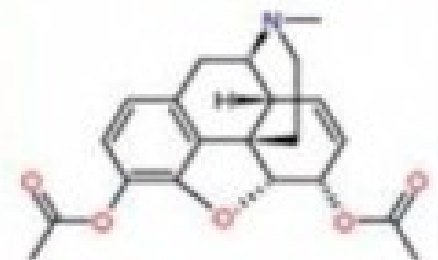


# Which is **heroin** and which is **oxycodone**?

Similar  
chemical  
structure leads  
to similar  
biological effect



OXYCONTIN (OXYCODONE)



HEROIN

# A Population-based Study on Chronic Pain – All-Cause Mortality and Treatment with Opioids

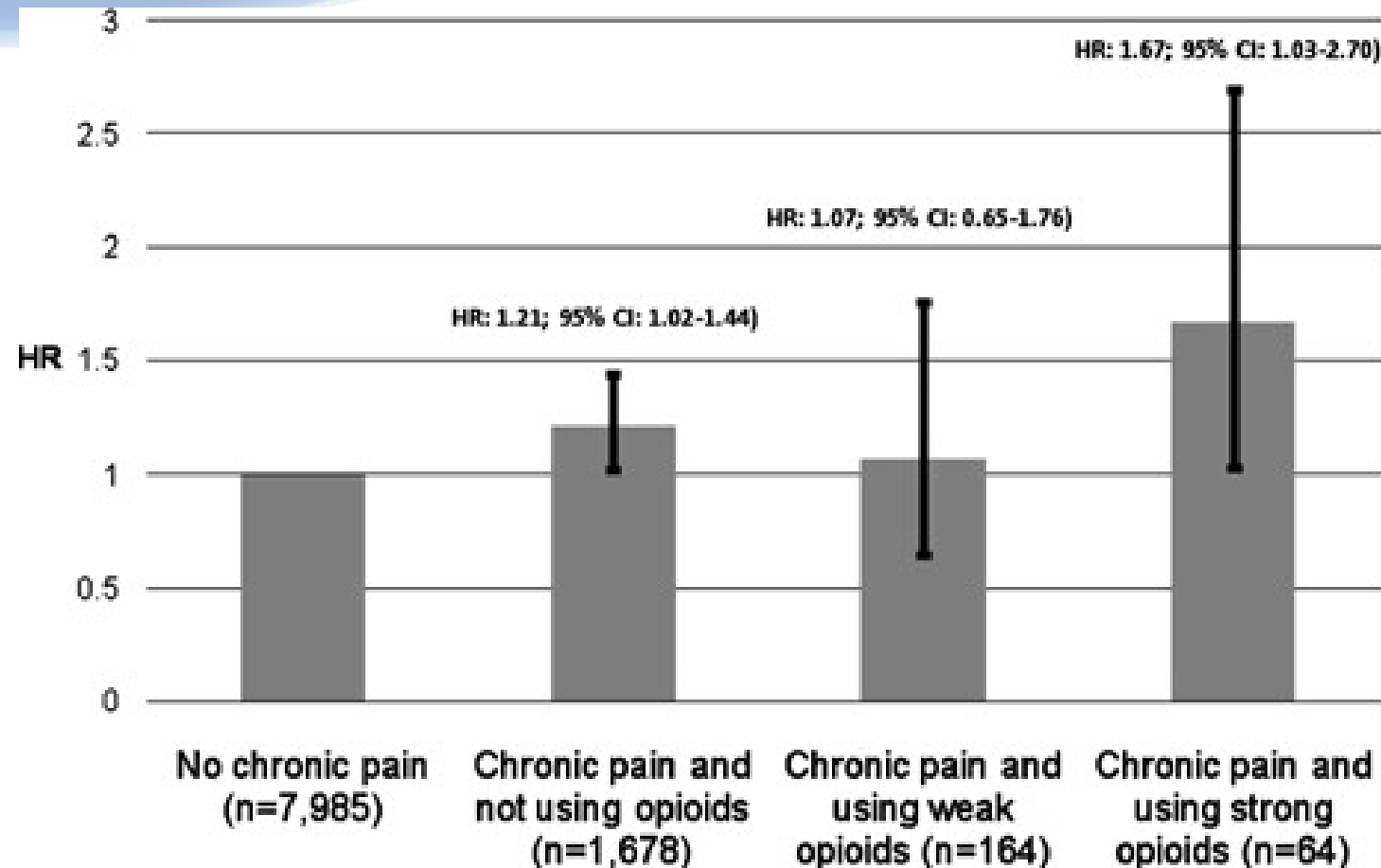


FIGURE 1. Hazard Ratios (HR) and 95% confidence intervals for all-cause mortality according to the chronic pain status and the use of opioids in 2000. Clin J Pain 2010; Volume 26, Number 9

# Points of Note

- **No increase in opioid education for providers**
  - e.g. how to write an Rx
- **Experts over-simplified opioid use**
- **Morbidity and mortality data related to opioid use and mis-use was largely ignored 2004-2012**  
e.g. opioid related deaths overtaking MVA related deaths ( occurred in IN 2008)

**In 2012 DENTISTS wrote about 20,000,000 prescriptions for opioid pain medications  
~ 105 opioid prescriptions *per* dentist**

# Perspective and Wisdom

**“Doing everything for everyone is neither tenable nor desirable. What is done should be inspired by *compassion* and guided by science and not merely reflect what the market will bear.”**

JAMA 1996; 269:3030

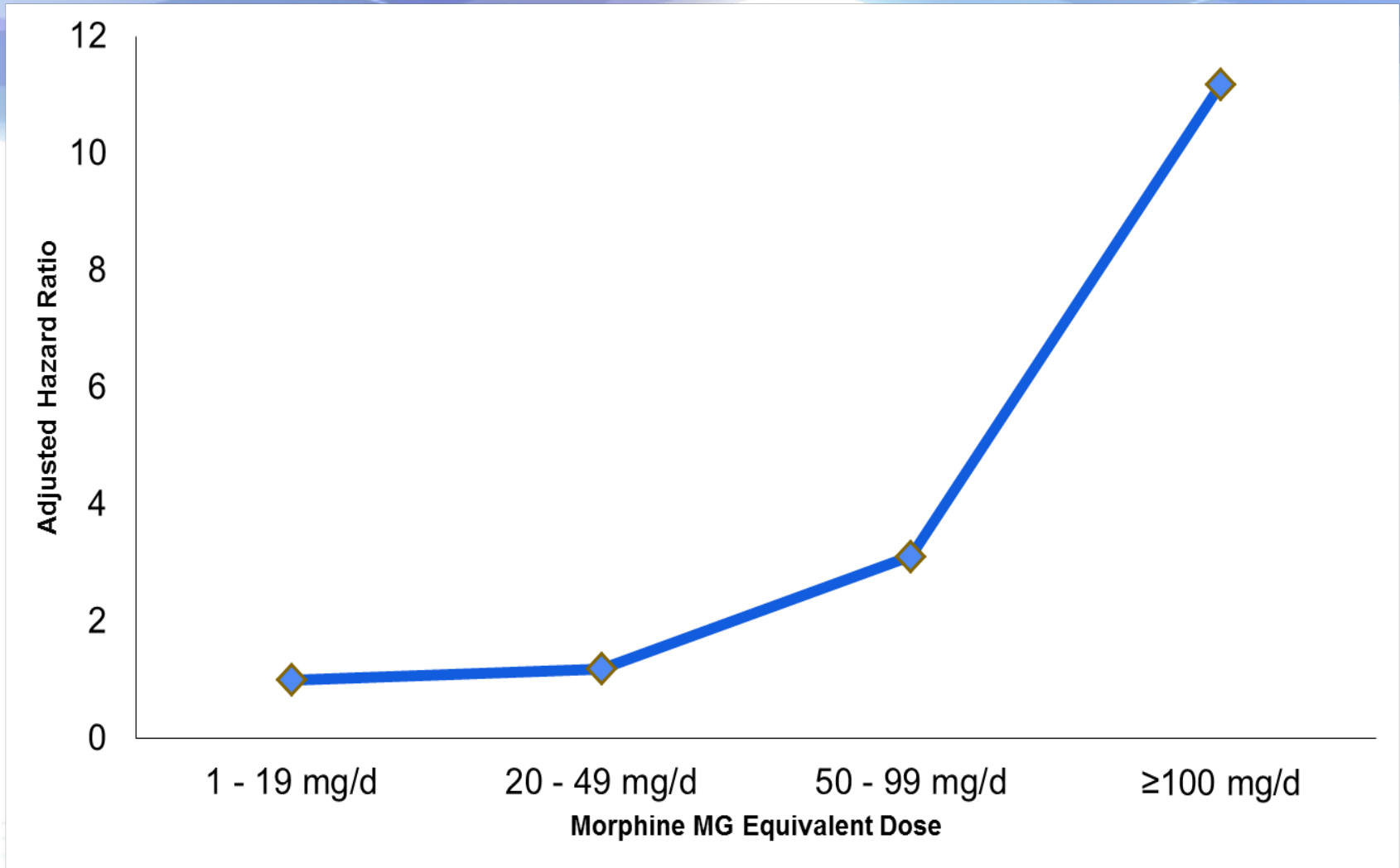


# ***Risk Factors***

## ***Pharmacological Factors***



# High Opioid Dose and Overdose Risk



Dunn et al. Opioid prescriptions for chronic pain and overdose.  
Ann Int Med 2010;152:85-92

# Risk of SUD/Abuse

OR (adjusted) when exposed to:

**122**                    **≥120 MED/day**

**29**                      **36-120 MED/day**

**15**                      **1-36 MED/day**

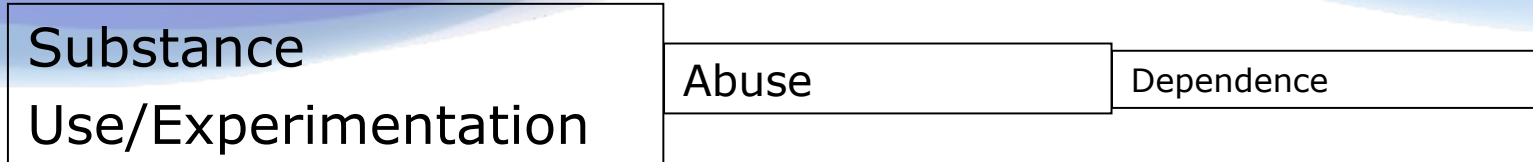
**1**                      **no opioid prescription**

(considered non-exposed)

Note: The risk of abusing drugs and developing a SUD dramatically increases with increasing morphine equivalent dose (MED) per day

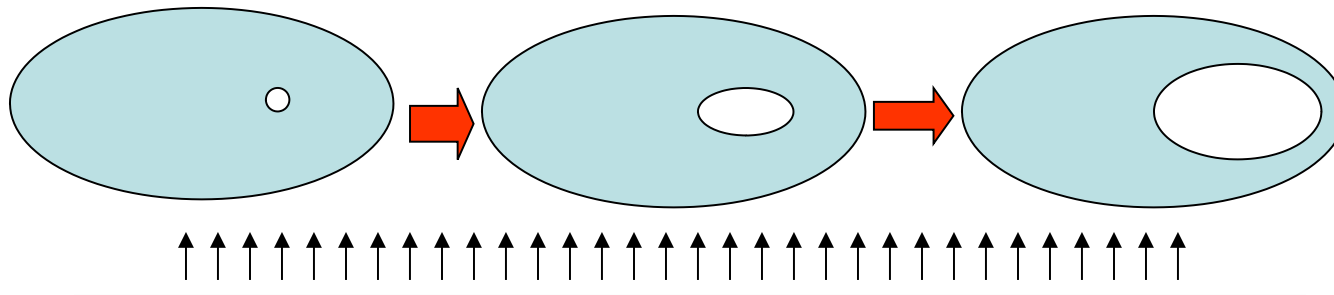
Clin J Pain 2014; 30(7):557-564

# The Disease Process of Addiction



Early Addiction  
(Substance Abuse)

Advanced Addiction  
(Substance Dependence)



**REPEATED DRUG HITS**

- Repertoire of adaptive behaviors: eating, sleeping, social, occupational, sexual behavior, etc.
- Drug seeking/drug taking

**HOMETOWN CLINIC**

John Doe, M.D.  
Family Practice  
1234 Your Address  
YourCity, GA 98765  
(987) 654-3210  
Fax (987) 654-3211



Lic. #: A12345  
DEA #: AA7654321  
NPI #: 789456123

110922A12345 #00001

Name Miss. B. Havyor DOB 4/06/86  
Address 321 Sobriety Lane Date 1/16/18 MF



**Oxycodone/APAP 5 mg/325 mg**

**Sig. 1-2 po each 6-8 hrs for 2 days, 1 po each 6-10 hr for 2 days, 1 po each 8-12 hr as needed for 2 days, stop.  
(do not exceed 8/day) Disp.- twenty-four (24)**

Refill NR 1 2 3 4 5 Void After \_\_\_\_\_  Spanish

Do Not Substitute-Dispense As Written

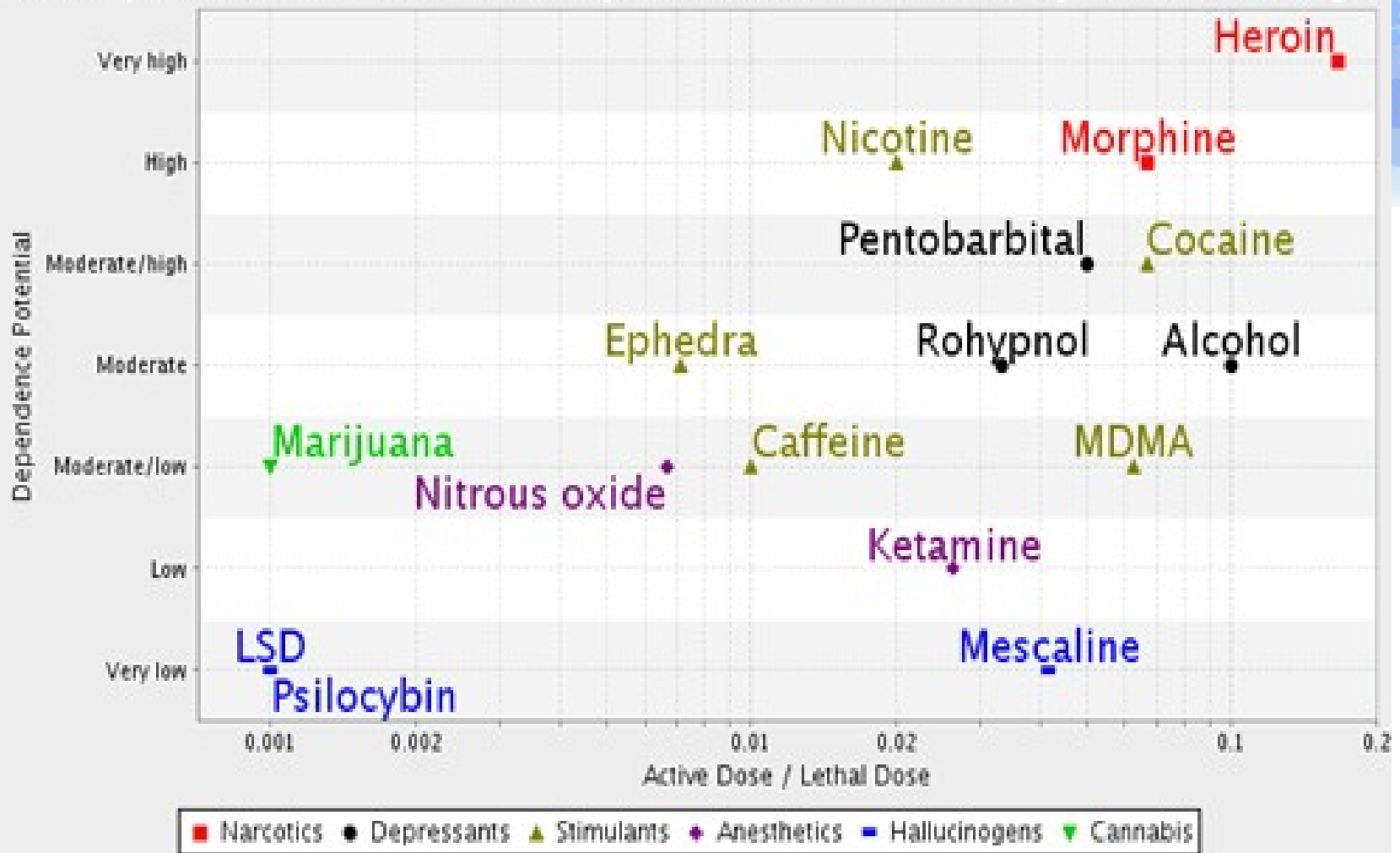
**P. G. Yuan MD**

Signature



SEE BACK FOR LIST OF SECURITY FEATURES

## Active/Lethal Dose Ratio and Dependence Potential of Psychoactive Drugs



Note: The **active dose / lethal dose** ratio is very high for cocaine, morphine and heroin. This indicates the danger of death from the abuse of these drugs is high if an abuser makes an error in the amount consumed

**Table 3. Factors Associated with the Risk of Opioid Overdose or Addiction.**

| Factor   | Risk  |
|--|---|
| Medication-related   |   |
| Daily dose >100 MME*   | Overdose, <sup>8</sup> addiction <sup>8</sup>   |
| Long-acting or extended-release formulation (e.g., methadone, fentanyl patch)          | Overdose <sup>14,41</sup>                       |
| Combination of opioids with benzodiazepines  | Overdose <sup>42</sup>                          |
| Long-term opioid use (>3 mo)†  | Overdose, <sup>43</sup> addiction <sup>44</sup> |
| Period shortly after initiation of long-acting or extended-release formulation (<2 wk) | Overdose <sup>45</sup>                          |
| Patient-related  |   |
| Age >65 yr   | Overdose <sup>46</sup>                          |
| Sleep-disordered breathing‡  | Overdose <sup>47</sup>                          |
| Renal or hepatic impairment§   | Overdose <sup>48</sup>                          |
| Depression   | Overdose, addiction <sup>49</sup>               |
| Substance-use disorder (including alcohol)   | Overdose, <sup>50</sup> addiction <sup>49</sup> |
| History of overdose  | Overdose <sup>51</sup>                          |
| Adolescence  | Addiction <sup>52</sup>                         |



# Predictors of Opioid Misuse

## Multivariate Analysis:

| <b>Model*</b>                     | <b>Odds Ratio</b> | <b>p-value</b> |
|-----------------------------------|-------------------|----------------|
| • <b>Age</b>                      | <b>0.95</b>       | <b>0.027</b>   |
| • <b>Drug or DUI Conviction</b>   | <b>2.58</b>       | <b>0.030</b>   |
| • <b>History of Cocaine Abuse</b> | <b>4.30</b>       | <b>0.001</b>   |
| • <b>History of Ethanol Abuse</b> | <b>2.60</b>       | <b>0.048</b>   |

**Note: 62/169 met misuse criteria**

- Young, male, Etohism

\* % = Positive urine cannabinoid and history of cocaine use were strongly correlated.

BMC Health Services Research 2006, 6:46



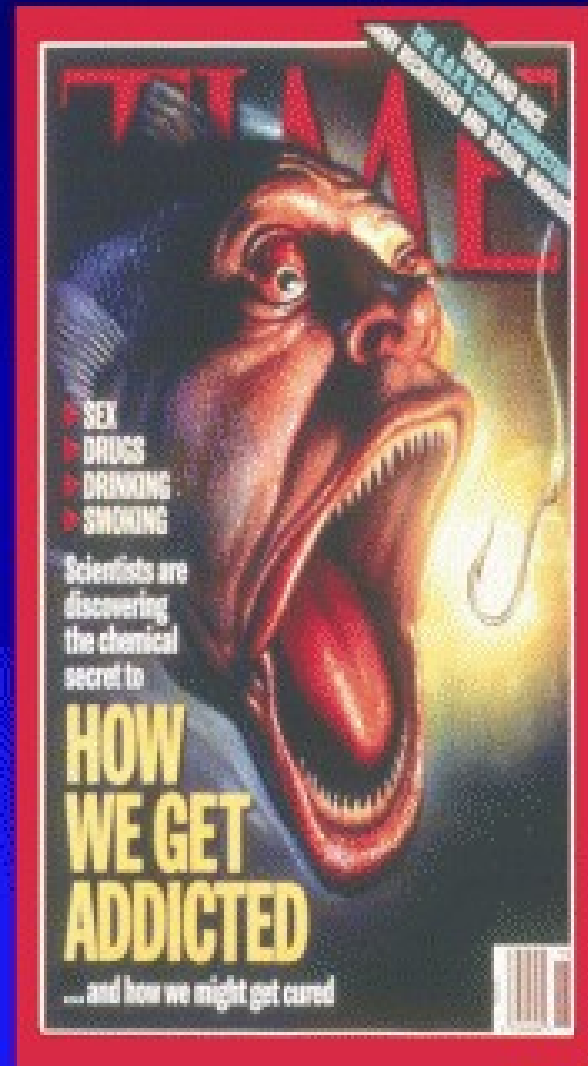
# ***Risk Factors***



## ***Biological Factors***

# *Why Do People Abuse Drugs?*

Drugs of Abuse Engage *Motivation* and *Pleasure Pathways* of the Brain



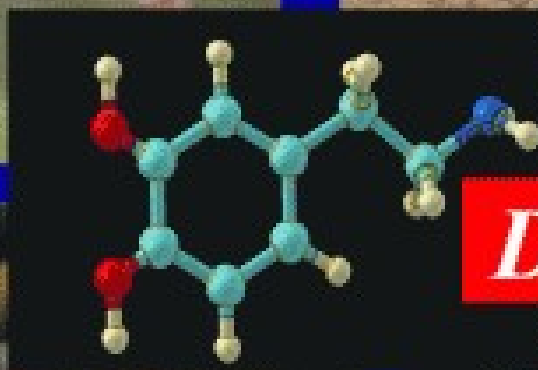
NIDA



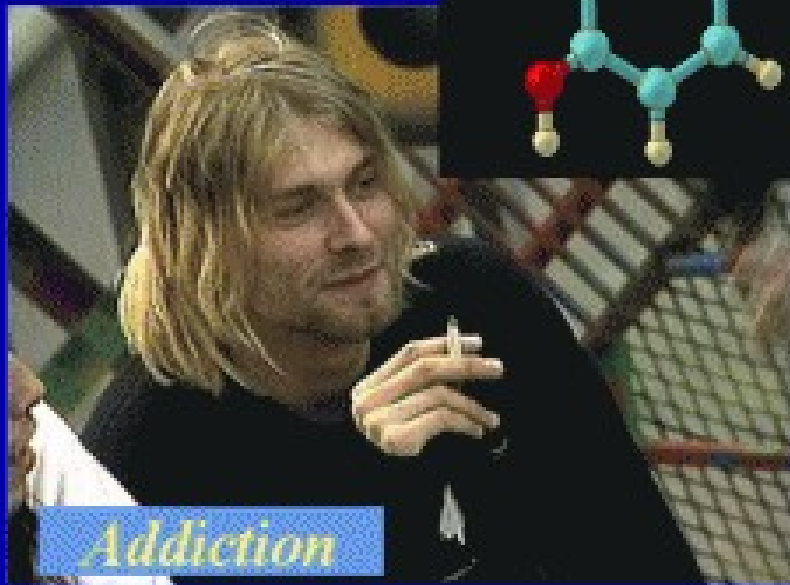
*Movement*



*Motivation*



***Dopamine***



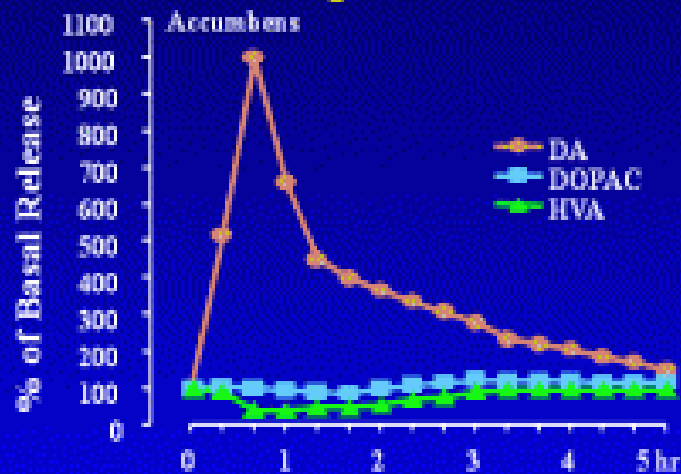
*Addiction*



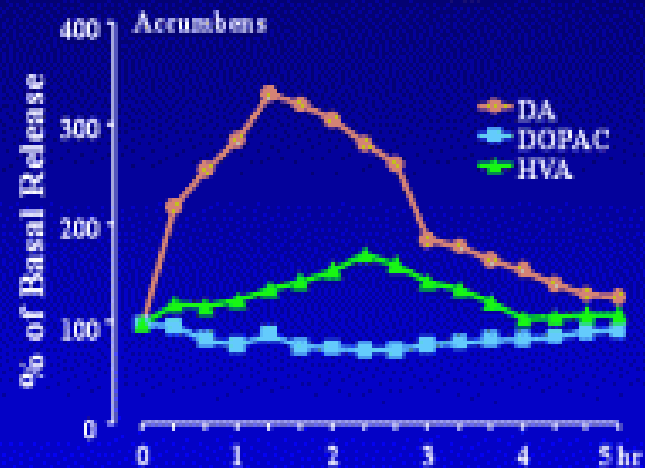
*Reward & well-being*

# Effects of Drugs on Dopamine Release

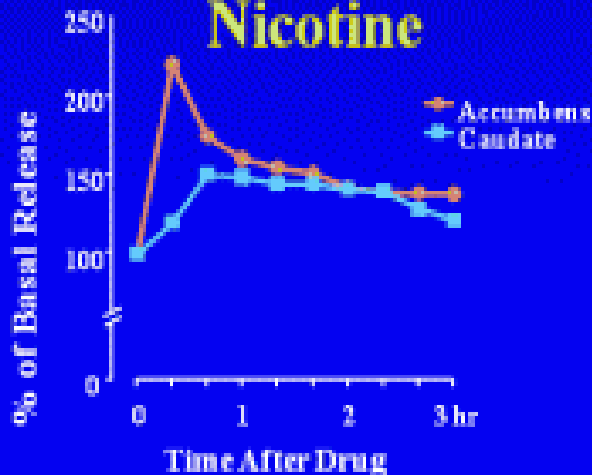
## Amphetamine



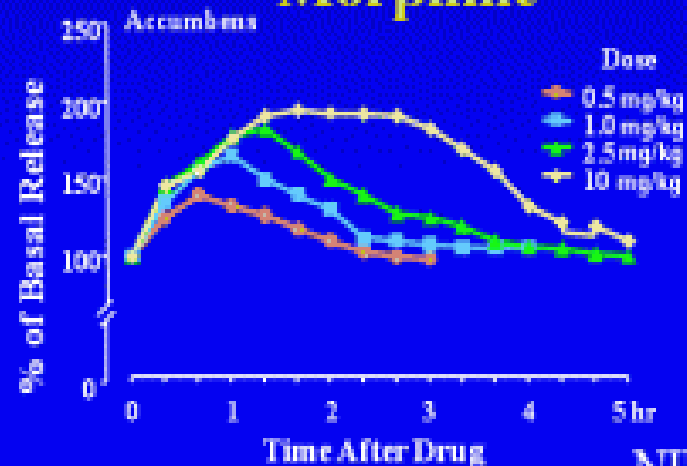
## Cocaine



## Nicotine



## Morphine



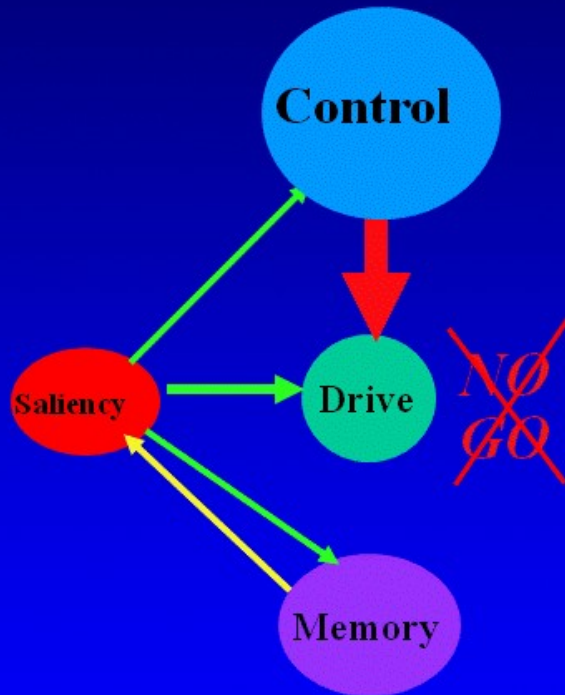
Di Chiara and Imperato, PNAS, 1988

NIDA

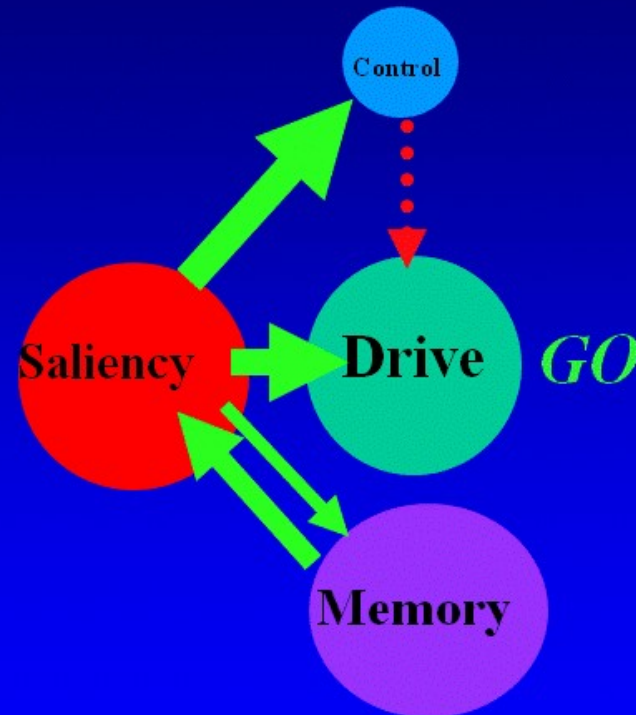
103

# Why Can't Addicts Just Quit?

Non-Addicted Brain



Addicted Brain



*Because Addiction Changes Brain Circuits*

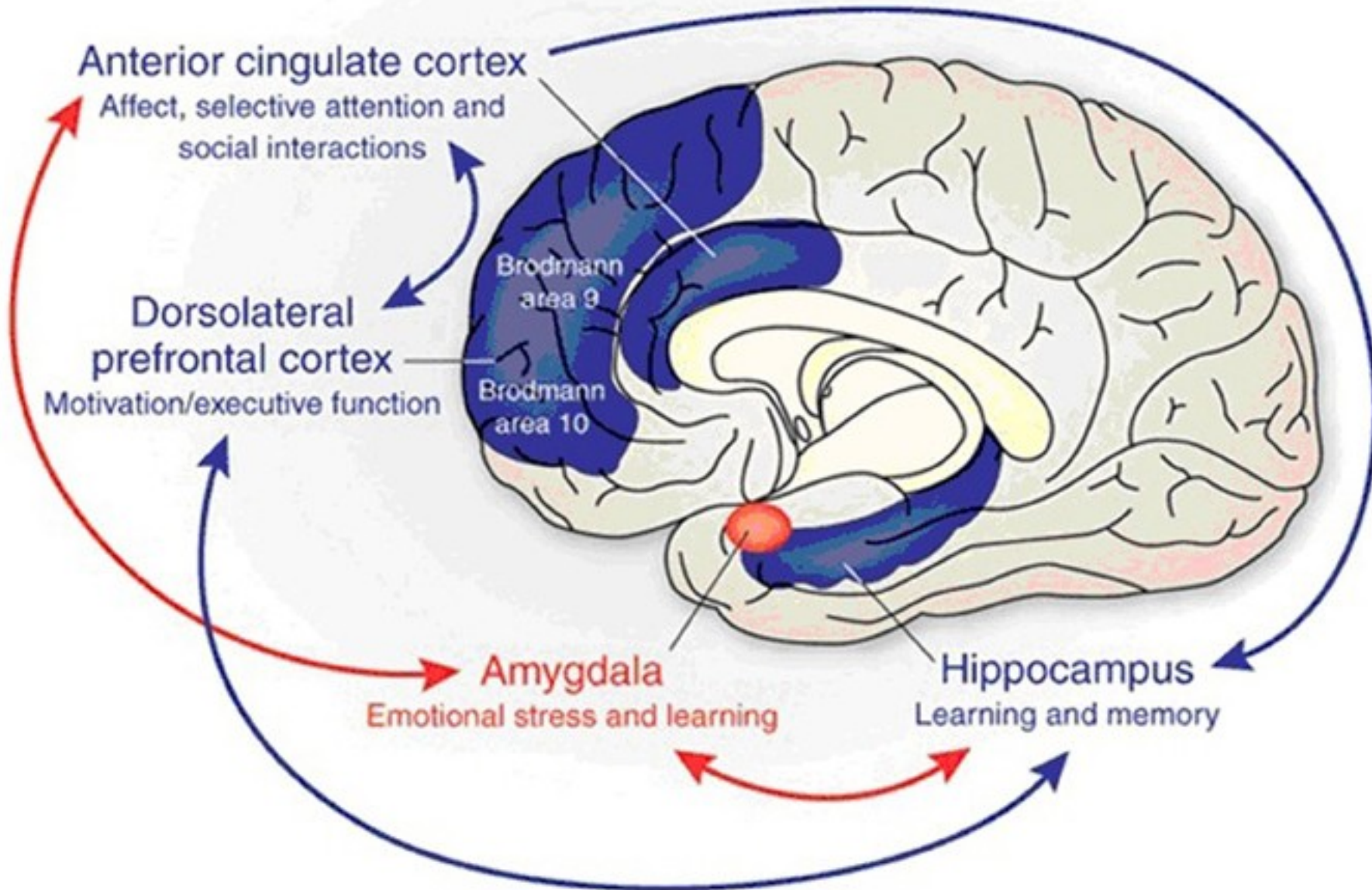
*Adapted from Volkow et al., Neuropharmacology, 2004.*

NIDA

## Addiction and Changed Brain Circuits



# The corticolimbic system

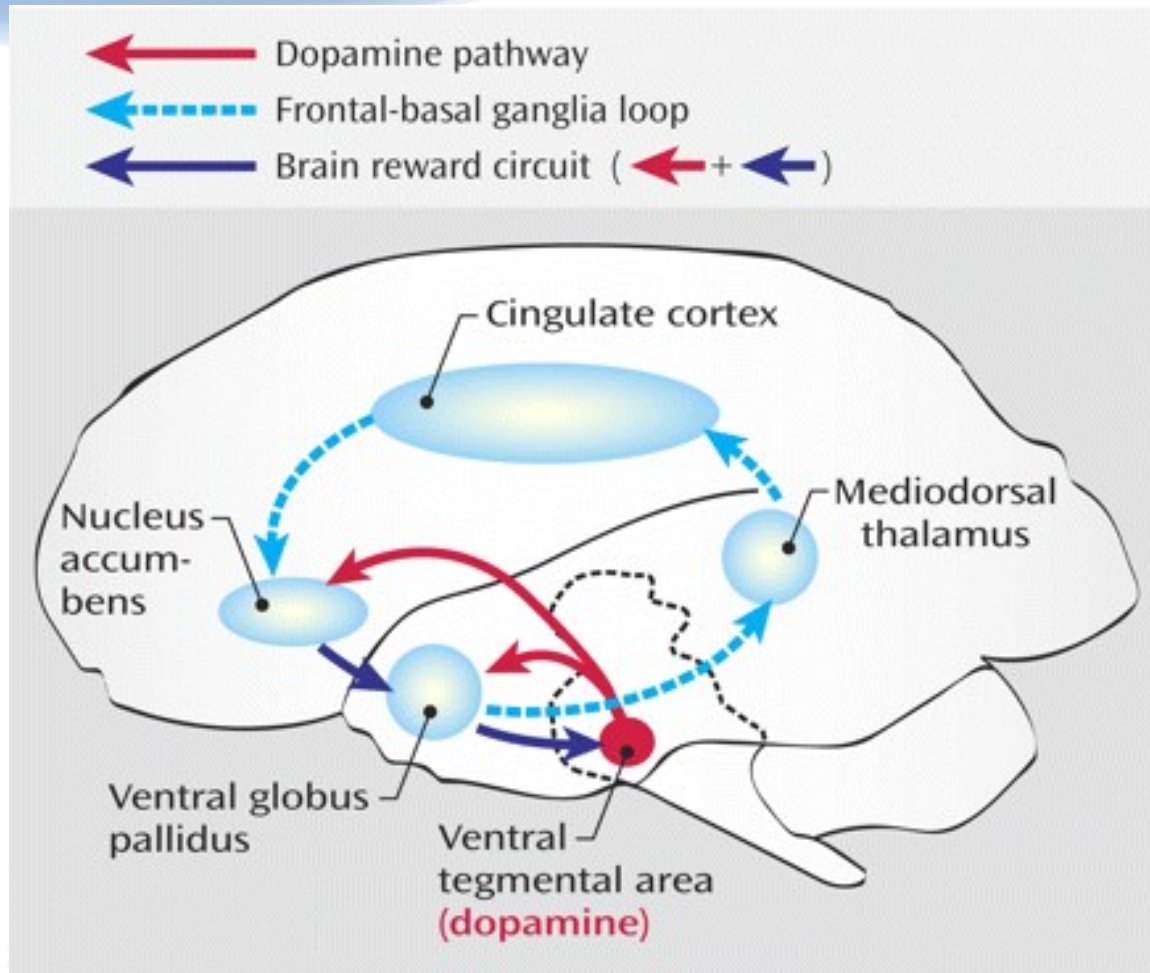


## Brain Disease

# Plasticity: Hard Wired Addiction

- **Conditioning triggered by drug causes enhanced DA signaling when the addict experiences conditioned cues (seeking cues)**
- **This drives motivation to seek out and procure**
- **Activation of PFC and striatal regions**
- **Therefore, regional deficits induced by drug use link PFC/striatal to loss of control and compulsive drug intake when he/she is exposed to and or takes drug**
- **Deficits reduce addicts' sensitivity to natural reinforcers (harder to find pleasure/satisfaction)**

# Not a failure of morals or character

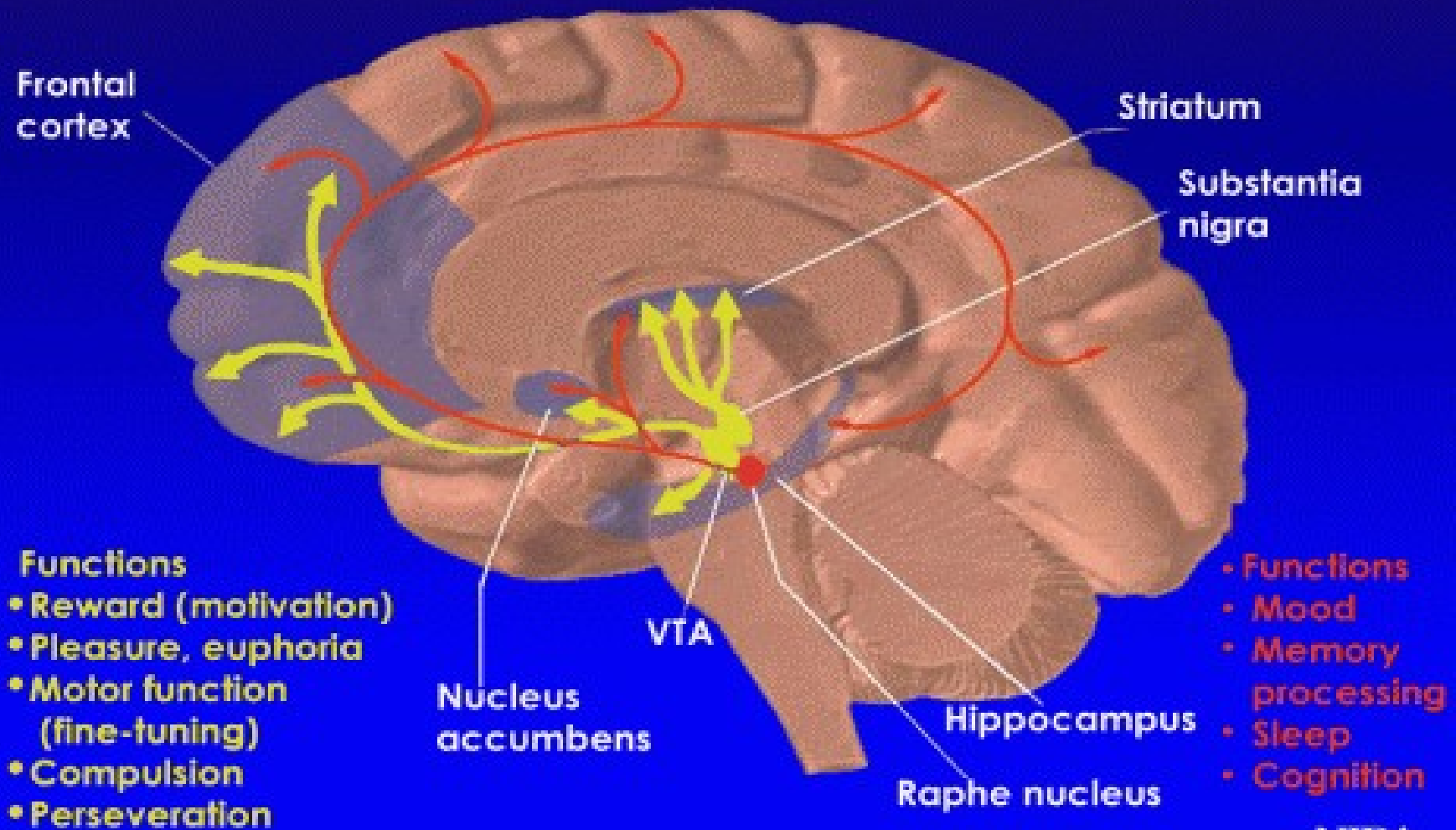


- **Environment**
- **Genetic**
- **Mental illness**
- **Youth to 25**
- **Neuroplastic**
- **Chronic**



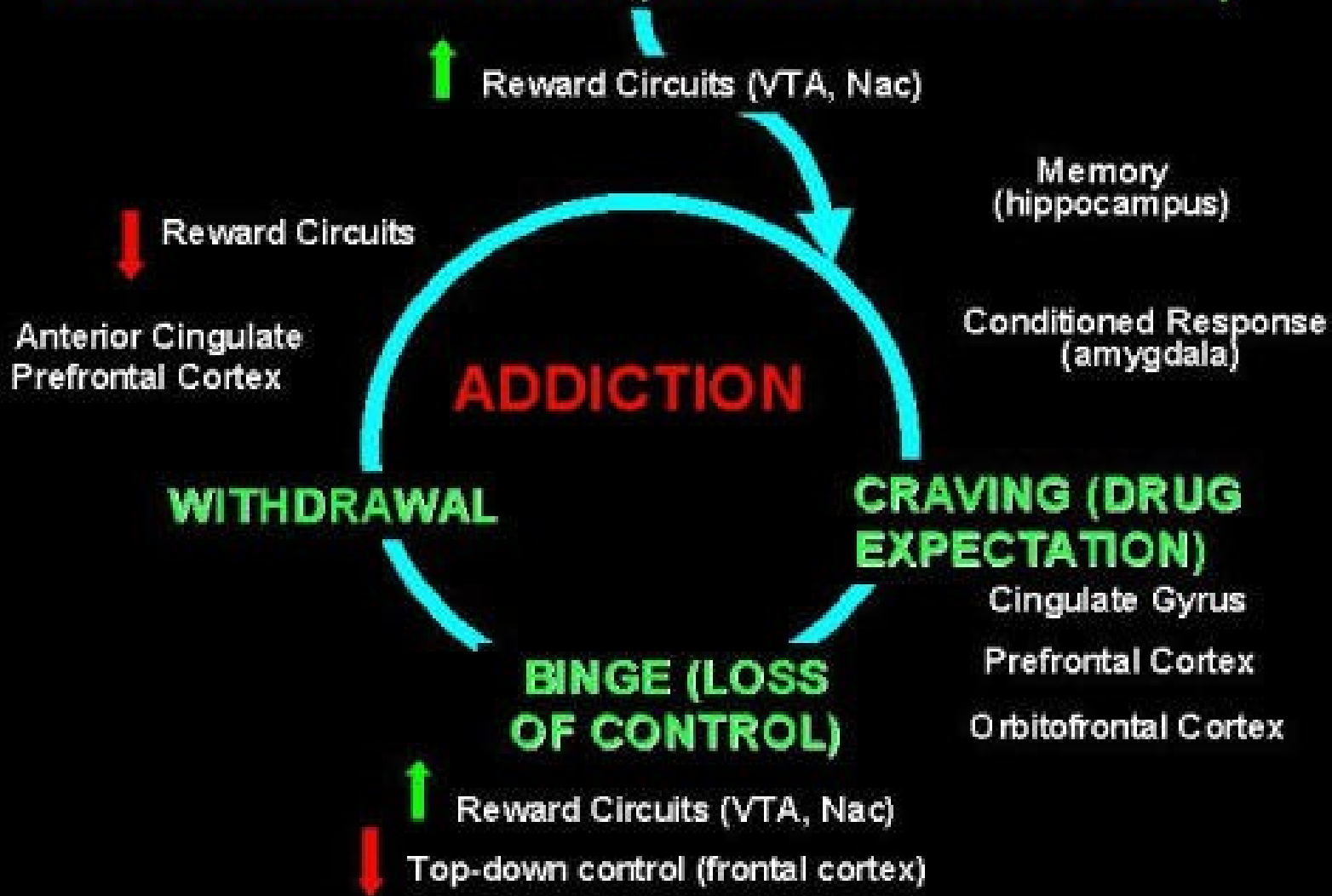
# Dopamine Pathways

# Serotonin Pathways



NIDA

# DRUG REINFORCEMENT (SALIENCE ATTRIBUTION)





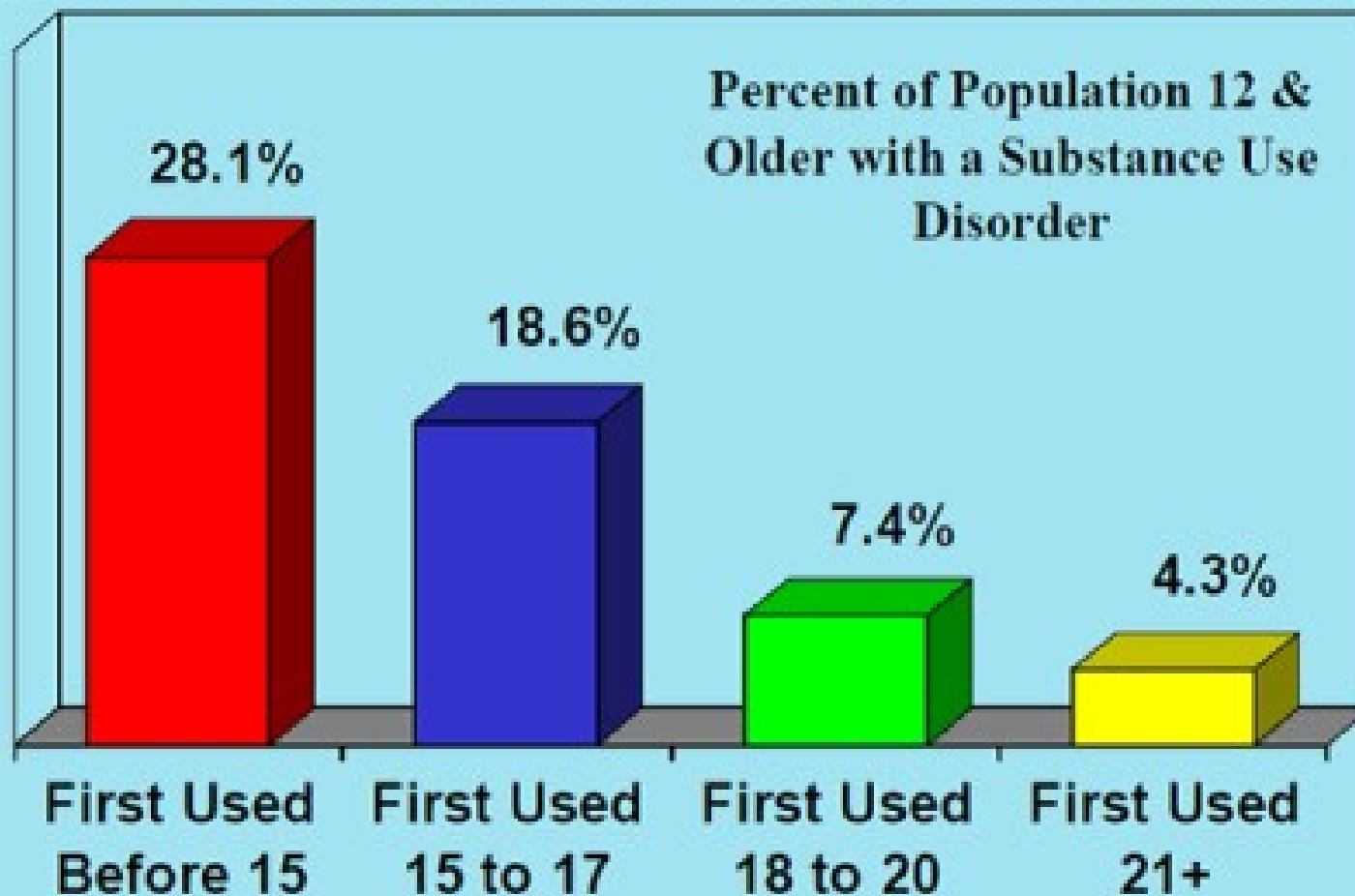
# ***Risk Factors***



## ***SUD and Age***



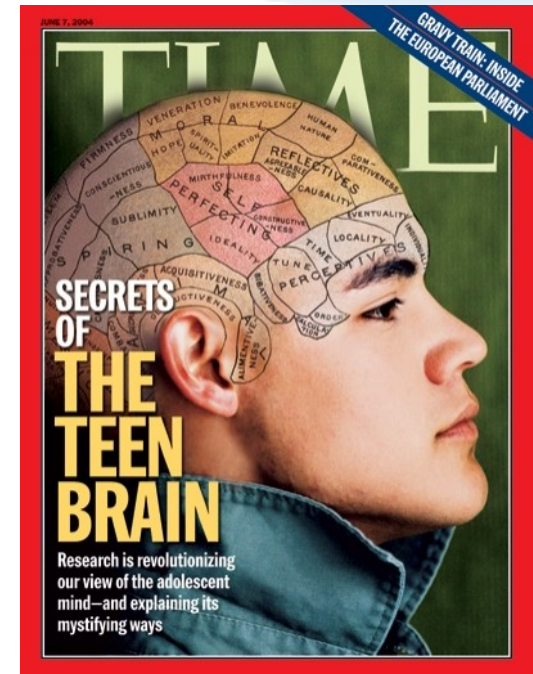
# The Earlier Teens Use Any Substance, the Greater the Risk of Addiction



Source: CASA analysis of the *National Household Survey on Drug Use and Health* (NSDUH), 2009.

# Adolescent Brain (<25 years old)

- **90% adults with substance abuse began smoking, drinking or using drugs < 18yo (tobacco, alcohol, and drugs)**
  - **Primed to take risks, immature decision making, judgment, impulse control**
- **Addictive substance use physically alter brain structure & function faster & more intensely than in adults**
  - **Interferes with brain development**
  - **Further impairing judgment**
  - **Significantly increase the risk of addiction**

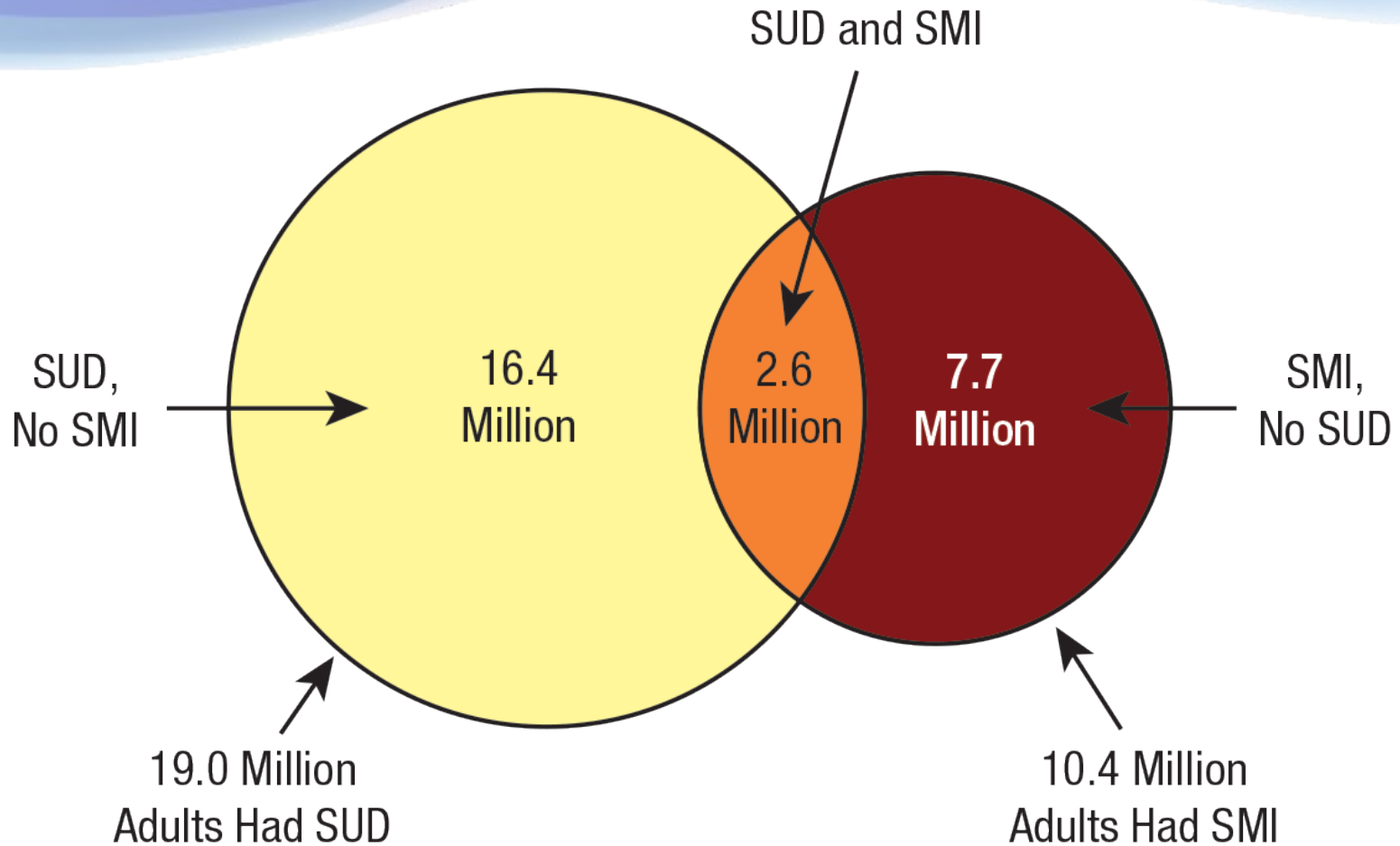




# ***Risk Factors***

## ***SUD and Mental Illness***

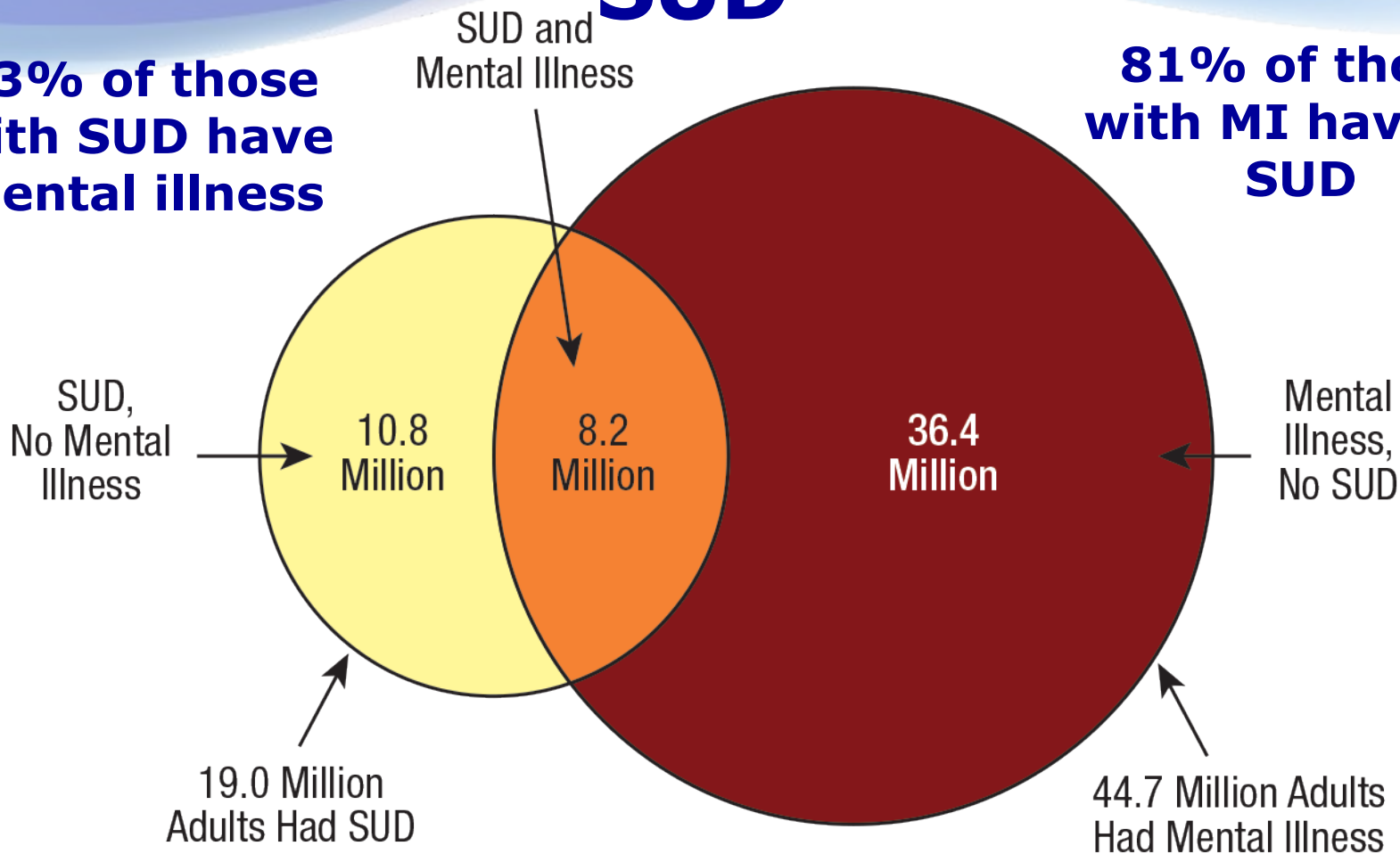
# Overlap of SERIOUS Mental Illness (SMI) and SUD



# Overlap of Mental Illness and SUD

**43% of those with SUD have mental illness**

**81% of those with MI have no SUD**



**2016 NSDUH**

**TABLE 2. Estimated Prevalence of Depression, Anxiety, and Substance Use Disorders in Commonly Occurring Chronic Pain Conditions**

| Variable  | Prevalence (%) |
|---|----------------|
| <b>Depression</b>   |                |
| Spinal pain (lumbar, thoracic, or neck) <sup>26-29</sup>    | 2-56           |
| Neuropathic pain <sup>33-36</sup>                           | 4-12           |
| Fibromyalgia <sup>17-23</sup>                               | 21-83          |
| Migraine headache <sup>37-41</sup>                          | 17-28          |
| Temporomandibular joint disorder <sup>24,25</sup>           | 16-65          |
| Pelvic pain <sup>42-46</sup>                                | 19-22          |
| Abdominal pain <sup>30,32</sup>                             | 9-54           |
| Arthritis <sup>23,37,38,47-49</sup>                         | 3-39           |
| <b>Anxiety</b>  |                |
| Spinal pain (lumbar, thoracic, or neck) <sup>26-29,38</sup> | 1-26           |
| Neuropathic pain <sup>34-36</sup>                           | 5-27           |
| Fibromyalgia <sup>18-21,23</sup>                            | 18-60          |
| Migraine headache <sup>38,39,41</sup>                       | 2-45           |
| Temporomandibular joint disorder <sup>50-52</sup>           | 15-65          |
| Pelvic pain <sup>42,53</sup>                                | 12-41          |
| Abdominal pain <sup>30,32</sup>                             | 21-51          |
| Arthritis <sup>23,37,38,48,49</sup>                         | 1-35           |
| <b>Substance use disorder</b>                               |                |
| Spinal pain (lumbar, thoracic, or neck) <sup>26-29</sup>    | 4-14           |
| Neuropathic pain <sup>54-56</sup>                           | 1-9            |
| Fibromyalgia <sup>19,20,23</sup>                            | 1-25           |
| Migraine headache <sup>40</sup>                             | 1-6            |
| Arthritis <sup>23,49</sup>                                  | 1-12           |

Current and 12-mo prevalence rates grouped together.



# ***Risk Factors***

- ***Chronic Pain***
- ***Mental Illness***
- ***Substance Use Disorders (SUD)***

***COMPLICATED ASSOCIATIONS***

***Cause and Effect ??***



***Simplistic,  
Failed and not  
Science Based***

# ***Responses*** *by*

- ***Health Care Providers***
- ***Communities***

***Responses***  
***by***

***Health Care Providers***

# Difficult Starting Point

- **Education Deficiency**
- **HCAHPS/Satisfaction Surveys**
- **Pain as 5<sup>th</sup> Vital Sign**
- **Predatory Sales and unscrupulous Pharma**
- ***EBM* (eminence based medicine)**
  - **Reflexive and Automated Opioidism**
- **Expectation-Reality Disequilibrium**
- **Majority people with SUDs do not feel a need to obtain treatment for the SUD.**

# Low Hanging Fruit?

- **Prevalence of opioid abuse in chronic pain patients ranges between 20-24% across health-care settings.**

**Pain 2010, 150(2):332–339**

- **Lifetime prevalence of DSM-V OUD those on chronic opioids: 9.7 % moderate & 3.5 % severe OUD**

**Substance Abuse and Rehabilitation 2015:6 83–91**

**P. MacKie's opinion for prevalence of OUD among patients on opioids for chronic pain:  
10% - 18%**



# Healthcare Provider Toolbox:

[www.bitterpill.in.gov](http://www.bitterpill.in.gov)



## *First Do No Harm:*

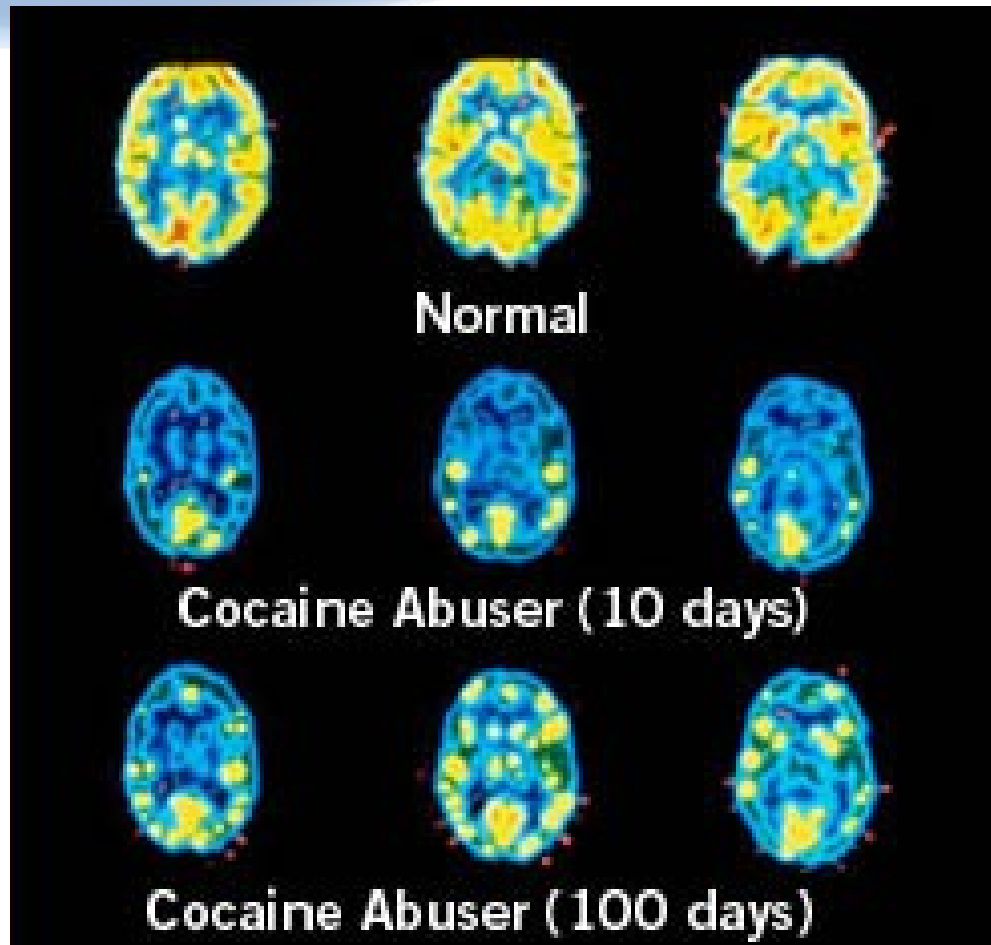
The Indiana HealthCare Providers Guide to the Safe, Effective Management of Chronic Non-Cancer Pain

**A comprehensive  
“Clinical Resource”  
to assist you in  
managing your  
patients with  
chronic pain**

# **Integrative Addiction Care and Methadone**

- **2005 Study with full complement of behavioral, psychological, medical and social support systems**
- **\$15-30 benefit for each \$1.0 spent on programs**
  - 1. Less healthcare utilization**
  - 2. Reduced spread of infectious illnesses**
  - 3. Fewer overdoses**
  - 4. Better employment**
  - 5. Reduction in crime**

# Medicalize SUD



**Chronic  
Brain  
Disease**

# Opioid Addiction Treatment Options

- **Detoxification:**
  - **Medication-assisted**
  - **Abstinence-based**
- **Medication Assisted Treatment (MAT):**
  - **Methadone**
  - **Buprenorphine-w/o naloxone**
  - **Naltrexone**
- **Abstinence-based therapy:**
  - **Long-term residential**
  - **Intensive outpatient**
  - **Behavioral therapies , (NA)**

# Medically Assisted Therapy (MAT)

## Naltrexone (*Vivitrol*)

- **Antagonist – blocks all effects of opioids**
- **Oral and injectable forms (long-lived)**
- **Must be totally detoxed prior to use**
- **Effective for opioid and alcohol addiction treatment**
- **Can “override” blockade with high doses of opioids**
- **Risk of overdose, hepatotoxicity, injection reactions**
- **Works best in highly motivated individuals – parole, probation, early release**

# **MAT (cont.)**

## **Buprenorphine (*Subutex/Suboxone*)**

- **Partial agonist**
- ***Suboxone* has antagonist,  
\* naloxone**
- **Decreased risk of overdose/abuse**
- **Office-based treatment**
- **Sublingual dosing**
- **Physicians DEA training/certification**
- **Limitations on number of people an individual physician can treat**
- **Covered by Medicaid**



### Characteristics of Medications for Opioid-Addiction Treatment.

| Characteristic  | Methadone  | Buprenorphine  | Naltrexone  |
|-----------------|--|--|---|
| Brand names     | Dolophine, Methadose   | Subutex, Suboxone, Zubsolv   | Depade, ReVia, Vivitrol   |
| Class           | Agonist (fully activates opioid receptors)   | Partial agonist (activates opioid receptors but produces a diminished response even with full occupancy)   | Antagonist (blocks the opioid receptors and interferes with the rewarding and analgesic effects of opioids)   |
| Use and effects | Taken once per day orally to reduce opioid cravings and withdrawal symptoms  | Taken orally or sublingually (usually once a day) to relieve opioid cravings and withdrawal symptoms   | Taken orally or by injection to diminish the reinforcing effects of opioids (potentially extinguishing the association between conditioned stimuli and opioid use)                                |
| Advantages      | High strength and efficacy as long as oral dosing (which slows brain uptake and reduces euphoria) is adhered to; excellent option for patients who have no response to other medications | Eligible to be prescribed by certified physicians, which eliminates the need to visit specialized treatment clinics and thus widens availability           | Not addictive or sedating and does not result in physical dependence; a recently approved depot injection formulation, Vivitrol, eliminates need for daily dosing                                 |
| Disadvantages   | Mostly available through approved outpatient treatment programs, which patients must visit daily   | Subutex has measurable abuse liability; Suboxone diminishes this risk by including naloxone, an antagonist that induces withdrawal if the drug is injected | Poor patient compliance (but Vivitrol should improve compliance); initiation requires attaining prolonged (e.g., 7-day) abstinence, during which withdrawal, relapse, and early dropout may occur |

# Access to MATs Saves Lives

**A study of heroin-overdose deaths in Baltimore between 1995 and 2009 found an association between the increasing availability of methadone and buprenorphine and reduction in mortality with a 50% decrease in fatal overdoses**

Am J Public Health 2013; 103:917-22

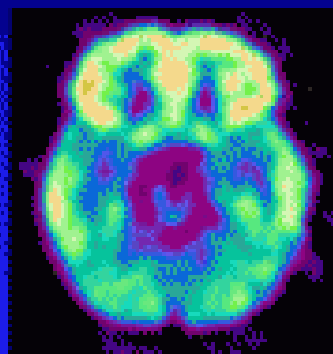
# Outcomes far better with MAT

| <u>Outcomes</u>   | <u>No MAT</u> | <u>Methadone</u> |
|-------------------|---------------|------------------|
| Retention         | 154/1000      | 684/1000         |
| Morphine +urine   | 701/1000      | 463/1000         |
| Criminal Activity | 118/1000      | 46/1000          |
| Mortality         | 17/1000       | 8/1000           |

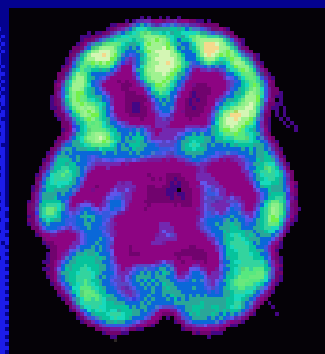
# *Addiction is Like Other Diseases...*

- It is preventable
- It is treatable
- It changes biology
- If untreated, it can last a lifetime

## **Decreased Brain Metabolism in *Drug Abuser***

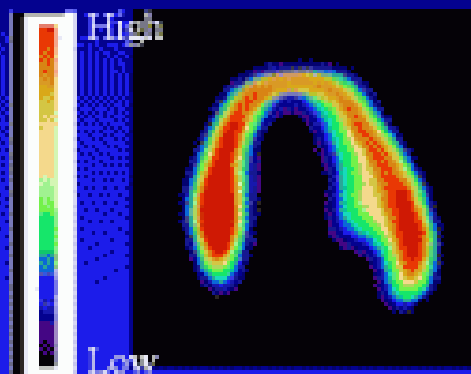


**Healthy Brain**

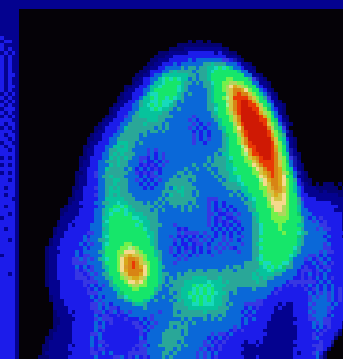


**Diseased Brain/  
Cocaine Abuser**

## **Decreased Heart Metabolism in *Heart Disease Patient***



**Healthy  
Heart**



**Diseased Heart**

*Research supported by NIDA addresses all of these  
components of addiction.*

# Summary

- **OUD and SUD are common**
- **Risk Factors include-Genetics, chaotic environment, exposure, youth and mental illness**
- **Providers can be judicious with opioids and still provide adequate analgesia**
- **OUD is present in 5-25 % of those receiving opioids chronically for pain**

# Summary (cont.)

- **Ask and or use survey tools to help identify those with OUD and use open non-judgmental language**
- **Knowing current or past OUD may help reduce risk of iatrogenic relapse**
- **MAT saves lives, money and is underused**



# ***Responses*** *by*

## ***Communities***

- ***Legislatures***
- ***Dental Boards***
- ***Organizations***

# eSB 226: 7 Day Emergency Rules

- **July 1, 2017**
- **Exclusions For Emergency Rule**
  - **MAT, cancer, palliative/hospice**
- **Adult 1<sup>st</sup> time Rx by the prescriber**
- **All persons < 18 yrs.**
- **Professional judgement out**
- **Partial Refill Request**

# eSB 226: 7 Day Emergency Rules

**1) If the prescription is for an adult who is being prescribed an opioid for the first time by the prescriber, the initial prescription may not exceed a seven (7) day supply.**

**2) If the prescription is for a child who is less than eighteen (18) years of age, the prescription may not exceed a seven (7) day supply**

- **Partial Refill Request**
- **Professional judgement out & document**

# eSB 226: 7 Day Emergency Rules

- **Partial Refill Request**
  - **Guardian/legal representative of or the Patient**
  - **30 days and then forfeit remainder**
  - **E.g. may elect to fill 12 of 24 tablet Rx and determine if more is required before 30 days**
- **Professional judgement out & document**
  - **If > 7 days of opioids are to be given, there must be language in the medical record justifying the professional judgement of longer duration Rx**

# Medical Licensing Board Rules

## Pain's 10 Commandments

- Thou shall diagnosis with appropriate care, get old records
- Thou shall do psychological assessment
- Risk Stratification Tool
- Thou shall provide informed consent and prognosis with Treatment Agreement and functional goals
  - Exit strategy/protocol , ETOH and NAS

# Medical Licensing Board Rules

## Pain's 10 Commandments (cont.)

- Thou may use trial of opioid therapy and modalities
  - safe storage of medication
- Thou shall use a Pain Assessment Tool
- Thou shall see the patient at 4 months or sooner
- Thou must employ drug monitoring & PDMP(pill counts)
- Thou *may not* have paucity of documentation
- When > 60 MED- formal re-evaluation and education



# Exemptions

**Patients that are exempt from monitoring under these rules include those who are:**

- **Terminally ill**
- **Involved with a palliative care service**
- **Managed in a hospice program**
- **Residents of a registered nursing home**

# Late to the Dance

- Eskenazi Health **2011**
- American Academy of Neurology **2014**
- National Safety Council **2014**
- Most Legislatures *by* **2015**
- Centers for Disease Control Guidelines **2016**
- IU's Grand Challenge **2017** and \$ 50,000,000
- **American Dental Association 2018**
  - Supports Mandates on Opioid Prescribing and Continuing Education

# **ADA Policy States:**

- **The ADA supports mandatory continuing education in prescribing opioids & other controlled substances**
- **The ADA supports statutory limits on opioid dosage and duration of no more than seven days for the treatment of acute pain, consistent with the CDC evidence-based guidelines**
- **The ADA supports dentists registering with & utilizing prescription drug monitoring programs to promote the appropriate use of opioids and deter misuse and abuse**

# ***Considerations when Managing Pain***

- ***Alternative interventions***
- ***Risk stratification***
- ***Assess for SUD/ODU***  
*Before and during treatment*
- ***Assessment of mental status***
- ***Informed consent***
- ***Periodic visits***
- ***7-day rule***
- ***Aaron's rule – availability of Naloxone***

# Never start that which you will not stop

## Exit Strategy at Onset



***“It sort of makes you stop and think, doesn’t it”***

# ***Alternative Interventions***



***“It sort of makes you stop and think, doesn’t it”***



# Non-Pharmacologic Interventions

- Education
- Ice/Heat
- Exercise
  - Aerobic, ROM
  - strength
- Yoga, Tai Chi
- PT/OT
- Nutrition
- Manual
  - Massage
  - Chiropractic
- Acupuncture
- CBT, mindfulness, hypnosis
- Relaxation Response
- Tobacco cessation, weight loss
- Counseling
- Interventional pain modalities
- Education

# Non-Opioid Medications

## MSK/Inflammatory pain

- Acetaminophen
- NSAIDS
- Topical anesthetics (lidocaine)
- Anti-inflammatory cream
- Steroid injections
- Muscle relaxants
- Whole food plant-based nutrition

## Restore Sleep

- Melatonin
- TCA's
- Trazadone
- Doxepin
- Aroma therapy

## Neuropathic pain

- TCA's (SOR-A)
- Topical anesthetics
- Linoleic acid
- Neuropathic creams
- SNRI's (SOR-A)
- Anticonvulsants

## Visceral pain

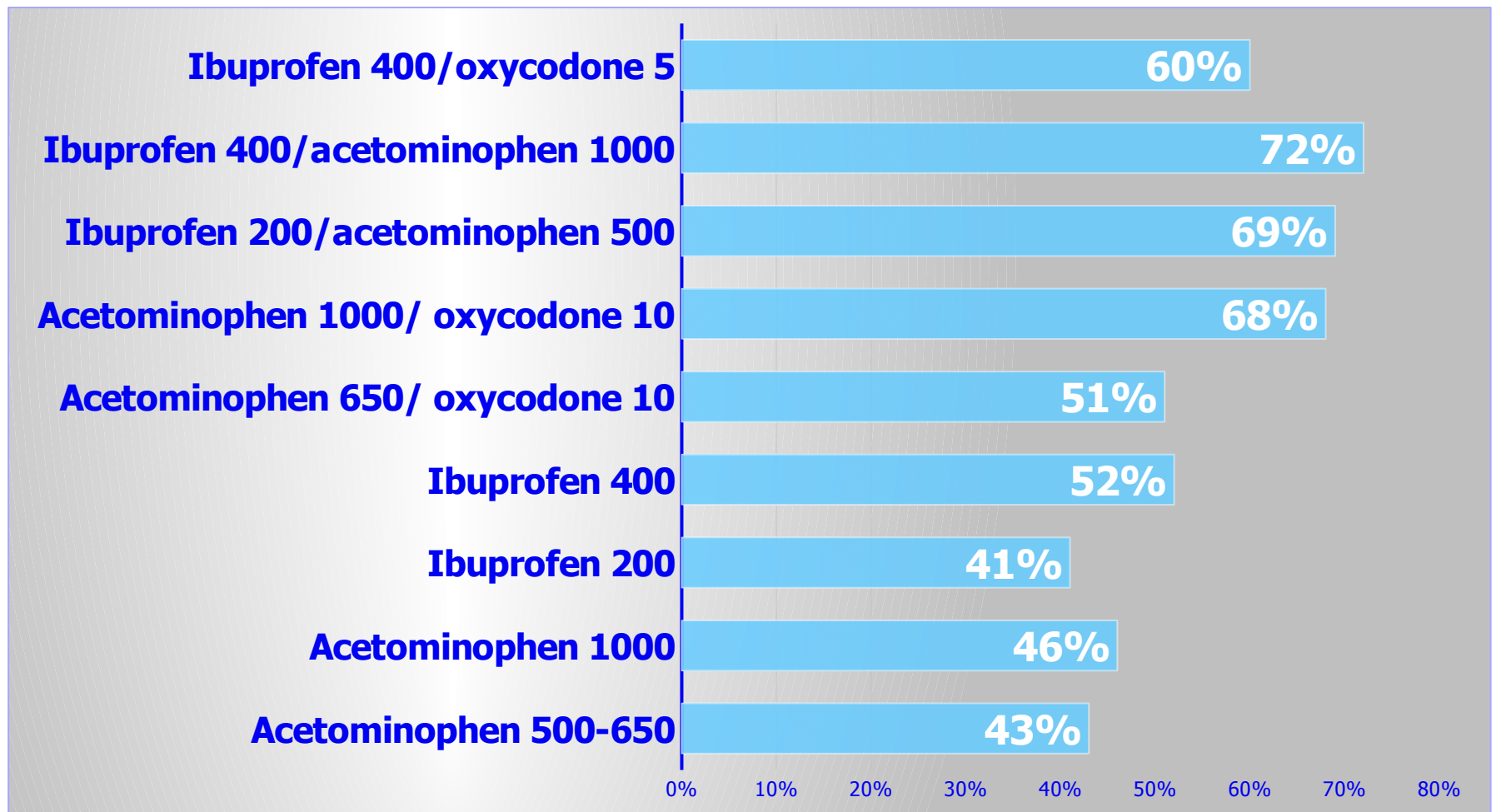
- NSAIDS/acetaminophen
- Antispasmodics

**Table 1.** Efficacy data from high-quality studies for analgesic agents available in the United States in order of effectiveness (most to least) according to NNTB\*. <sup>22,24</sup>

| DRUG OR DRUG COMBINATION, DOSE                        | NNTB | 95% CONFIDENCE INTERVAL | AT LEAST 50% MAXIMUM PAIN RELIEF OVER 4-6 HOURS, % |         | MEAN OR MEDIAN TIME TO REMEDIATION, HOURS |                 |
|---|------|-------------------------|--|---------|---|-----------------|
|   |      |                         | Active   | Placebo | Active                                    | Placebo         |
| Ibuprofen Plus Acetaminophen, 400 Milligrams/1,000 mg | 1.5  | 1.4 to 1.7              | 72   | 6       | 8.3                                       | 1.7             |
| Ibuprofen Plus Acetaminophen, 200 mg/500 mg           | 1.6  | 1.5 to 1.8              | 69   | 6       | 7.6                                       | 1.7             |
| Acetaminophen Plus Oxycodone, 1,000 mg/10 mg          | 1.8  | 1.6 to 2.2              | 68   | 13      | 9.8                                       | 1.5             |
| Diclofenac (Potassium), 100 mg                        | 1.9  | 1.7 to 2.3              | 65   | 13      | 6.3                                       | 2.0             |
| Ketoprofen, 25 mg                                     | 2.0  | 1.8 to 2.3              | 62   | 12      | 46 <sup>†</sup>                           | 79 <sup>†</sup> |
| Diclofenac (Potassium), 50 mg                         | 2.1  | 1.9 to 2.5              | 64   | 17      | 4.5                                       | 1.7             |
| Diflunisal, 1,000 mg                                  | 2.1  | 1.8 to 2.6              | 62   | 15      | 10.9                                      | 3.2             |
| Ibuprofen (Fast-Acting), 200 mg                       | 2.1  | 1.9 to 2.4              | 57   | 10      | 43 <sup>†</sup>                           | 78 <sup>†</sup> |
| Ibuprofen (Fast-Acting), 400 mg                       | 2.1  | 1.9 to 2.3              | 65   | 18      | 32 <sup>†</sup>                           | 82 <sup>†</sup> |
| Ibuprofen Plus Caffeine, 100 mg/200 mg                | 2.1  | 1.9 to 3.1              | 59   | 10      | 26 <sup>†</sup>                           | 60 <sup>†</sup> |
| Ketoprofen, 100 mg                                    | 2.1  | 1.7 to 2.6              | 66   | 18      | 43 <sup>†</sup>                           | 85 <sup>†</sup> |
| Acetaminophen Plus Codeine, 800-1,000 mg/60 mg        | 2.2  | 1.8 to 2.9              | 53   | 7       | 5.0                                       | 2.3             |

# Single Dose Oral Analgesics for Acute Post-Operative Pain

## Percent of patients 50% pain relief



OXYCODONE 5 = PLACEBO

# Oral Analgesics for Postoperative Pain

| Analgesic(s) | Dose (mg) | NNT vs Placebo<br>≥ 50% maximum pain relief<br>over 4-6 hours |
|--------------|-----------|---|
|--------------|-----------|---|

~50,000 participants

## SINGLE AGENTS:

|                      |      |      |
|----------------------|------|------|
| Ibuprofen            | 600  | 2.7  |
| Naproxen             | 500  | 2.7  |
| Celecoxib            | 400  | 2.6  |
| Acetaminophen (APAP) | 1000 | 3.6  |
| Oxycodone            | 15   | 4.6  |
| Codeine              | 60   | 12.0 |
| Gabapentin           | 250  | 11.0 |

~460 high-quality studies  
(mostly dental extractions)

## COMBINATIONS:

|                       |          |     |
|-----------------------|----------|-----|
| Ibuprofen + APAP      | 400+1000 | 1.5 |
| Ibuprofen + oxycodone | 400+5    | 2.3 |
| APAP + oxycodone      | 325+5    | 5.4 |
| APAP + codeine        | 300+30   | 6.9 |



# Perform your own EVALUATION

- Take a thorough history
- Perform a targeted physical exam
- Establish a working diagnosis
- Do appropriate tests
- Obtain & review records of past care

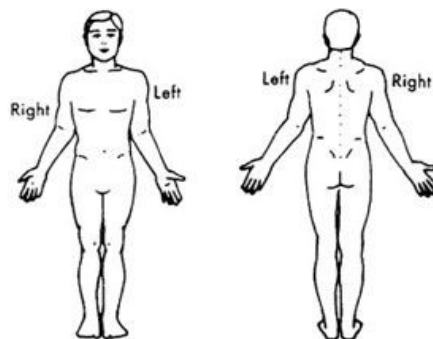
## FORM 3.2 Brief Pain Inventory

Date \_\_\_ / \_\_\_ / \_\_\_ Time: \_\_\_\_\_

Name: \_\_\_\_\_  
Last First Middle Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?  
 1. Yes 2. No

2) On the diagram shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **worst** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10  
 No pain pain as bad as you can imagine

4) Please rate your pain by circling the one number that best describes your pain at its **least** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10  
 No pain pain as bad as you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **average**

0 1 2 3 4 5 6 7 8 9 10  
 No pain pain as bad as you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **right now**.

0 1 2 3 4 5 6 7 8 9 10  
 No pain pain as bad as you can imagine

7) What treatments or medications are you receiving for your pain?  
 \_\_\_\_\_  
 \_\_\_\_\_

8) In the Past 24 hours, how much **relief** have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received

0% 10 20 30 40 50 60 70 80 90 100%  
 No Complete relief  
 relief relief

9) Circle the one number that describes how, during the past 24 hours, pain has **interfered** with your:

A. General activity  
 0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

B. Mood  
 0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

C. Walking ability  
 0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

D. Normal work (includes both work outside the home and housework)

0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10  
 Does not Completely  
 interfere interferes



# ***Risk Stratification***

## ***More Than Classic Aberrancy***

- **Physical**
- **Family history**
- **Social/Domestic**
- **Mental Health**
- **PDMP**
- **Rx Combinations**
- **Stable housing?**
- **Toxicology data**
- **Releases from Providers**
  - “fired”
- **Age <45, esp. < 25**
- **Tobacco use**
- **Chaos/ Life Trauma Hx**
- **Legal history**
  - Web inquiries EZ
  - DOC-site
- **Abuse (sexual) history**
  - Esp. when young
- **Repeated traumas**
  - Non-sports related

## **Especially Important**

- **Assess Risk for substance abuse/harm**
- **Assess Mental health status**

# ***Assessment for OUD***

***Screenings for prior or current  
opioid use before treatment***

# Substance Abuse Assessment – Survey Tools

Ask patients about any past or current history of **substance abuse** (alcohol, Rx meds, or illicit) prior to initiating treatment for chronic pain with opioids

- **ORT** – Opioid Risk Tool
- **SOAPP** – Screener/Opioid Assessment for Patients in Pain (starting opioids)
- **COMM** – Common Opioid Misuse Measure (pts already using opioids)



These survey tools will  
be available at:  
[www.bitterpill.in.gov](http://www.bitterpill.in.gov)

Any truth is better than indefinite doubt



## Prescription Drug Monitoring

Check **INSPECT**

# ***Assessment of mental health status***

***Screenings for mental illness  
before treatment***



**Table 3. Factors Associated with the Risk of Opioid Overdose or Addiction.**

| Factor   | Risk  |
|--|---|
| Medication-related   |   |
| Daily dose >100 MME*   | Overdose, <sup>8</sup> addiction <sup>8</sup>   |
| Long-acting or extended-release formulation (e.g., methadone, fentanyl patch)          | Overdose <sup>14,41</sup>                       |
| Combination of opioids with benzodiazepines  | Overdose <sup>42</sup>                          |
| Long-term opioid use (>3 mo)†  | Overdose, <sup>43</sup> addiction <sup>44</sup> |
| Period shortly after initiation of long-acting or extended-release formulation (<2 wk) | Overdose <sup>45</sup>                          |
| Patient-related  |   |
| Age >65 yr   | Overdose <sup>46</sup>                          |
| Sleep-disordered breathing‡  | Overdose <sup>47</sup>                          |
| Renal or hepatic impairment§   | Overdose <sup>48</sup>                          |
| Depression   | Overdose, addiction <sup>49</sup>               |
| Substance-use disorder (including alcohol)   | Overdose, <sup>50</sup> addiction <sup>49</sup> |
| History of overdose  | Overdose <sup>51</sup>                          |
| Adolescence  | Addiction <sup>52</sup>                         |

# **Pain and Mental Illness**

**41 million with mental illness, (2011, National Survey)**

- 1. Magnifies medical/somatic symptoms**
- 2. Elevation of Cost**
- 3. Diminishes treatment success**
- 4. Treat it yesterday and augment if needed.**

**Depression can interfere with the management of pain and requires treatment for adequate pain outcomes**

| Condition                            | Prevalence Chronic Pain Patients                        |
|--------------------------------------|---|
| Depression                           | 33% - 54% <sup>22,23</sup>                              |
| Anxiety Disorders                    | 16.5% - 50% <sup>22,24</sup>                            |
| Personality Disorders                | 31% - 81% <sup>25,26</sup>                              |
| PTSD                                 | 49% veterans <sup>27</sup> ; 2% civilians <sup>24</sup> |
| Substance Use Disorders              | 15% - 28% <sup>22,25</sup>                              |
| PTSD, posttraumatic stress disorder. |   |

Gen Hosp Psychiatry. 2012;34(1):46-52

Curr Psychiatry Rep. 2006;8(5):371-376

J Clin Psychol Med Settings. 2011;18:145-154f

SCOPE of Pain Boston Universtiy

**16% with mental illness get 51% of opioid**

J Am Board Fam Med 2017; 30:407– 417

# Mental Health Assessment – Survey Tools

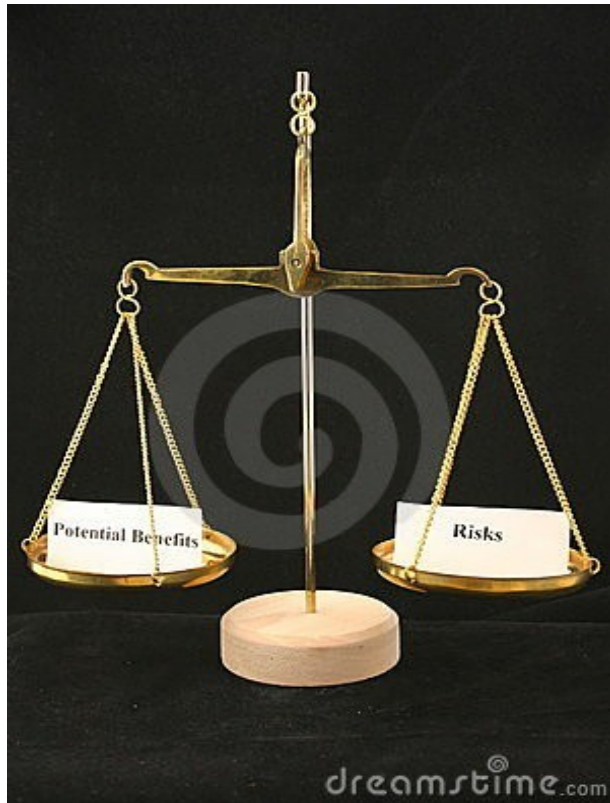
**Chronic pain may be caused, influenced or modulated by ...**

- Depression (PHQ-2, PHQ-9)
- Post Traumatic Stress Disorder
- Anxiety/Panic Disorder (GAD-7)



**Note: Treat any underlying psychiatric diagnosis first or, at least, concurrently**

# ***Informed Consent when prescribing opioid medications***



- **Discuss the risks and benefits of opioid treatment**
- **Provide clear explanation to help patients understand key elements of treatment plan**
- **Counsel women of child-bearing age about the potential for fetal opioid dependence and neonatal abstinence syndrome (NAS)**



# Informed Decision

## Possible Benefits

- **Less pain**
  - Rarely > 30-50%
  - Only 4 mo.
- **Function/QOL**
- **Getting on Disability**

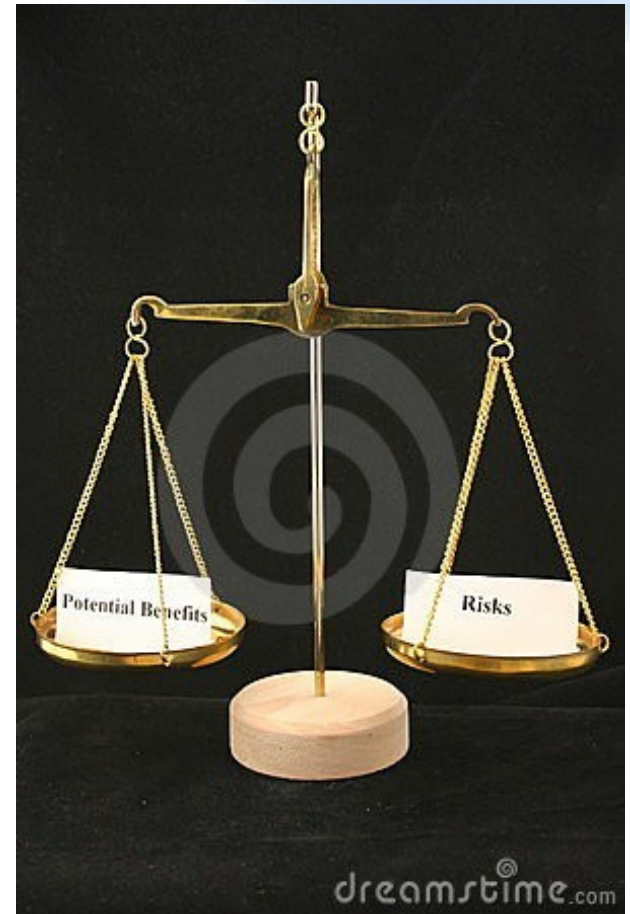
## Possible Adverse Rxns

- **Disordered sleep**
- **Gastroparesis**
- **Hypogonadism**
- **Osteoporosis/fractures**
- **Myocardial infarction**
- **Neonatal Abstinence Syndrome**
- **OD and death**
- **Opioid Induced hyperalgesia**
- **Opioid use Disorder**



# Review and Sign a Treatment Agreement

- Goals of treatment
- Consent and drug monitoring with random pill counts
- Prescribing policies, prohibition of sharing medications and requirement to take meds as prescribed
- Information on pain meds prescribed by other physicians
- Reasons that opioid therapy may be changed or discontinued
- Counsel women of child-bearing age about the potential for fetal opioid dependence & neonatal abstinence syndrome (NAS).



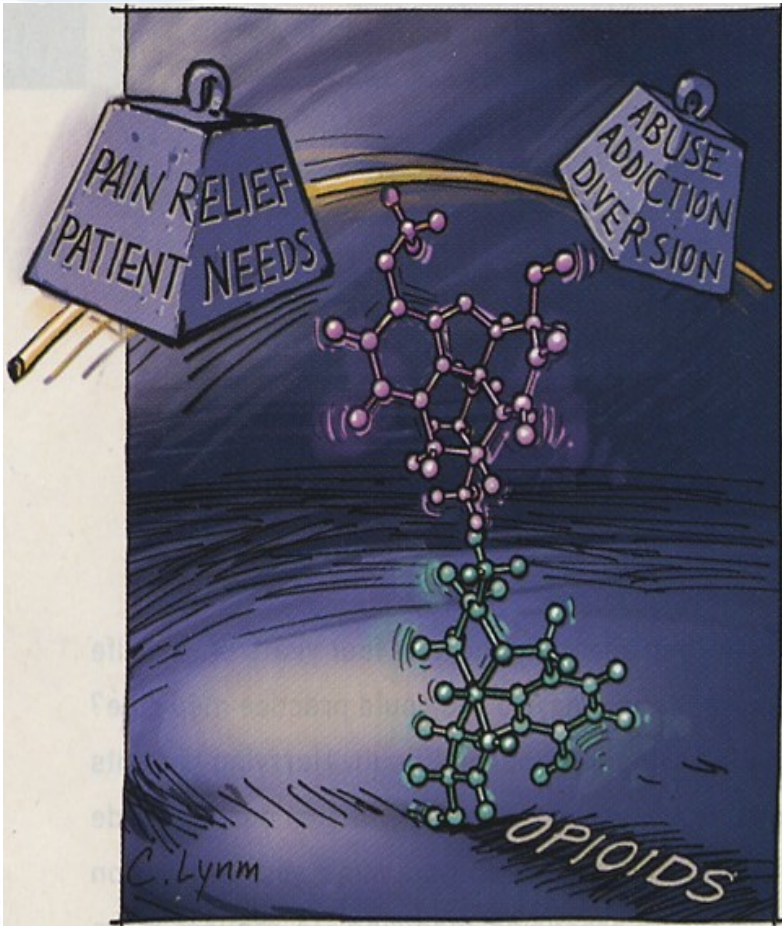
# ***Periodic Scheduled Visits***

- **Evaluate patient progress**
- **Monitor compliance**
- **Set clear expectations**
- **Q 4mo, if stable  
(minimum)**
- **Q 2mo, if changing meds;  
more often as needed**



**AFFECT + ACTIVITIES (FUNCTION) + ANALGESIA + ADVERSE  
EFFECTS + ABERRANT**

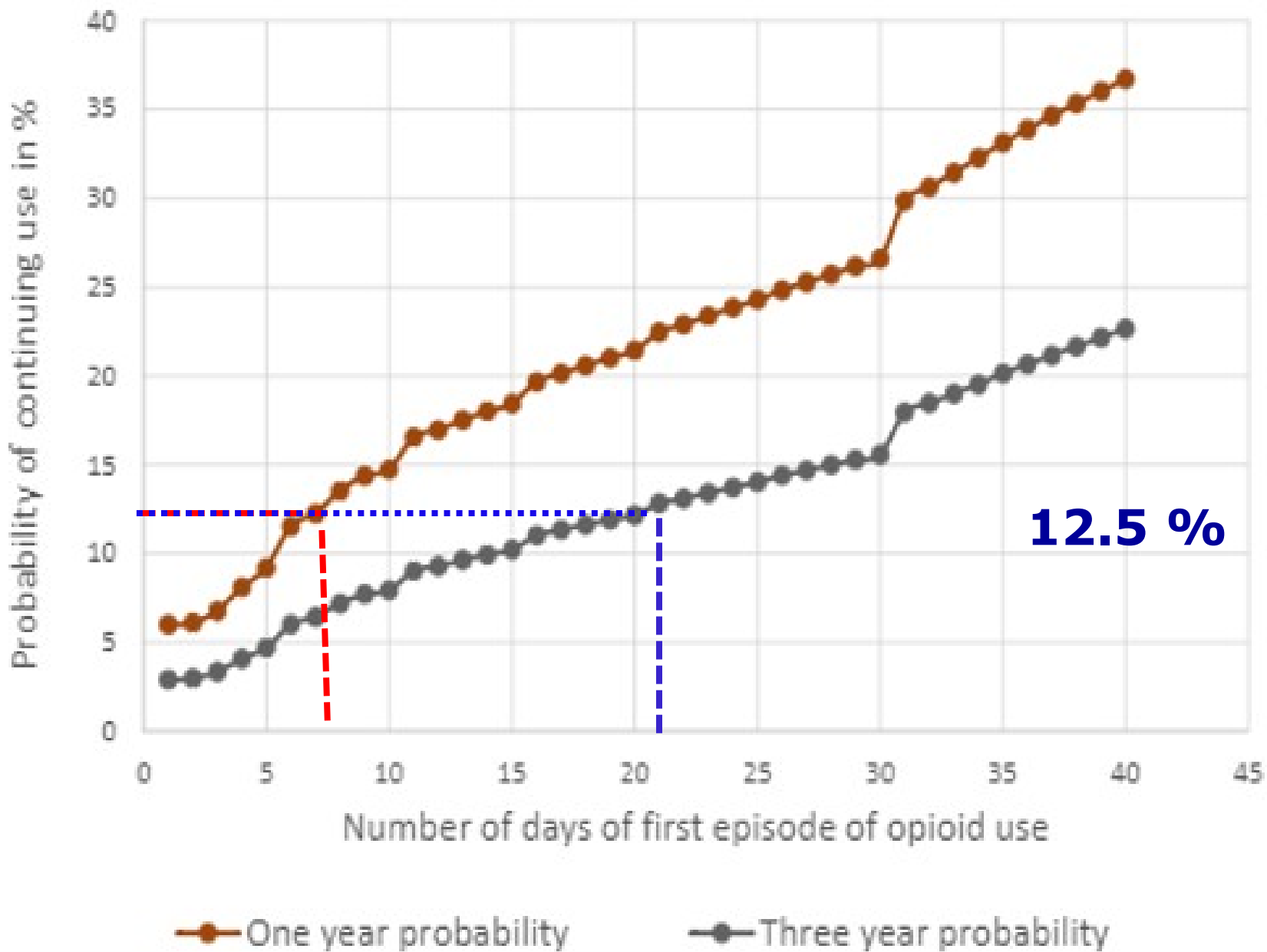
# ***Reassessment is required when MME $\geq$ 60***



- **Face-to-face review to reassess your patient**
- **Formulate/document a revised assessment and treatment plan**
- **Discuss the increased risk for adverse outcomes (including death) with higher opioid doses if that is what you plan to do**

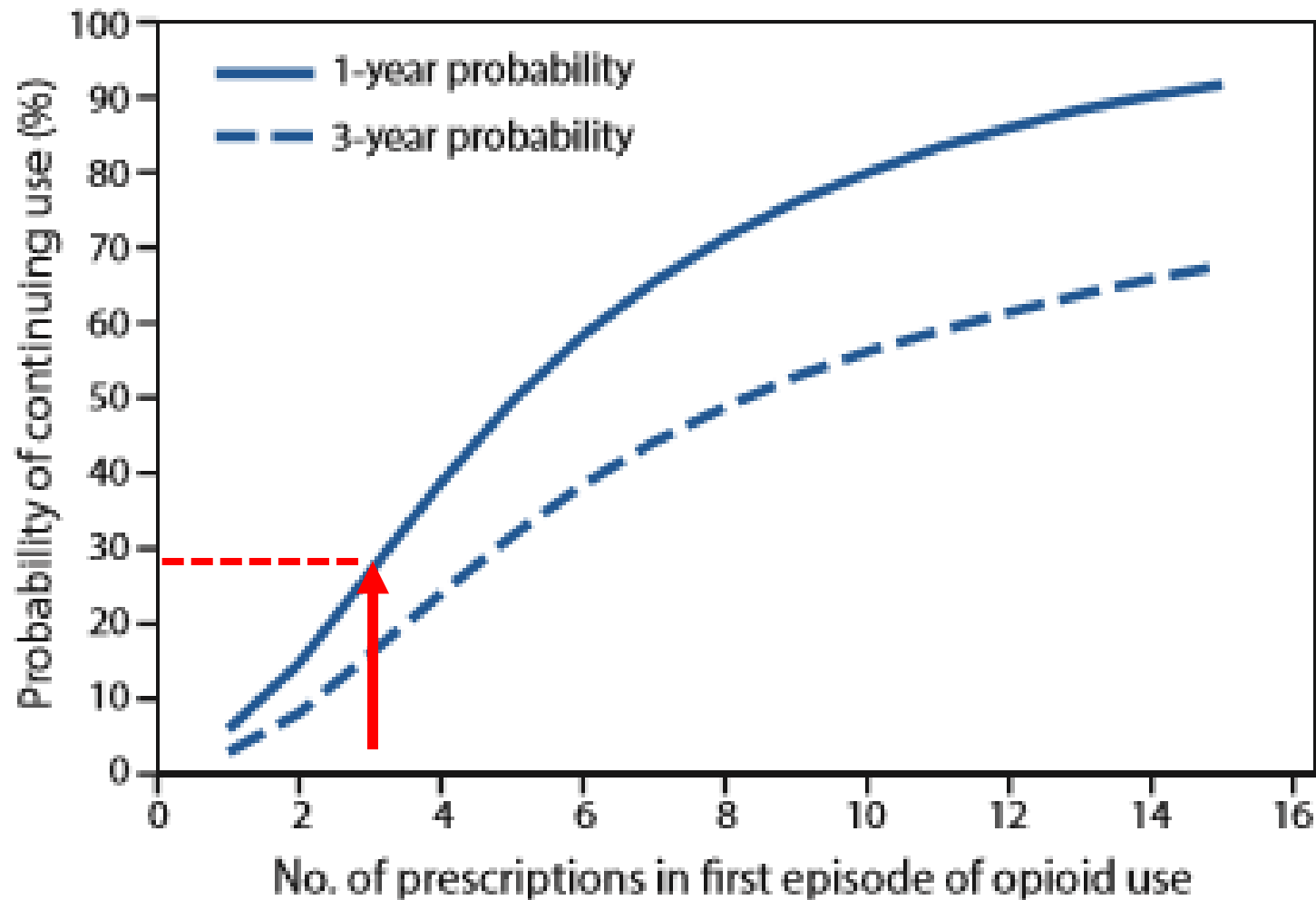
# ***Opioid Use Disorder and the 7 day Rule***

## **Limits on prescribing opioid medications**



**12.5 %**

**FIGURE 2. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions\* in the first episode of opioid use — United States, 2006–2015**





# Indiana Laws

**2014 – Chronic Opioid Prescribing Law**

**2017 – 7 Day Prescribing Law**

**2018 – CME requirement- 2 hrs each 2 years**

*CME must address opioid prescribing and opioid abuse*

**2018 – INSPECT requirement**

# Senate Bill 221 (Effective July 1, 2018)

Requires checking **INSPECT** each time before prescribing an **opioid or benzodiazepine to any patient** (No specific exceptions for hospice, palliative care, or LTC patients)

Effective date depends on situation:

Applies **7/1/2018** for practitioners with INSPECT integrated into EMR

Applies **1/1/2019** for practitioners providing services in

- The ER; or pain management clinic

Applies **1/1/2020** to practitioners providing services in a hospital

Applies **1/1/2021** to all practitioners

Patients on pain management contract –q 90dPractitioners

# Points to Note

- **If an opioid naïve person is given a 7 day Rx for opioids there is a 12.5 % chance of this person being on opioids @12 months**
- **A 21 day Rx is associated with 12.5 % risk of being on opioids at 3 years**
- **Similarly, the more Rxs one receives, the more likely opioid use will continue to 12 months or even 36 months**

# General Surgery in Vermont – Opioid Pills

- **N 127 of 330 total patients**
- **Pill = 5 mg oxycodone**
- **Phone survey**
- **Based on patient recall**

**TABLE 2. Opioid Pills Taken**

| <b>Operation</b>  | <b>Partial Mastectomy</b> | <b>Partial Mastectomy With Sentinel Node Biopsy</b> | <b>Laparoscopic Cholecystectomy</b> | <b>Laparoscopic Inguinal Hernia Repair</b> | <b>Open Inguinal Hernia Repair</b> |
|-------------------|---------------------------|---|-------------------------------------|--|------------------------------------|
| Surveys completed | 20                        | 21  | 48                                  | 20   | 18                                 |
| Pills prescribed  | 415                       | 490   | 1450                                | 650  | 540                                |
| Pills taken       | 61 (14.7%)                | 126 (25.7%)   | 474 (32.7%)                         | 189 (14.7%)                                | 168 (31.1%)                        |
| Pills remaining   | 354 (85.3%)               | 364 (74.3%)   | 976 (67.3%)                         | 461 (85.3%)                                | 372 (69.9%)                        |

**1.9% obtained a refill**

# General Surgery in Vermont – Opioid Pills

TABLE 2. Opioid Pills Taken

| Operation         | Partial Mastectomy | Partial Mastectomy With Sentinel Node Biopsy | Laparoscopic Cholecystectomy | Laparoscopic Inguinal Hernia Repair | Open Inguinal Hernia Repair |
|-------------------|--------------------|--|------------------------------|-------------------------------------|-----------------------------|
| Surveys completed | 20                 | 21   | 48                           | 20                                  | 18                          |
| Pills prescribed  | 415                | 490  | 1450                         | 650                                 | 540                         |
| Pills taken       | 61 (14.7%)         | 126 (25.7%)                                  | 474 (32.7%)                  | 189 (14.7%)                         | 168 (31.1%)                 |
| Pills remaining   | 354 (85.3%)        | 364 (74.3%)                                  | 976 (67.3%)                  | 461 (85.3%)                         | 372 (69.9%)                 |

3

6

10

9

9.3

**Average number of pills used**

# Defining Optimal Length of Opioid Pain Medication – Prescription After Common Surgical Procedures

- **Cohort study of 215,140**
- **Median observed prescription lengths were**
  - 4 days for general surgery procedures
  - 4 days for women’s health procedures
  - 6 days for musculoskeletal procedures.
- **Rx lengths associated with lowest refill rates**
  - 9 days for general surgery
  - 13 days for women’s health,
  - 15 days for musculoskeletal procedures.

AMA Surg 2018; 153(1):37-43

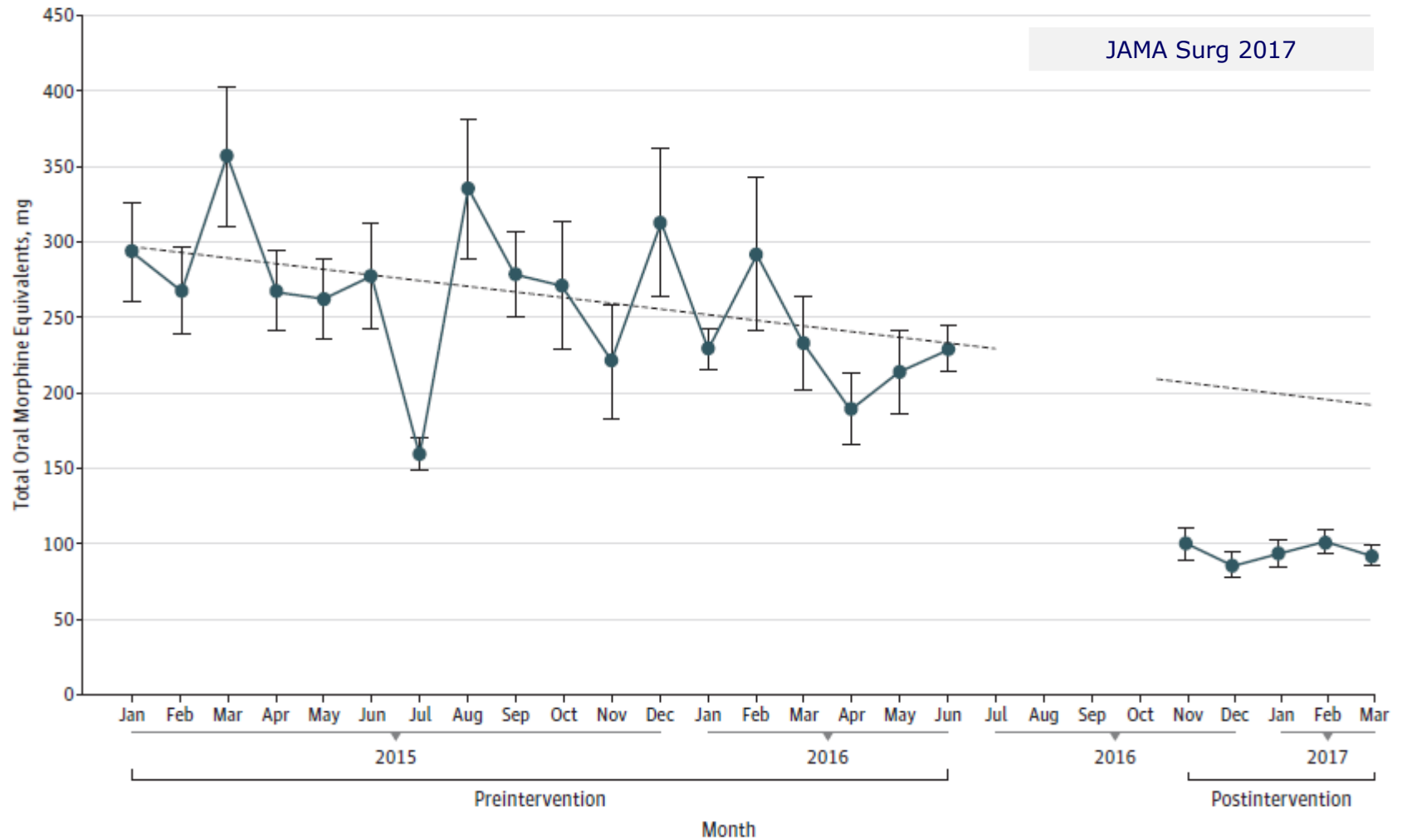


# Post-op Prescription Guidelines – Elective Laparoscopic Cholecystectomy

- **University of Michigan**
- **November 2016 to March 2017**
- **Median opioid prescribed 250 to 75 mg**
- **Median opioid used from 30 to 20 mg ( $P = .04$ ),  
with no change in Pain Score**
- **2.5% Pts requested refills vs. 4.1% in the pre-guideline**
- **APAP/NSAID use from 21 to 49 % (little home change)**

**Reduction in opioid prescribing through  
evidence-based prescribing guidelines**

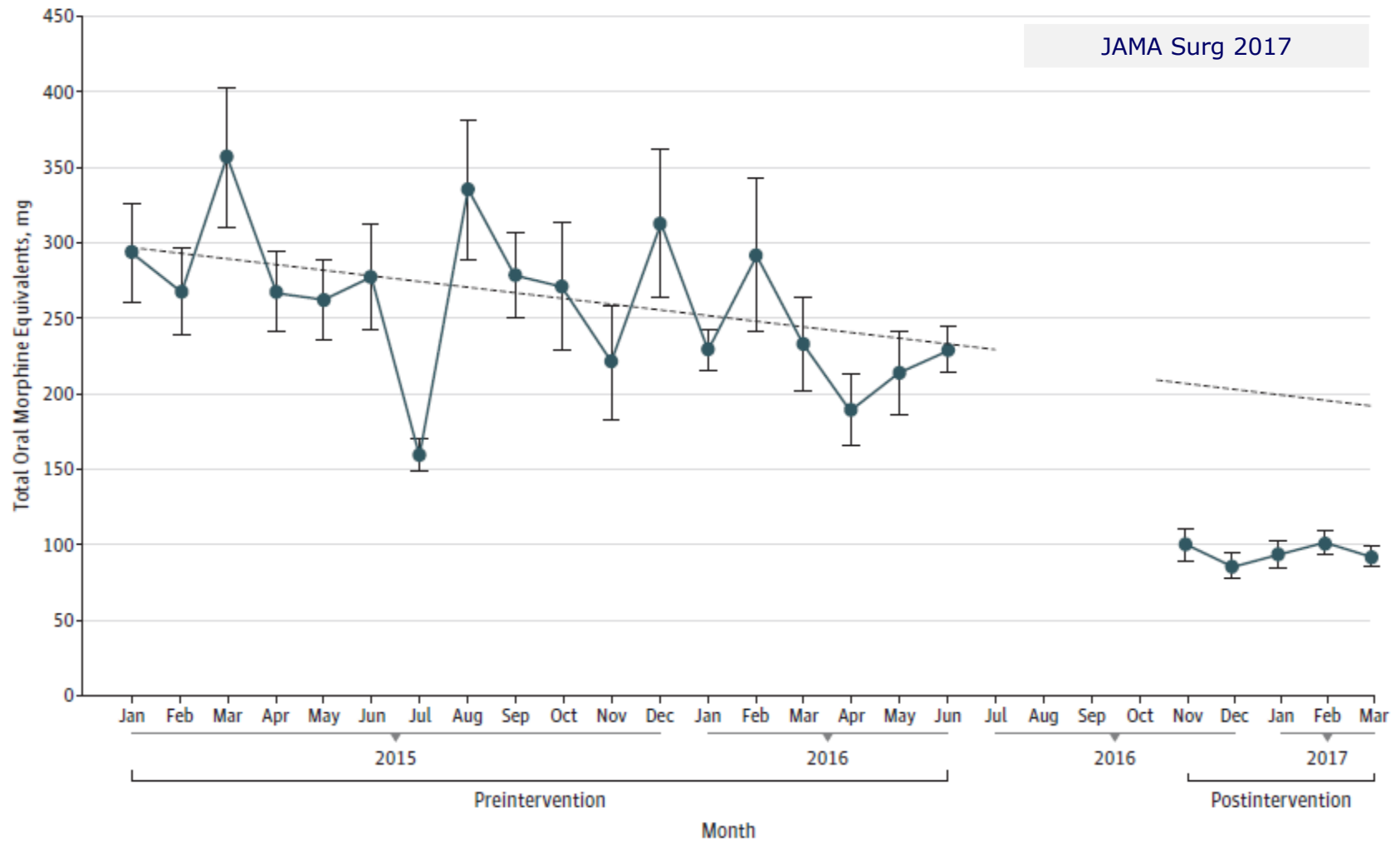
Figure. Reduction in Postoperative Opioid Prescribing After Implementation of Prescribing Guidelines.



Following the implementation of evidence-based prescribing guidelines, opioid prescriptions were significantly reduced from an equivalent of approximately 45 pills of hydrocodone, 5 mg, to approximately 15 pills ( $P < .001$ ). The dashed line represents the expected decline in prescribing prior to the study intervention.

**Reduction of from 45 to 15 pills per prescription using guidelines**

Figure. Reduction in Postoperative Opioid Prescribing After Implementation of Prescribing Guidelines.



Following the implementation of evidence-based prescribing guidelines, opioid prescriptions were significantly reduced from an equivalent of approximately 45 pills of hydrocodone, 5 mg, to approximately 15 pills ( $P < .001$ ). The dashed line represents the expected decline in prescribing prior to the study intervention.

**This represents 7000 fewer pills among this cohort** 179

# Post-Operative Opioid Prescribing Recommendations

## UPDATED 2019

| Procedure   | Oxycodone*<br>5mg tablets | Procedure   | Oxycodone*<br>5mg tablets |
|---|---------------------------|---|---------------------------|
| Laparoscopic Cholecystectomy                        | 10                        | Hysterectomy – Vaginal, Lap/Robotic, or Abdominal             | 15                        |
| Open Cholecystectomy                                | 15                        | Cesarean Section  | 15                        |
| Appendectomy – Lap or Open                          | 10                        | Breast Biopsy or Lumpectomy                                   | 5                         |
| Hernia Repair – Major or Minor                      | 10                        | Lumpectomy + Sentinel Lymph Node Biopsy                       | 5                         |
| Colectomy – Lap or Open                             | 15                        | Sentinel Lymph Node Biopsy Only                               | 5                         |
| Ileostomy/Colostomy Creation, Re-siting, or Closure | 15                        | Wide Local Excision ± Sentinel Lymph Node Biopsy              | 20                        |
| Open Small Bowel Resection or Enterolysis           | 20                        | Simple Mastectomy ± Sentinel Lymph Node Biopsy                | 20                        |
| Thyroidectomy                                       | 5                         | Modified Radical Mastectomy or Axillary Lymph Node Dissection | 30                        |
| Sleeve Gastrectomy                                  | 10                        | Carotid Endarterectomy  | 10                        |
| Prostatectomy                                       | 10                        | Total Hip Arthroplasty  | 30                        |
| Laparoscopic Anti-reflux (Nissen)                   | 10                        | Total Knee Arthroplasty                                       | 50                        |
| Laparoscopic Donor Nephrectomy                      | 10                        | Dental  | 0                         |
| Cardiac Surgery via Median Sternotomy               | 15                        |   |                           |

\*The recommendations remain the same if prescribing hydrocodone 5mg

# Points to Note

- **Post-op pain can be managed with much less opioids than used in the past**
- **Gynecologic, General and Orthopedic post-op care can all use less opioids**
- **Patients/guardians can request partial fills on Rx's and obtain the balance before 30 days**
- **Over 7 days of opioids for new patients and for those under 18 requires appropriate documentation in the medical record**

# 2016 - FDA Black Box Warning

Health care professionals should **limit prescribing opioid pain medicines with benzodiazepines (or other **CNS depressants**) only to patients for whom alternative treatment options are inadequate.**

If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.



# Opioid SR and Benzo

- **Greater pain, pain interference with life, and lower feelings of self-efficacy with respect to their pain**
- **Being prescribed “higher risk” (>200 MED)**
- **Antidepressant and/or antipsychotic medications**
- **Substance use (including more illicit and injection drug use, alcohol use disorder, and daily nicotine use)**
- **Greater mental health comorbidity and Health Costs**

# What about Methadone?

- A complex medication with a long half-life, highly variable pharmacologic properties and many drug-drug interactions
- It represented about **3% of opioid prescribing**
- It was responsible for about **30% of opioid-related deaths**

*Be very cautious when co-prescribing*



# ***Assessment for OUD***

***Screenings for opioid use  
during treatment***

# Three Objectives:

Any truth is better than indefinite doubt

## Prescription Drug Monitoring

**INSPECT**

### Drug Monitoring

**Urine**

**Blood**

**Saliva**

### Pill Counting

**Early and late**

**Providers hands-off**



## Prescription Drug Monitoring Program

- **Use PDMP regularly for new and established patients to detect unsafe patterns of medication acquisition.**
- **PDMP is free and easy to use; [www.in.gov/inspect](http://www.in.gov/inspect)**
- **PDMP query @ initiation**
- ***Min. 4 times per year (CDC)***



**Thank you  
Pharmacists!**

# Urine Drug Monitoring

**UDM has evolved to become a standard of care when prescribing opioids**

- **Detecting illicit substances**
- **Monitoring patient adherence to prescribed medications**
  
- **UDM - at initiation of an opioid trial & at least annually (starting 12/2014)**
  
- **Interpretation is critical**

**“You’re in trouble” or Urine Trouble**







INDIANA UNIVERSITY



# ***Aaron's Law***

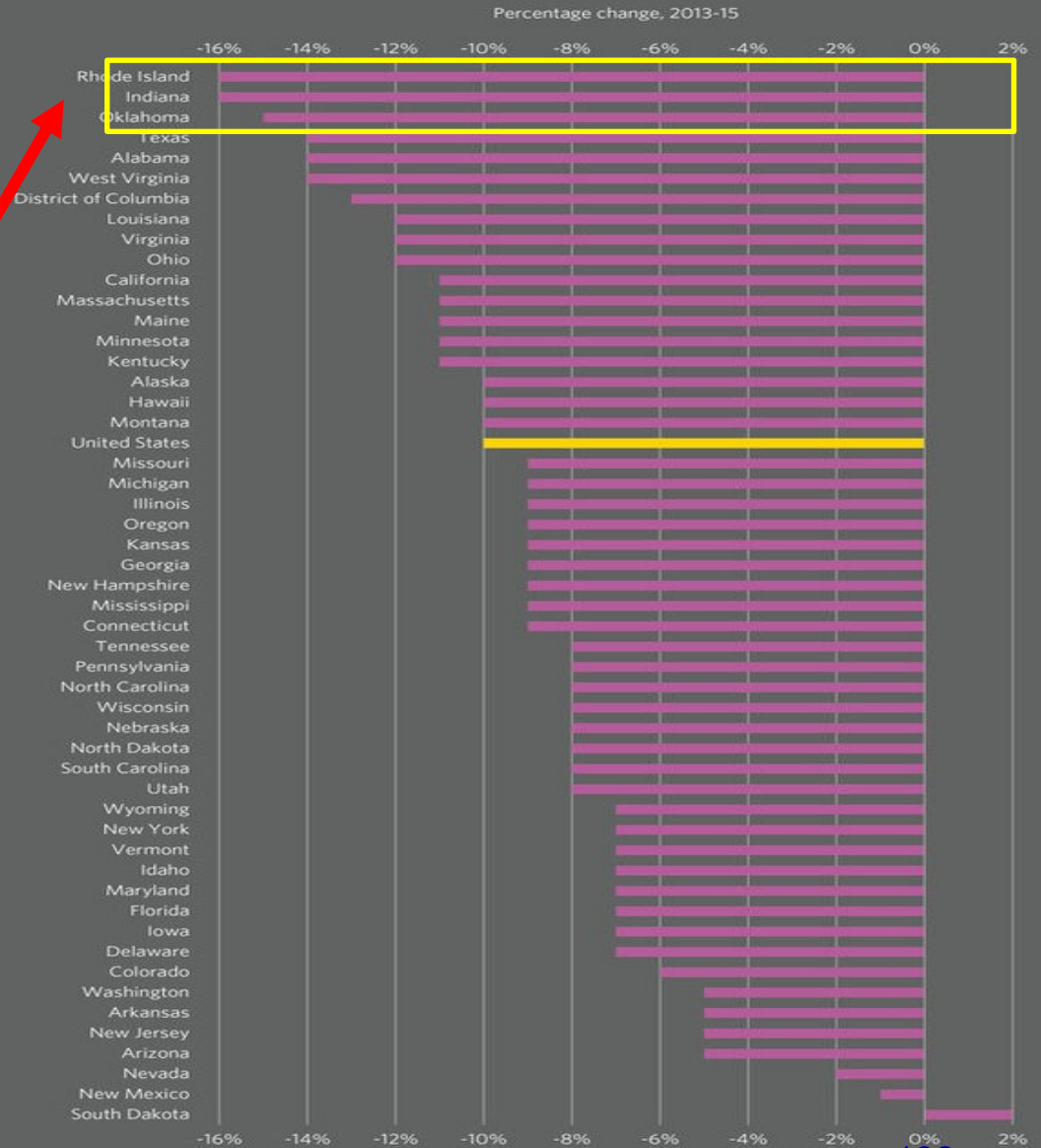
- **Named after Aaron Sims, a young Hoosier who lost his battle with heroin addiction in 2013**
- **April 2015: Aaron's Law was signed by Indiana Governor Mike Pence**
- **Allows anyone to get naloxone and make it legal for anyone to administer the drug**
- **Allows a pharmacist to dispense naloxone to an individual without a prescription**

## ***Some Improvement***

***Recent changes in the approach to pain management and the reduction on reliance on opioid medications is having an effect***

## Opioid Painkiller Prescriptions

State initiatives and increased awareness of the opioid epidemic have spurred physicians to take a more cautious approach to prescribing opioid painkillers. The national rate of opioid prescribing dropped 10 percent between 2013 and 2015, falling in every state but South Dakota.



## Indiana

Large drop in  
opioid prescriptions  
from 2013 to 2015



# Primary Care Monitoring of Long-Term Opioid Therapy among Veterans with Chronic Pain

**Table 2** Documentation of guideline-concordant opioid management processes

| Process                             | N (%) with Process       |                               |                                  | P value <sup>‡</sup> |
|-------------------------------------|--------------------------|-------------------------------|----------------------------------|----------------------|
|                                     | Full Cohort<br>(N = 169) | No Opioid<br>Misuse (N = 114) | Any Potential<br>Misuse (N = 55) |                      |
| Reassessment of pain                | 105 (62)                 | 66 (58)                       | 39 (71)                          | 0.102                |
| Assessment of pain-related function | 32 (19)                  | 16 (14)                       | 16 (29)                          | 0.019                |
| Assessment of adherence             | 40 (24)                  | 24 (21)                       | 16 (29)                          | 0.249                |
| Assessment of alcohol or drug use   | 24 (14)                  | 10 (9)                        | 14 (26)                          | 0.004                |
| Assessment of adverse effects       | 38 (23)                  | 21 (18)                       | 17 (31)                          | 0.068                |
| Opioid agreement*                   | 19 (11)                  | 9 (8)                         | 10 (18)                          | 0.047                |
| Urine drug testing <sup>†</sup>     | 25 (15)                  | 6 (5)                         | 19 (35)                          | <0.001               |

\* Counted as present if any agreement was present in the records; <sup>†</sup> counted as present if ordered by any provider within 12 months; <sup>‡</sup> P value is from chi-square test of comparison between patients with and without evidence of any potential opioid misuse (any combination of serious nonadherence, minor nonadherence, or substance abuse).



## ***Some Improvement***

**However, still have many challenges, including ...**



## People with SUDs may not seek treatment

- ~~Pain as 5<sup>th</sup> Vital Sign~~ ★
- ~~HCAHPS/Satisfaction Surveys~~ ★
- ~~Expectation-Reality Disequilibrium~~ ★
- ~~Reflexive and Automated Opioidism~~ ★
- ~~Ignorance = Educational Opportunity~~ ★
- **The majority of people with SUDs do not feel a need to obtain treatment for the SUD and or can't easily access**

***Our prime purpose in this life is to help others.  
If you can't help them, at least don't hurt them.***  
**HHDL**

- **Opioids are helpful in short term**
- **Opioid use poses risks with acute or chronic use**
- **Safe and disciplined approach must be employed**
- **Rx opioid troubles are decreasing**
- **Polymodal approaches should be used**
- **Opioid Use Disorder needs to be understood and those with it compassionately and safely helped**

# ***Lessons Learned***

- *The U.S. and Indiana are in the midst of an **opioid epidemic**. A large and increasing portion of the population that are using opioids inappropriately and have an **opioid use disorder (OUD)***
- *The **patients you treat** may be using opioids, either through prescriptions or illicitly*
- *You can check whether your patients have received prescription medications through pharmacies by using **INSPECT***
- *It is important to obtain an accurate **history of medication and drug use** by you patients, as this may influence how you prescribe pain medications*
- *Patients with a **OUD complicate the legitimate management of orofacial pain** in these patients*

# ***Lessons Learned (cont.)***

- *Individuals who are misusing opioid medications may also have a **mental illness** that needs to be recognized and managed in order to appropriately and effectively manage their pain*
- *There are **guidelines** that have been published (online) by recognized authorities in opioid abuse and pain management that provide specific information about pain management for both **acute pain** and **chronic pain***
- *Please refer to these guidelines for the latest information on pain management and the role of prescription medications, especially in context to the current opioid epidemic*