CME Disclosure Acknowledgement Notification

All relevant financial relationships have been mitigated.
All other planners/speakers have no financial relationships.

This form must be provided to learners prior to engaging in the educational program.

Roper St. Francis Healthcare is accredited by the Medical Association of Georgia to provide Continuing Medical Education for physicians.

The Roper St. Francis Healthcare designates this enduring activity for a maximum of 7.0 *AMA PRA Category 1 Credits™.* Physicians should claim only the credit commensurate with the extent of their participation in the activity.

2.00 of the 7.00 hours on pharmacotherapeutic education is pharmacotherapeutic/controlled substance prescriptive authority content. These 2.00 hours fulfill the South Carolina Board of Medical Examiners Opioid education mandate related to approved procedures of prescribing and monitoring controlled substances.

Financial Relationships:

Name	Name of Ineligible companies with which relevant financial relationships	Nature of Relationship
Dr. Robert Oliverio	Pfizer	Leadership Advisory Panel
Dr. Toby Fugate	Gilead Sciences	Speaker
Dr. Richard Pierce	Sensus Healthcare	Employee, Medical Director, Stockholder

No Commercial Support was provided for this program.
No Learner contact information will be shared without learner approval.
Additional Resources have been provided in the enduring presentations.

ROPER ST. FRANCIS HEALTHCARE

Controlled Substance Prescribing in South Carolina

A FOCUS ON OPIOIDS

Primary Care Symposium

Location: Trident Technical College

February 8, 2025

Samuel K. Parish, MD, FASAM
Addiction Medicine/Family Medicine
Roper Saint Francis Physician Partners

ROPER ST. FRANCIS HEALTHCARE

CME Disclosure Statement: F. Strait Fairey, MD – Primary Care Symposium 2025

Samuel K. Parish, MD, speaker has no financial relationships with ineligible companies whose primary business is producing, marketing, selling re-selling, or distributing healthcare products used by or on patients.

A Preamble to Controlled Substance Prescribing

Post-Prandial Somnolence

Samuel K. Parish, MD

We all started somewhere

Why I chose to study medicine and not play professional basketball.

Who was the first President you remember as a child?

Chicago Hope
1994-2000

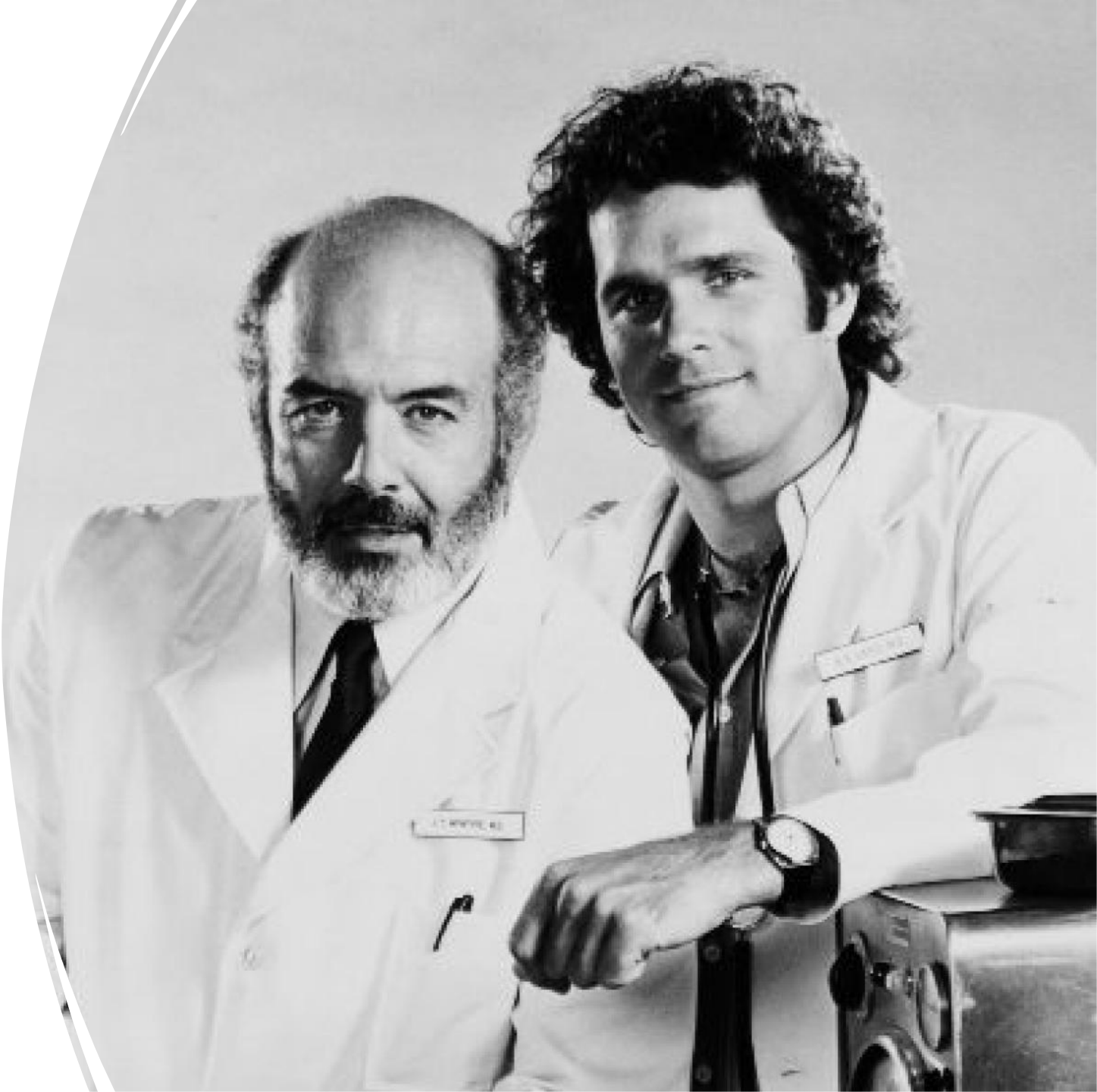
ER
1994-2009

Scrubs
2001-2010

House, MD
2004-2012

Grey’s Anatomy
2005-present

Trapper John, MD 1979-86



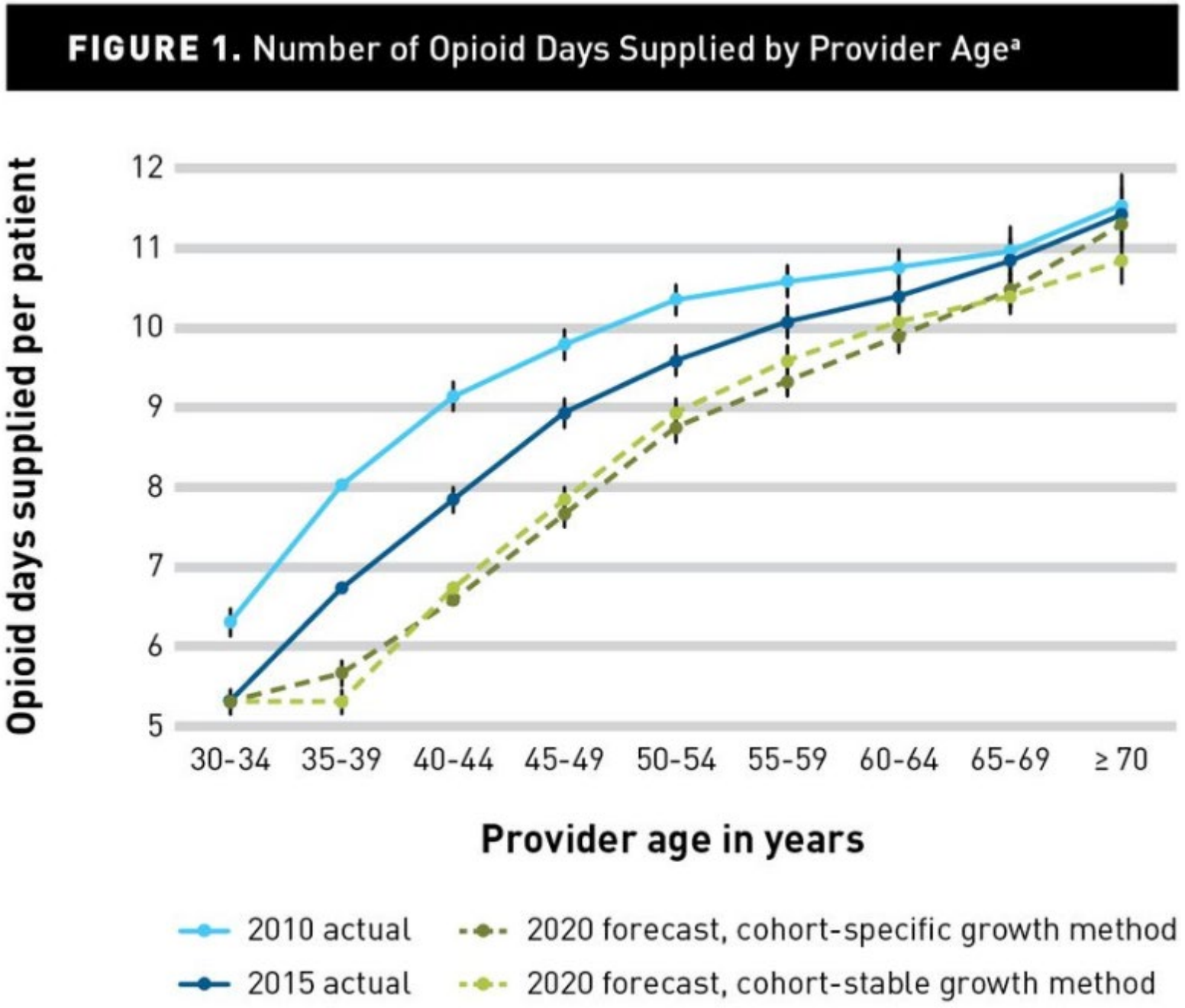
St. Elsewhere 1982-88

Marcus Welby, MD 1969-76

Dr Ben Casey 1961-66

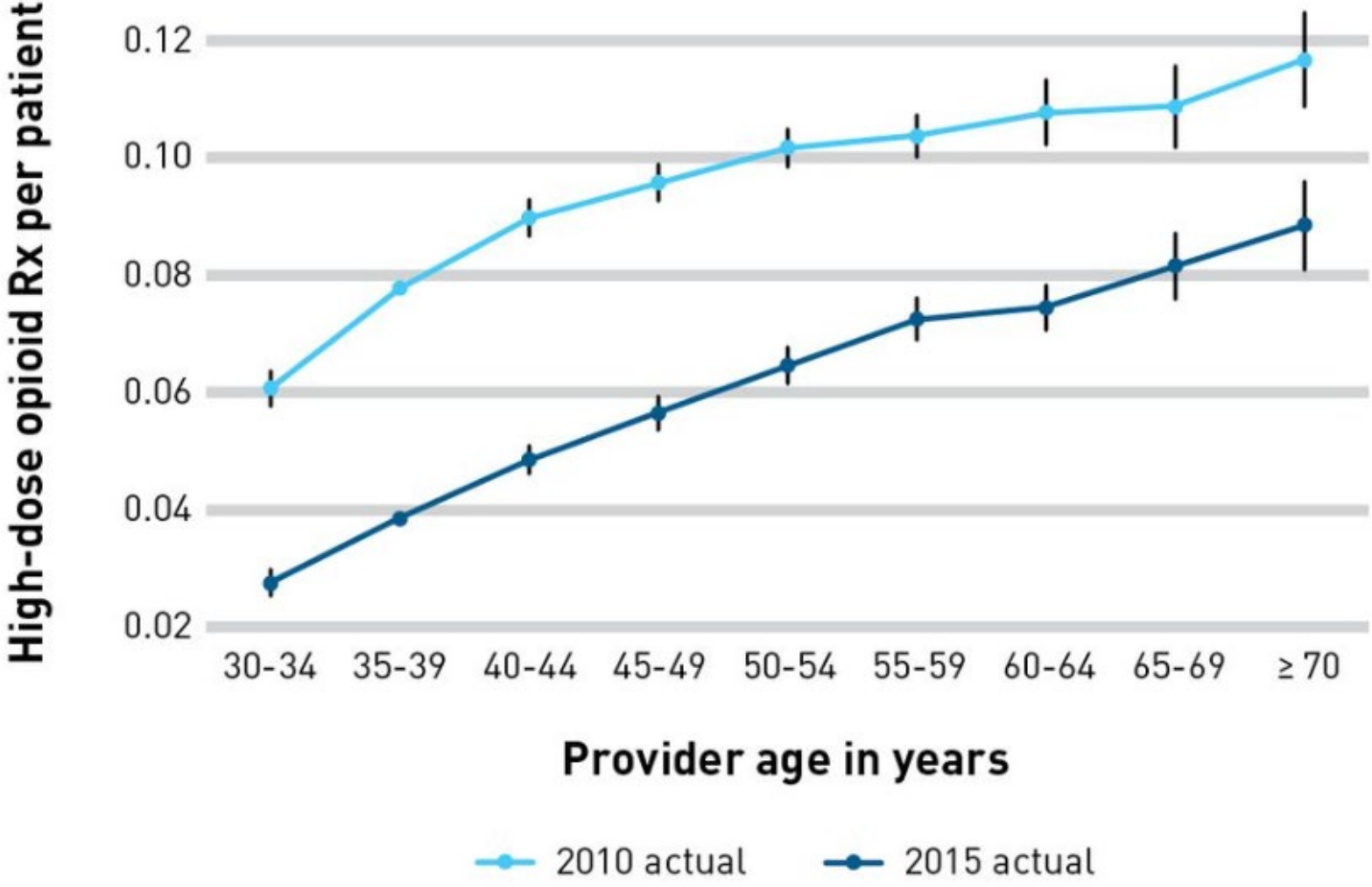
Dr Kildare
1961-66

The relationship between provider age and opioid prescribing behavior



- Baker LC, Kessler DP, Vaska GK. The relationship between provider age and opioid prescribing behavior. Am J Manag Care. 2022 May;28(5):223-228.

FIGURE 3. Count of High-Dose Opioid Prescriptions (> 90 MME/day) by Provider Age[a]



Learning Objectives:

- Review of the CME Mandatory Requirement
- Controlled Substances: A Century of Laws
- Epidemiology: national and state trends in substance use
- Pain: State Laws and Federal Guidelines
- Pain: Acute and Chronic pain management issues
- Opioid Use Disorder: overview of screening, diagnosis, and treatment options

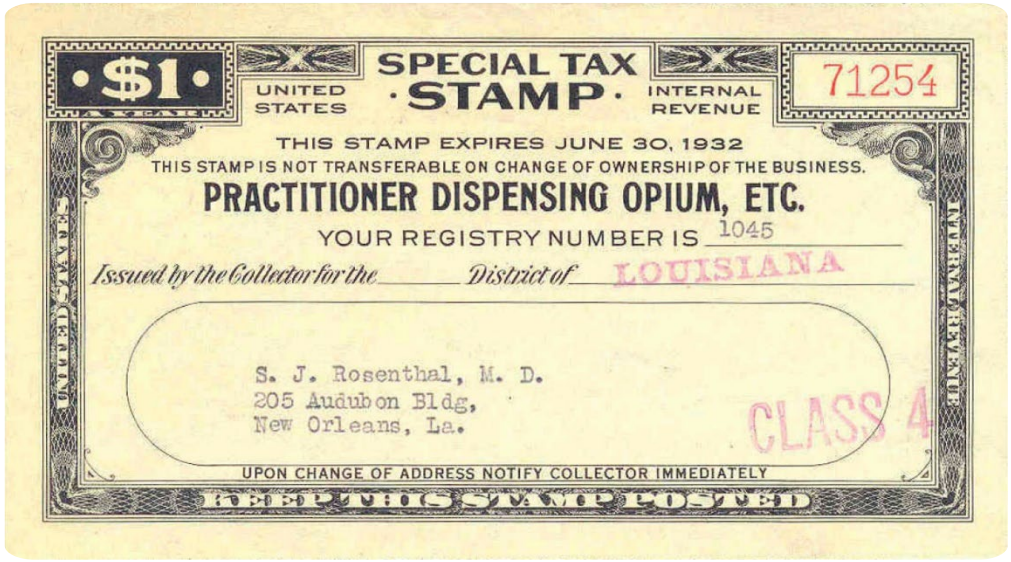
SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS' STATEMENT

ON CME HOURS ON CONTROLLED SUBSTANCES

South Carolina Code § 40-47-40(2)(a), regarding continuing education required for renewal, states that at least two (2) hours of the forty-hour requirement should be related to approved procedures of prescribing and monitoring controlled substances listed in Schedules II, III, and IV.

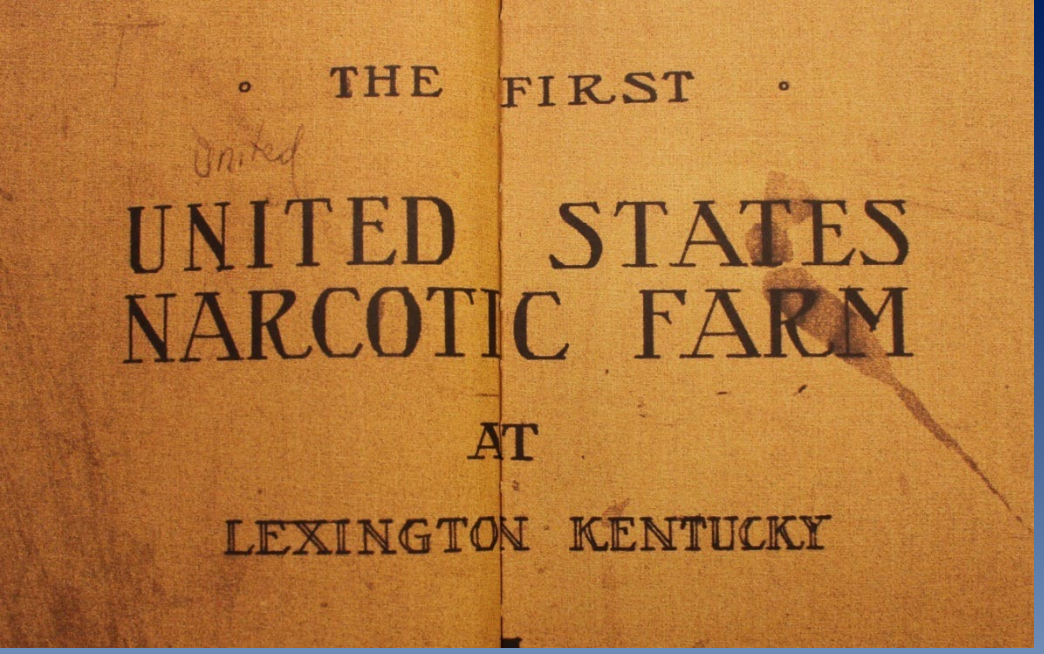
The 1906 Pure Food and Drug Act

- Required manufacturers to include on labels the amounts of alcohol, morphine, opium, cocaine, heroin, or marijuana extract in each product
- Marked the beginning of involvement by the government in drug manufacturing
- Did not prohibit distribution of dangerous preparations



Harrison Act of 1914

- Established Registration & Taxation on opiates and cocaine
- Administered by U.S. Treasury Dept.
- Law interpretation/Supreme Court decisions:
- Penalties for doctors– 3000 served jail time; 20,000 paid fines
- Arrests– drug users and doctors; and increased illegal drug trade
- Redefined an addict as a criminal not a patient
- Changed perception of society and professionals about addiction



Lexington Narcotic Farm:

- Opened 1935
- Capacity: 1000-1500
- Renamed U.S. Public Health Service Hospital
- 1000 acre farm/dairy/furniture & garment production
- Music/recreational activities
- Addiction Research Center

What was Relapse Rate after discharge? 94%

Controlled Substances Act of 1970

(Title II of Comprehensive Drug Abuse Prevention and Control Act of 1970)

- Legislation replaced all previous federal laws pertaining to drug control
- Established schedules for Controlled Substances
- Created the Drug Enforcement Agency (DEA)
- Created National Institute on Drug Abuse (NIDA)

Drug Enforcement Agency: Drug Scheduling

Schedule 1

no currently accepted medical use and a high potential for abuse

Examples:

- Heroin
- LSD
- Marijuana
- Ecstasy (MDMA)

Schedule 2

high potential for abuse, with use potentially leading to severe psychological or physical dependence

Examples:

- Hydrocodone (moved 2014)
- Oxycodone
- Hydromorphone
- morphine
- Fentanyl
- Amphetamine stimulants
- Methadone

Schedule 3

moderate to low potential for physical and psychological dependence

Examples:

- Codeine
- Ketamine
- Anabolic steroids
- Testosterone
- Buprenorphine

Schedule 4

low potential for abuse and low risk of dependence

Examples:

- Alprazolam
- Diazepam
- Lorazepam
- Zolpidem
- tramadol

Schedule 5

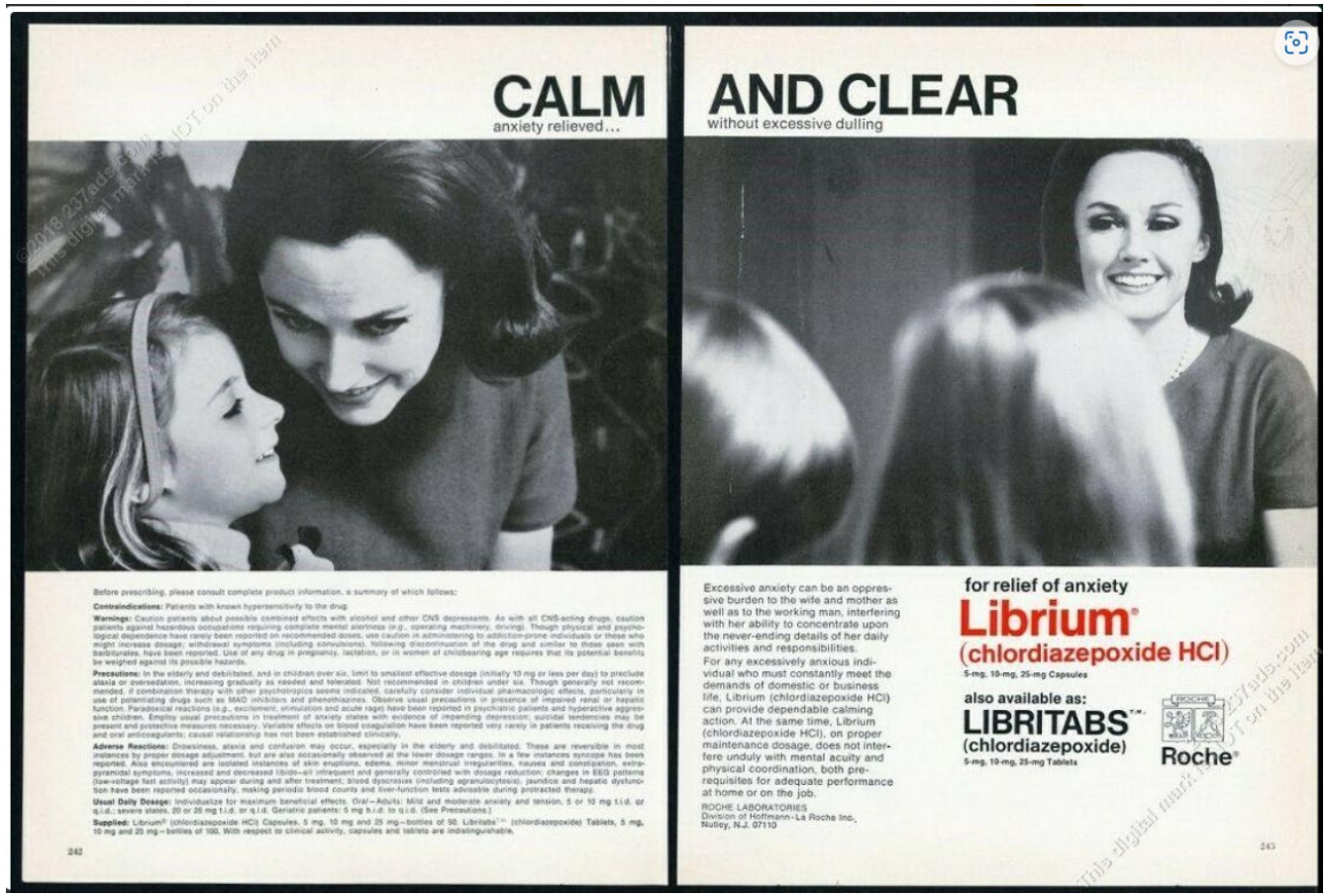
lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics

Examples:

- Diphenoxylate/atropine
- Pregabalin
- Cough meds with <200mg codeine

DEA Drug Scheduling: //www.dea.gov/drug-information/drug-scheduling. Accessed 12/17/2022.

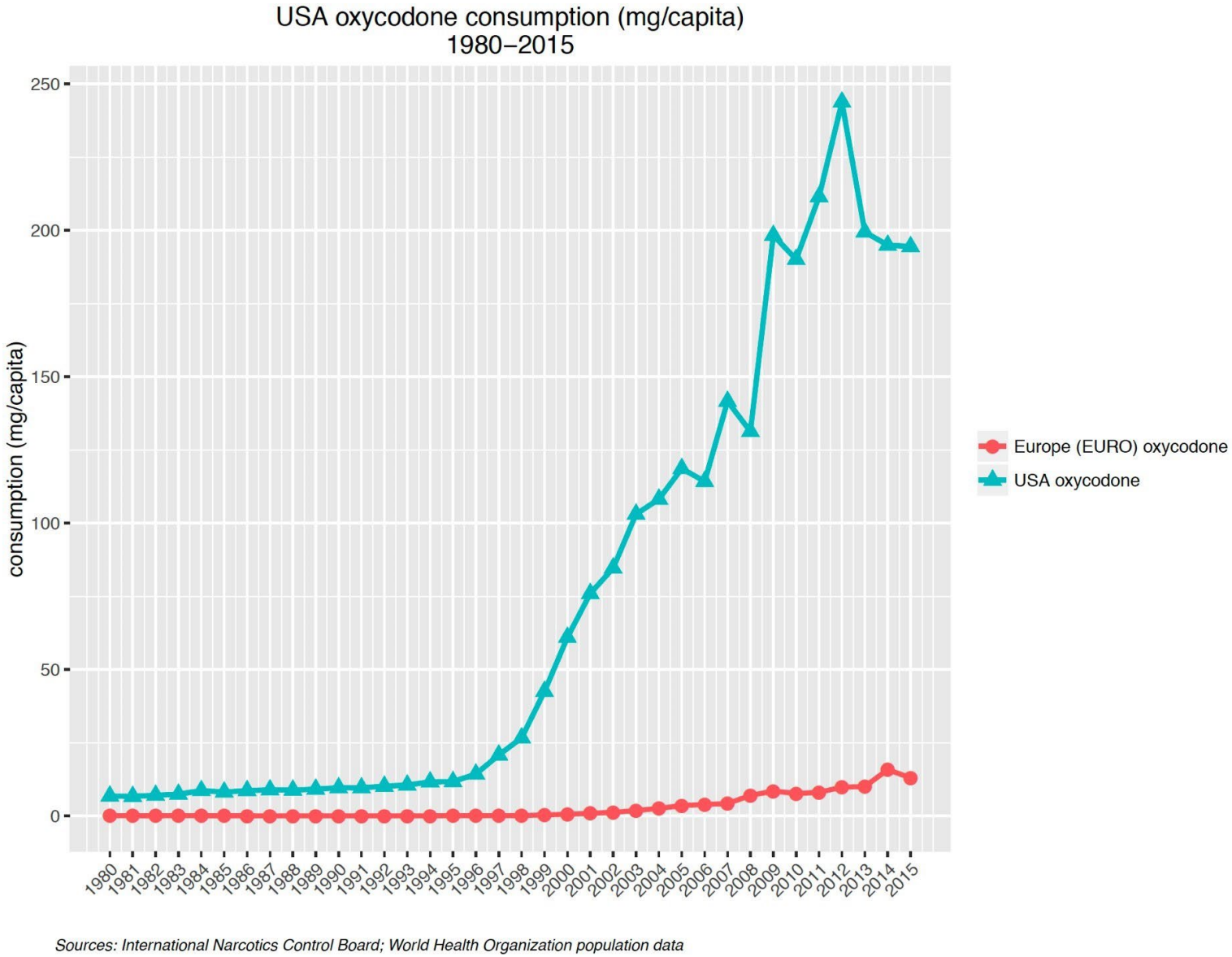
Are we influenced by Marketing?



Top 5 Controlled Substances Dispensed in 2023

1. dextroamphetamine sulf-saccharate/amphetamine sulf-asparate (Adderall, Adderall XR, Mydaysis)
2. hydrocodone bitrate/acetaminophen (Vicodin, Lortab)
3. tramadol HCl (Ultram)
4. alprazolam (Xanax)
5. zolpidem tartrate (Ambien)

South Carolina Prescription Monitoring Program: 2023 Annual Report. SC-DHEC, May 2024.



Sources: International Narcotics Control Board; World Health Organization population data

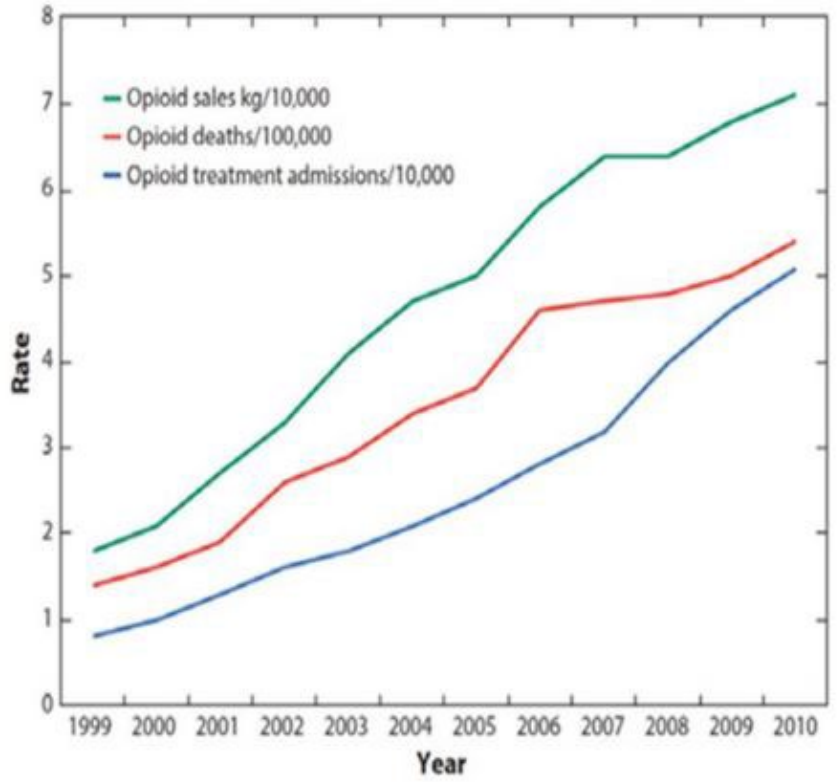


FIGURE 1
CDC chart 1999–2010, February 28, 2018, Congressional testimony "Combatting the Opioid Crisis," made before the Committee on Energy and Commerce, Subcommittee on Health U.S. House of Representatives (5): "The CDC has shown that a sharp increase in prescriptions for opioids resulted in a corresponding rise in addiction and overdose deaths. This is a CDC graph. The green line represents opioid prescribing, the red line represents opioid deaths, and the blue line represents opioid addiction. The green line went up as opioid prescriptions started to soar, it led to parallel increases in addiction and overdose deaths (6)".

Correlation of:

- Opioid Sales
- Opioid related Deaths
- Opioid Treatment Admissions

Aubry L, Carr BT. Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010-2019. Front Pain Res (Lausanne). 2022 Aug 4;3:884674.

The New York Times

TUESDAY, MAY 1, 2001

U.S. Asks Painkiller Maker To Help Curb Wide Abuse

By BARRY MEIER

Federal officials have urged the maker of a widely abused narcotic painkiller to limit how it distributes and markets the drug, which has played a role in more than 100 fatal overdoses in several states.

Federal officials have also been in talks about withdrawing or modifying a claim that the painkiller, OxyContin, may be less prone to abuse than similar narcotics.

The moves come as the officials at the Drug Enforcement Administration start what they describe as the agency's first effort to curb misuse of a specific prescription drug. Previously, the agency had sought to reduce abuse of classes of drugs, but officials of the drug enforcement agency said the abuse problem involving OxyContin was so grave that it required unique action.

Terry Woodworth, a top official at the agency, said it was concerned that the promotion and distribution of OxyContin by its manufacturer, Purdue Pharma L.P., to doctors like general practitioners might have led to its wide misuse. The government has said that no prescription drug in the last 20 years has been so widely abused so soon after its release as OxyContin.

Mr. Woodworth said the agency slowed release would deter illicit use of the drug because abusers prefer the quick euphoric rush that immediately released narcotics provide

But in just a few years, abuse of OxyContin has become rampant, officials say. The treatment's users quickly discovered that they could defeat the time-released design by crushing or dissolving the tablet. That gave them immediate access to the drug's active ingredient, a synthetic form of morphine called oxycodone, which could then be snorted or injected.

Abusers and others have also been able to obtain OxyContin by going around to doctors and feigning pain. Experts have said that many family doctors and general practitioners have little experience in spotting drug abusers or monitoring how their patients use narcotics.

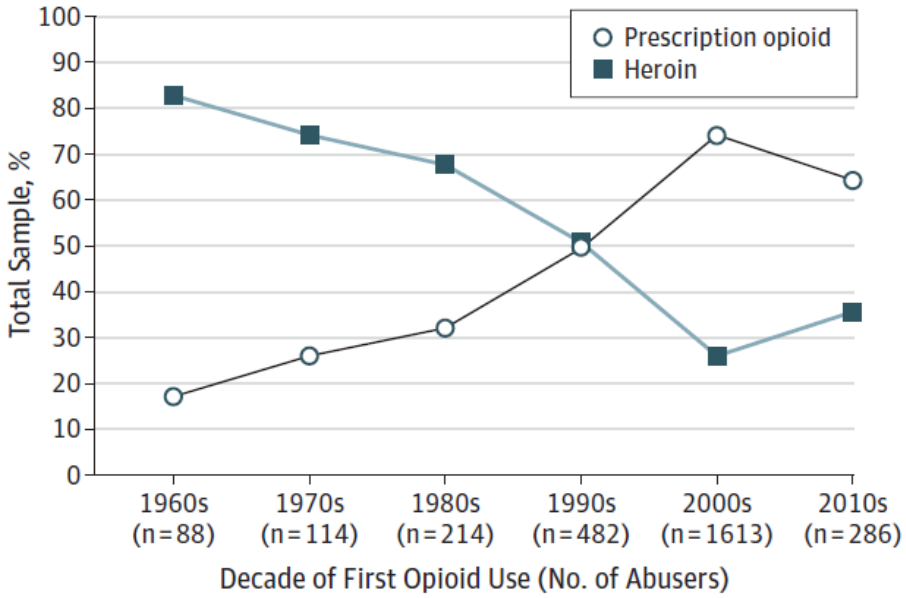
In recent years, OxyContin has been a factor in more than 120 drug overdose deaths, the authorities report. Communities in Maine, Kentucky and Virginia have been devastated by crime waves involving OxyContin addicts. The treatment has an extremely high street value of a dollar a milligram; a single 40-milligram pill would cost $40.

Purdue, a privately held company, has aggressively marketed the drug

Terry Woodworth, a top official at the agency, said it was concerned that the promotion and distribution of OxyContin by its manufacturer, Purdue Pharma L.P., to doctors like general practitioners might have led to its wide misuse. The government has said that no prescription drug in the last 20 years has been so widely abused so soon after its release as OxyContin.

A majority of people newly dependent on heroin report abusing prescription opioids first

Figure 1. Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of Abuse



Data are plotted as a function of the decade in which respondents initiated their opioid abuse.

Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. *JAMA Psychiatry.*2014;71(7):821-826.

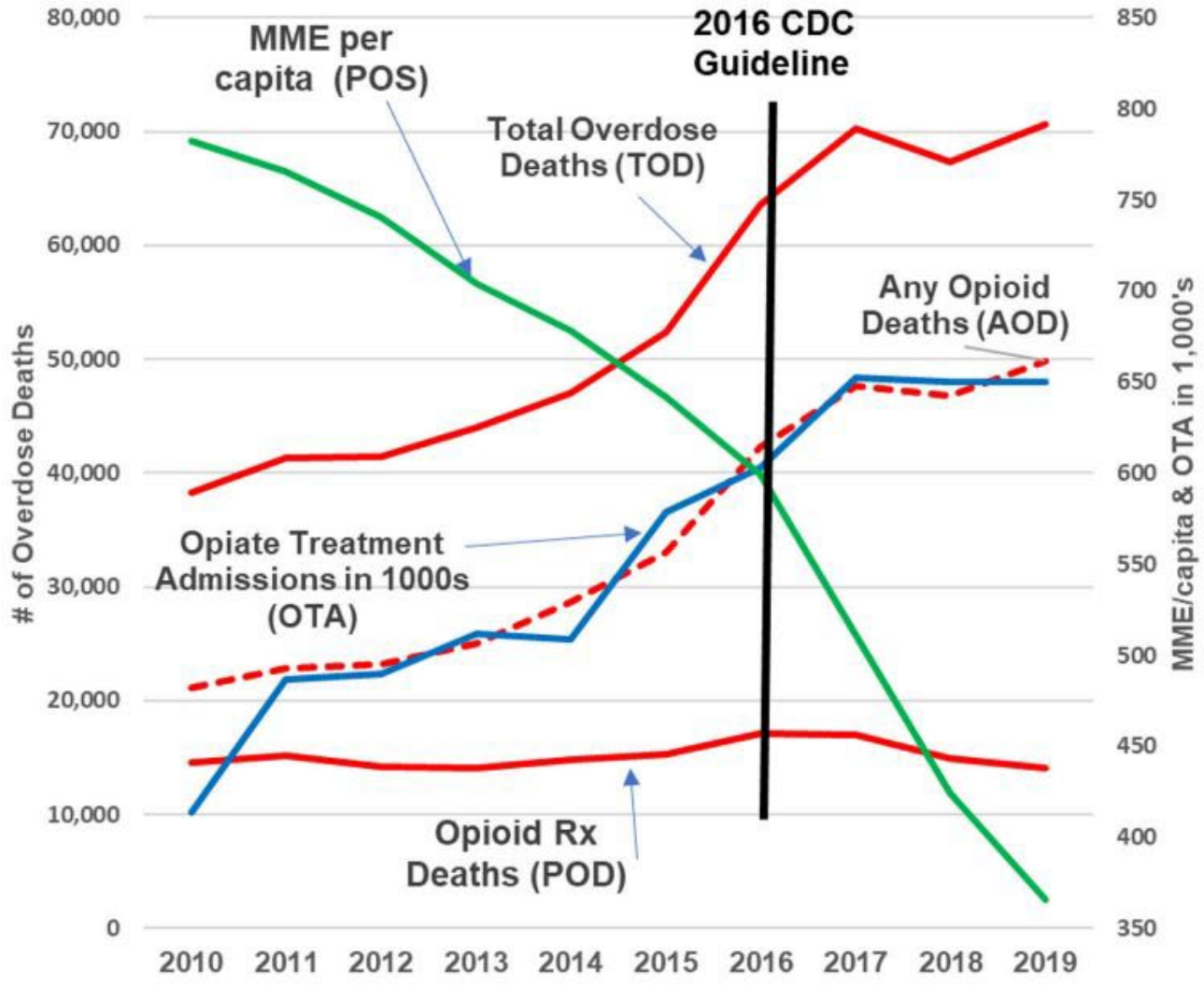
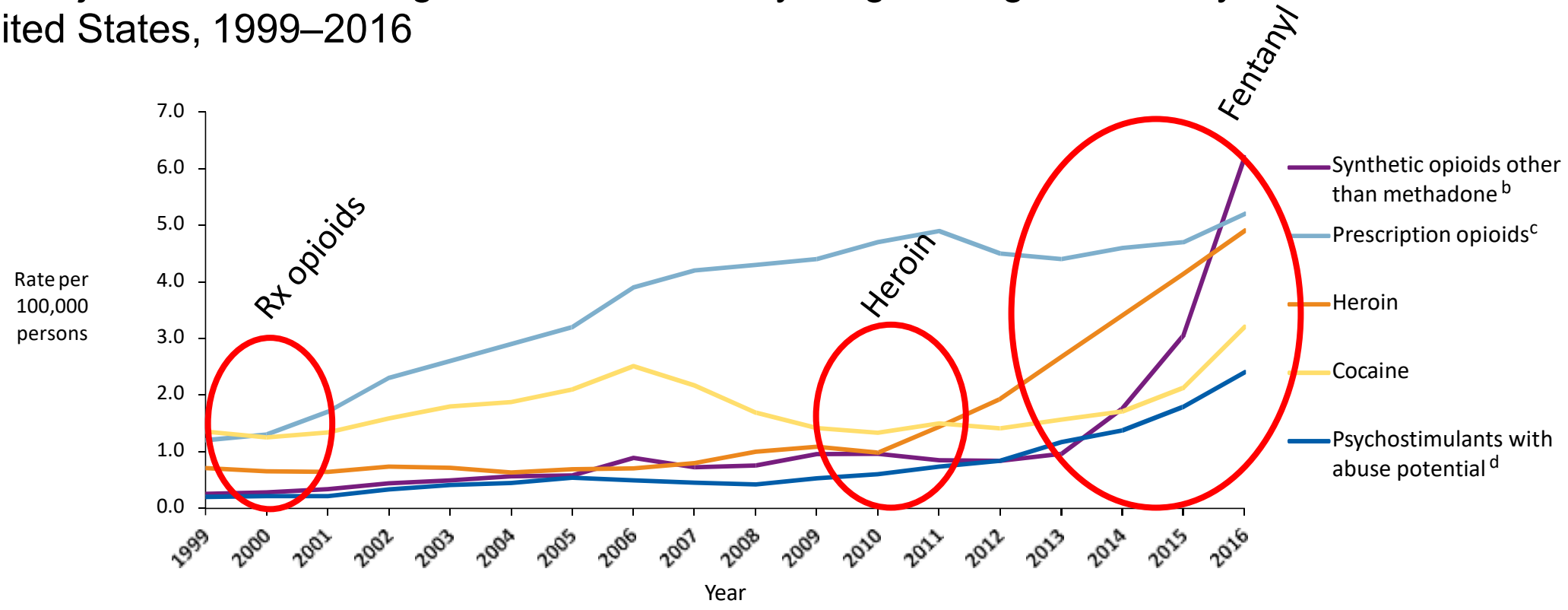


FIGURE 2
2010–2019 update. The green line represents opioid prescribing (POS, MME/capita); the red lines are opioid deaths (POD, AOD, and TOD); the blue line represents opioid addiction (OTA). Over the past decade, as the green line (prescription opioids) declined by +50%, prescription opioid deaths remained flat while opioid addiction, any opioid and total overdose deaths continued increasing "exponentially (9)".

Aubry L, Carr BT. Overdose, opioid treatment admissions and prescription opioid pain reliever relationships: United States, 2010-2019. Front Pain Res (Lausanne). 2022 Aug 4;3:884674.

Drug Overdose Mortality: 3 Waves of the Epidemic

Age-adjusted rates[a] of drug overdose deaths by drug or drug class and year — United States, 1999–2016



Source: National Vital Statistics System, Mortality File, CDC WONDER.

[a]Rate per 100,000 population age-adjusted to the 2000 U.S. standard population using the vintage year population of the data year. Because deaths might involve more than one drug, some deaths are included in more than one category. Specification on death certificates of drugs involved with deaths varies over time. In 2016, 15% of drug overdose deaths did not include information on the specific type of drug(s) involved Some of these deaths may have involved opioids or stimulants.

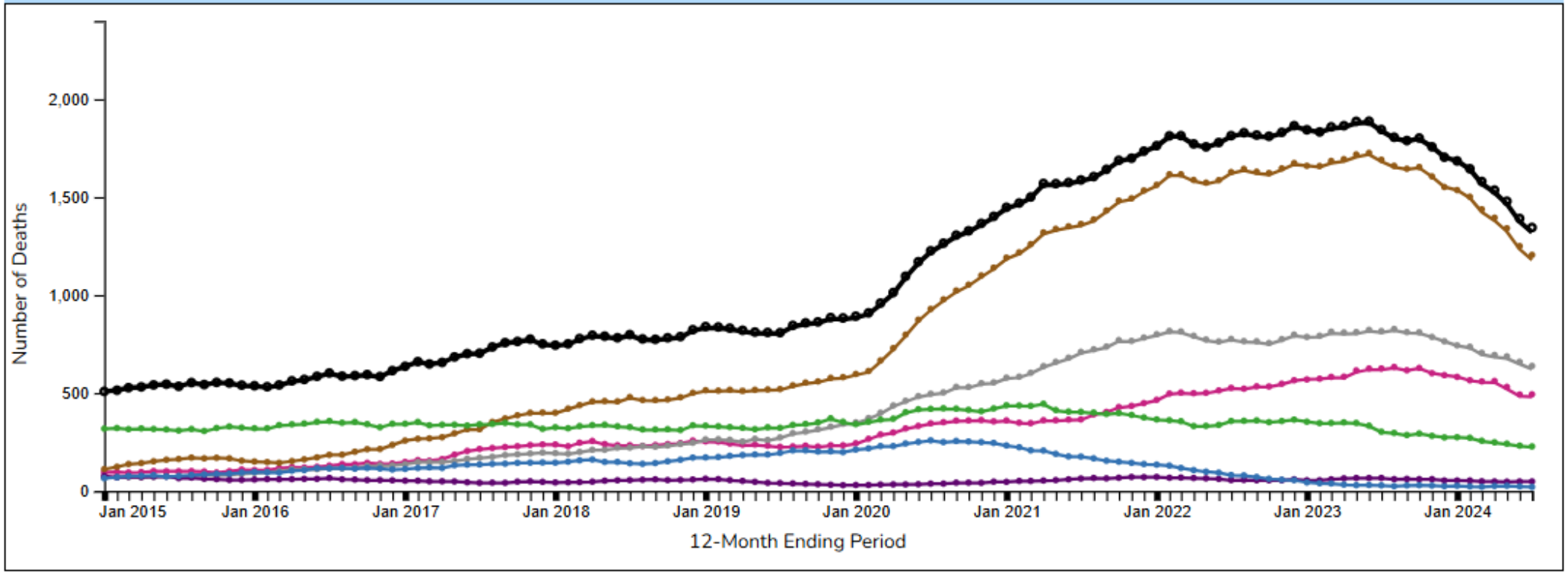
[b]Drug overdose deaths that involve synthetic opioids other than methadone (T40.4).

[c]Drug overdose deaths that involve natural and semi-synthetic opioids (T40.2) or methadone (T40.3).

[d]Drug overdose deaths that involve psychostimulants with abuse potential (T43.6).

South Carolina Drug-specific Overdose Data: thru July 2024

Figure 2. 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class: South Carolina



Legend for Drug or Drug Class

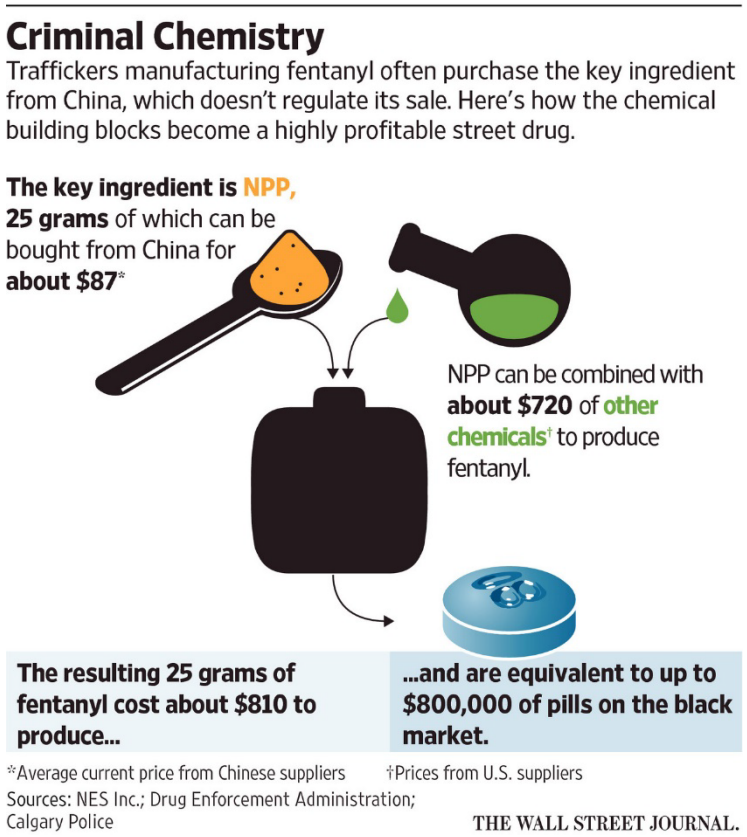
- Cocaine (T40.5)
- Heroin (T40.1)
- Methadone (T40.3)
- Natural & semi-synthetic opioids (T40.2)
- Psychostimulants with abuse potential (T43.6)
- Synthetic opioids, excl. methadone (T40.4)

---- Reported Value

O Predicted Value

https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Fentanyl



Left: Fentanyl powder.
(Source: Michigan State Police Situational Awareness Bulletin, 9/14/16.)
Right: Counterfeit 30mg Oxycodone pills containing fentanyl.
(Source: TN Bureau of Investigation.)

Pain in the US

- Pain is one of the most common reasons adults seek medical care
- Chronic pain affects 1 in 5 adults (2019)
- High-impact chronic pain affects 1 in 14 (having pain most days during last 3 months that limits life or work activities)
- Pain can impair physical functioning and mental health with reduced quality of life and increase risk of Substance Use Disorders and Suicidal risk
- Pain is complex and influenced by Biological, Psychological, and Social factors
- Successful treatment involves addressing all aspects

CDC Clinical Practice Guidelines 2022

Opioid Receptors

μ (mu) receptors

- μ 1: mediates analgesia (supraspinal),sedation, miosis, urinary retention, muscle rigidity, prolactin release
- μ 2: mediates respiratory depression

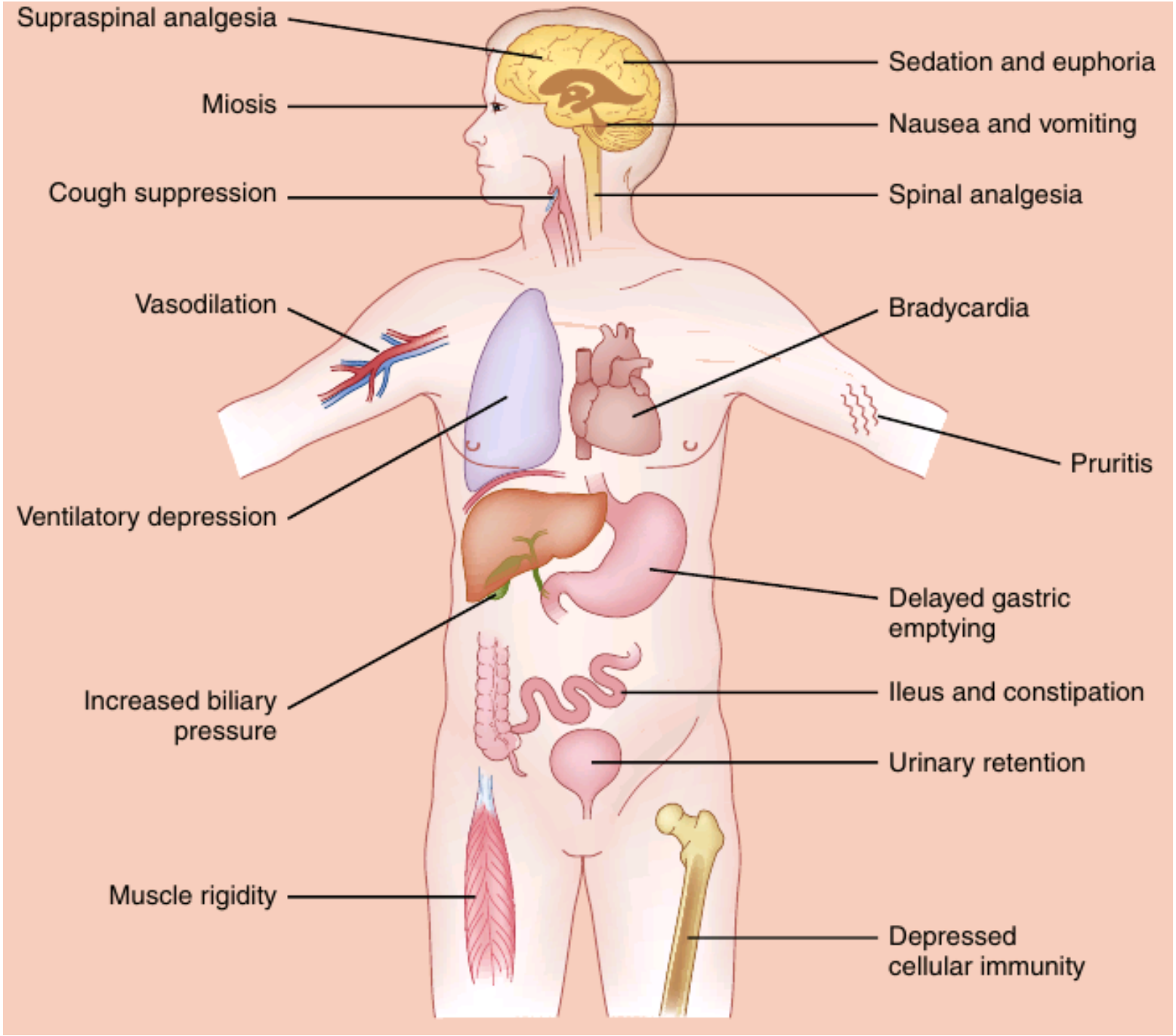
K (KAPPA) receptor

- K1: mediates spinal analgesia
- K3: mediates supraspinal analgesia

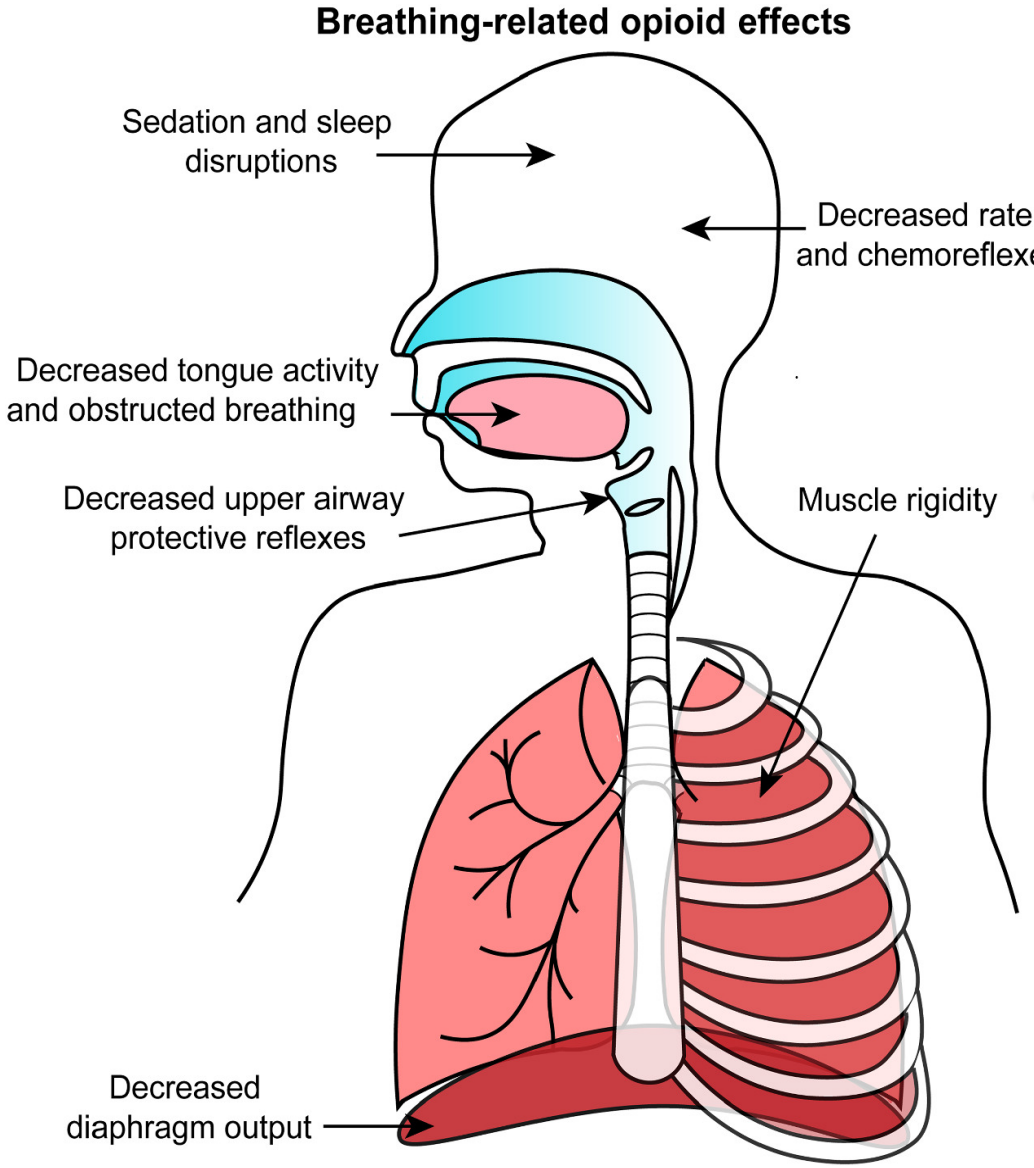
δ (delta) receptor: mediates analgesia at spinal level, respiratory depression and dependence.

The Gout by James Gillray. 1799. in The MET

Pharmacodynamic effects of opioids



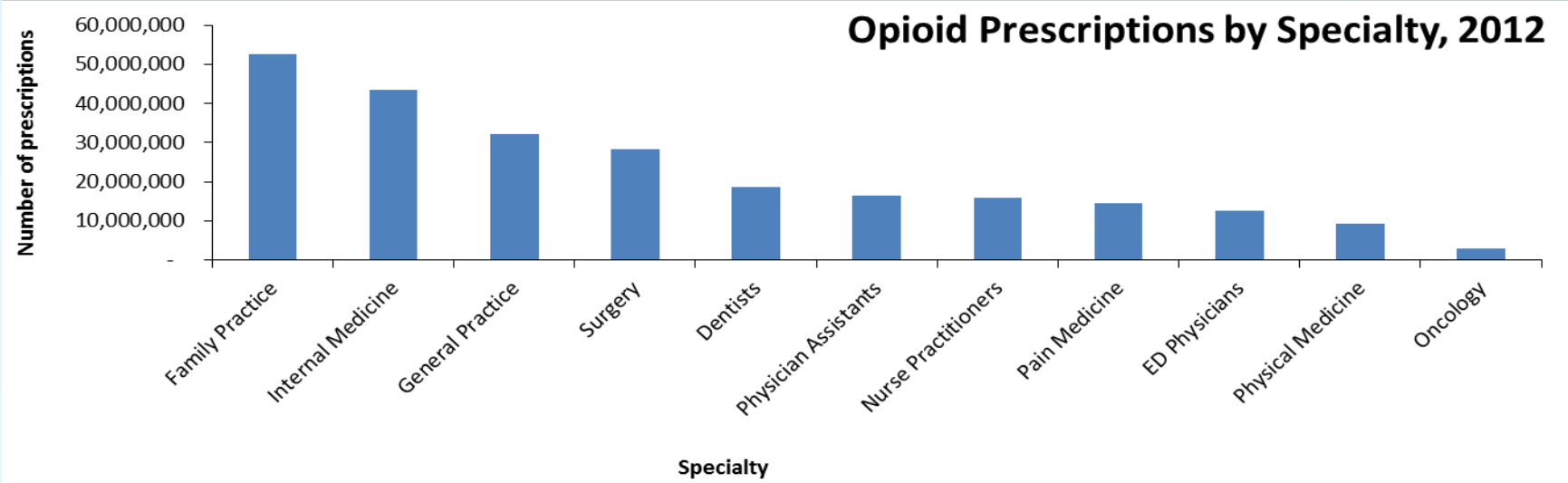
Understanding and countering opioid-induced respiratory depression



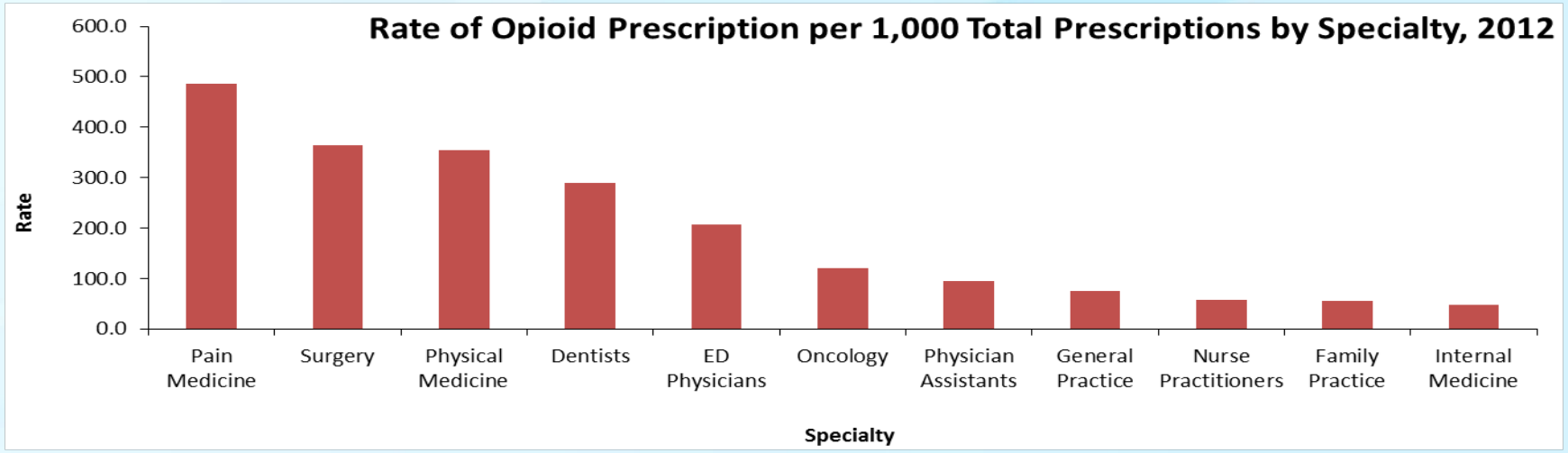
Wooden Chest Syndrome (WCS)

British J Pharmacology, Volume: 180, Issue: 7, Pages: 813-828, First published: 05 June 2021.

Primary care providers prescribe the most opioids



Pain specialists prescribe opioids most frequently



IMS Health, National Prescription Audit, United States, 2012

CDC Clinical Practice Guidelines - 2022

- Determining whether to Initiate Opioids for Pain
- Selecting Opioids and Dosages
- Deciding on Duration of Opioid Treatment and Follow-up plan
- Assessing Risk and Addressing Potential Harms of Opioid Use

CDC 2022 Clinical Practice Guidelines

https://www.cdc.gov/overdose-prevention/hcp/clinical-guidance/whats-different.html

Five Guiding Principles

1. Acute, subacute, and chronic pain needs to be assessed and treated independently of whether opioids are part of regimen.

2. Recommendations are voluntary and intended to support individualized, person-centered care. Flexibility is key.

3. Multimodal approach to pain: physical, behavioral, expected outcomes, and well-being

4. Avoid misapplying practice guideline beyond intended use or implementing policies that might lead to unintended and potentially harmful consequences

5. Attend to health inequities at all levels; culturally appropriate, accessible for those with disabilities, ensure access that is affordable, coordinated, effective nonpharmacologic and pharmacologic options

CDC Clinical Practice Guidelines 2022

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

A Notice by the Centers for Disease Control and Prevention on 12/20/2024

In 2022, CDC released the CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022, (2022 CDC Clinical Practice Guideline) which provided up to date evidence regarding pain management approaches and re-emphasizes the need for prescribers to be focused on patient-centered care to provide effective pain management. CDC is comprehensively evaluating the uptake, implementation, and outcomes of the 2022 CDC Clinical Practice Guideline on evidence-based care for pain management to understand its impact.

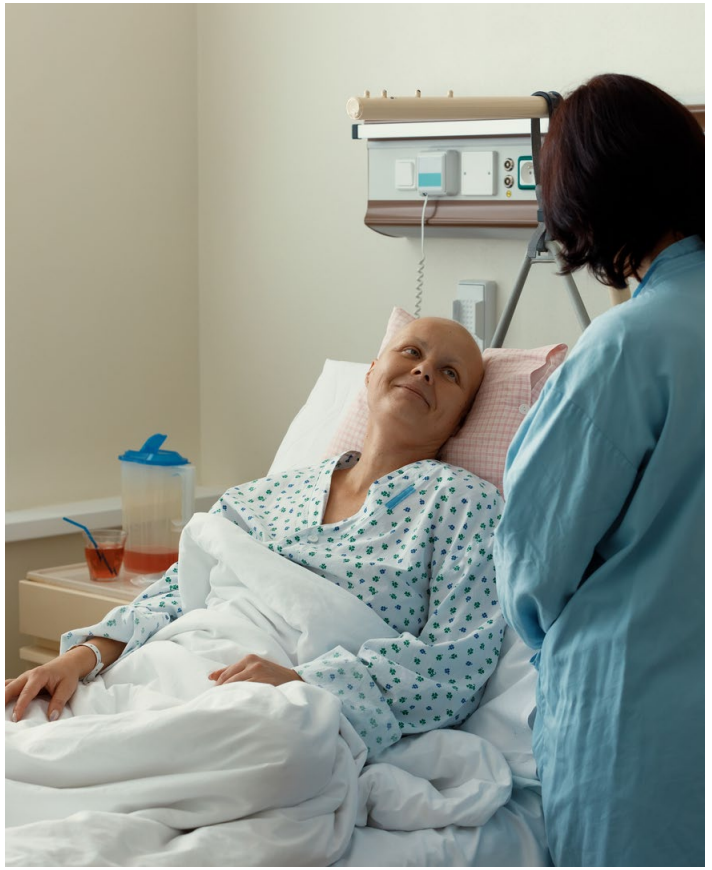
Pain Definitions

- Acute Pain: < 1 month
- Subacute Pain: 1-3 months
- Chronic Pain: > 3 months

CDC Clinical Practice Guidelines 2022

Exclusions

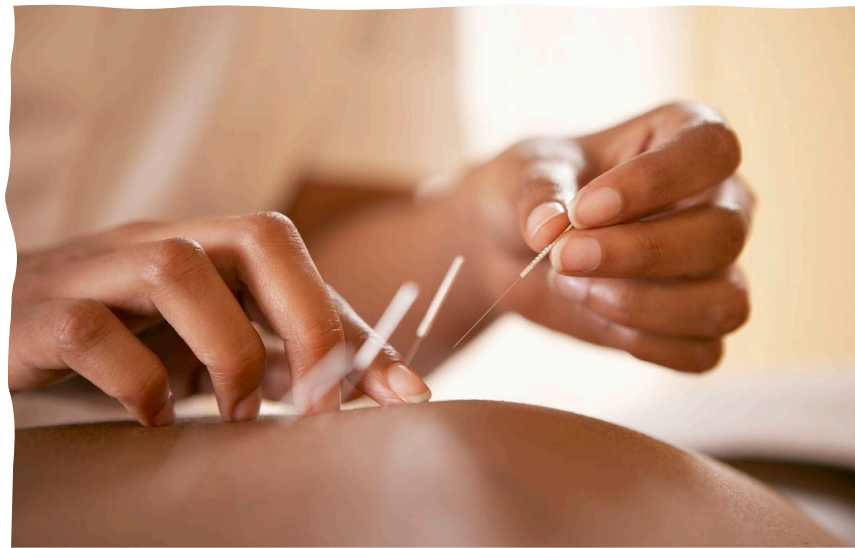
- Sickle Cell Disease
- Cancer-related pain
- Palliative Care
- End-of-life Care



CDC Clinical Practice Guidelines 2022

Determining whether to Initiate Opioids for Pain

- Recommendation #1 and #2:
- Nonopioid therapies are at least as effective as opioids for many common types of acute pain.
- maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient
- consider opioid therapy for acute, subacute, and chronic pain if benefits outweigh risks to the patient.
- Before prescribing opioid therapy for any level of pain, clinicians should discuss the realistic benefits and known risks of opioid therapy



Non Opioid Therapies

Nonpharmacologic Therapies

- Ice
- Heat
- Elevation
- Rest
- Immobilization and/or exercise
- Exercise (such as aerobic, aquatic, and/or resistance exercise)
- Exercise therapy (a prominent modality in physical therapy)
- Mind-body practices (e.g., yoga, tai chi, qigong)
- Weight loss
- Psychological therapy (e.g., cognitive behavioral therapy)
- Manual therapies
- Mindfulness-based stress reduction
- Acupuncture
- Massage
- Spinal manipulation

NonOpioid Pharmacologic therapies

- Topical or oral NSAIDs
- Topical lidocaine
- Acetaminophen
- Duloxetine
- TCAs
- Pregabalin
- Gabapentin (off label; is monitored as a controlled substance in several states)

Selecting Opioids and Dosages

Recommendation #3:

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

Recommendation #4:

- When opioids are initiated for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage.
- If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage
- carefully evaluate individual benefits and risks when considering increasing dosage
- avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients

Selecting Opioids and Dosages

- Recommendation #5:
- For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage.
- If benefits outweigh risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy.
- If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages
- if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids.
- Unless there are indications of a life-threatening issue such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages

Duration of Opioid Treatment and Follow-up Plan

Recommendation #6:

- When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids

Recommendation #7:

- Clinicians should evaluate benefits and risks with patients within 1–4 weeks of starting opioid therapy for subacute or chronic pain or of dosage escalation.
- Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients

South Carolina statute for Acute Pain: (approved/signed May 2018)

Section 44-53-360 of the 1976 Code is amended by adding an appropriately lettered subsection at the end to read:

(1) Initial opioid prescriptions for acute pain management or postoperative pain management must not exceed a seven-day supply, except when clinically indicated for cancer pain, chronic pain, hospice care, palliative care, major trauma, major surgery, treatment of sickle cell disease, treatment of neonatal abstinence syndrome, or medication-assisted treatment for substance use disorder. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new opioid prescription.

(2) This subsection does not apply to opioid prescriptions issued by a practitioner who orders an opioid prescription to be wholly administered in a hospital, nursing home, hospice facility, or residential care facility.

(3) A practitioner who acts in accordance with the limitation on prescriptions as set forth in this subsection is immune from any civil liability or disciplinary action from the practitioner's professional licensing board.

Assessing Risk and Addressing Potential Harms of Opioid Use

Recommendation #8:

- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss risk with patients
- Clinicians should work with patients to incorporate into the management plan strategies to mitigate risk, including offering naloxone

SC legislation about Opioid Antidote co-prescribing requirements:

SECTION 44-53-361. Prescriptions for opioid antidotes.

(A) A prescriber shall:

(1) offer a prescription or provide consistent with the existing standard of care and the FDA for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient if one or more of the following conditions are present:

(a) the prescription or offer consistent with the existing standard of care and the FDA dosage for the patient is fifty or more morphine milligram equivalents of an opioid medication per day;

(b) an opioid medication is prescribed or offered consistent with the existing standard of care and the FDA concurrently with a prescription for benzodiazepine; or

(c) the patient presents with an increased risk for overdose, including a patient with a history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant;

(2) consistent with the existing standard of care, provide education to patients receiving a prescription pursuant to item…

ASSESS OVERDOSE RISK

History of alcohol/ other substance use disorder

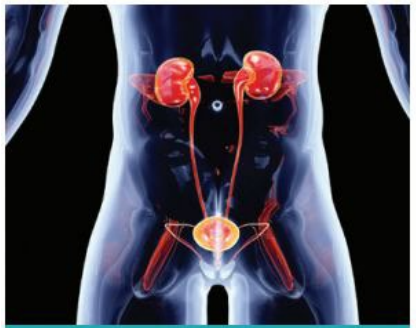
High daily doses of opioids

Switching from one opioid to another

Any opioid for pain + benzodiazepine or other sedative

Any opioid for pain + underlying mental health problem

Any opioid for pain + respiratory problems



Any opioid for pain + renal/liver disease or other conditions

Any active illicit use

History of opioid overdose or sedation

from PrescribeToPrevent.org

Opioid Risk Tool (ORT)

	Female	Male
Family history of substance abuse		
Alcohol	❑1	❑3
Illegal drugs	❑2	❑3
Prescription drugs	❑4	❑4
Personal history of substance abuse		
Alcohol	❑3	❑3
Illegal drugs	❑4	❑4
Prescription drugs	❑5	❑5
Age between 16-45 years	❑1	❑1
History of preadolescent sexual abuse	❑3	❑0
Psychological disease		
ADHD, OCD, bipolar, schizophrenia	❑2	❑2
Depression	❑1	❑1

Scoring

0-3: low risk
4-7: mod risk
>8: high risk

Webster LR, Webster RM. Pain Medicine, 2006

JustPlainKillers.com

South Carolina
DAODAS
Department of Alcohol and Other Drug Abuse Services

bitly

Table 1. The comparison of naloxone, nalmefene, and naltrexone.

Medication	Mechanism of Action	Pharmacokinetics/Dynamics	Uses	Routes of Administration
Naloxone	Antagonist of MOR	Half-life: 30–120 min Duration of Action: 1–4 h Metabolized by: Liver	Reversal of Opioid Overdose	Intranasal Subcutaneous Endotracheal Sublingual Intralungual Submental Intravenous Intramuscular
Nalmefene	Antagonists at MOR and DOR Partial agoist at KOR	Half-life: 8–11 h Duration of action: 1–4 h Metabolized by: Liver	Reversal of Opioid Overdose	Intravenous Intramuscular Subcutaneously
Naltrexone	Pure antagonist at the MOR, DOR, and KOR	Half life: 4 h for naltrexone and 13 h for active metabolite of 6 beta-naltrexol Duration of action: Metabolized by: Liver	Can reduce and suppress opioid and alcohol cravings Not used in opioid overdose	Oral Intramuscular

Edinoff AN, Nix CA, Reed TD, Bozner EM, Alvarez MR, Fuller MC, Anwar F, Cornett EM, Kaye AM, Kaye AD. Pharmacologic and Clinical Considerations of Nalmefene, a Long Duration Opioid Antagonist, in Opioid Overdose. Psychiatry International. 2021; 2(4):365-378.

Overdoses and non-opioid components: Effects not reversed by opioid antagonist

- Xylazine (alpha-2 agonist)
- Gabapentin
- Benzodiazepines
- Stimulants: cocaine, methamphetamines
- Synthetic cannabinoids

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Viewpoint

Increasingly powerful opioid antagonists are not necessary

Lucas G. Hill*, Claire M. Zagorski, Lindsey J. Loera

College of Pharmacy, The University of Texas at Austin, 2409 University Avenue, A1910, PHR 2.222G, Austin, TX 78712, United States

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Commentary

Stronger, longer, better opioid antagonists? Nalmefene is NOT a naloxone replacement

Alexander F. Infante[a,*], Abigail T. Elmes[a], Renee Petzel Gimbar[a], Sarah E. Messmer[b], Christine Neeb[c], Jennie B. Jarrett[a]

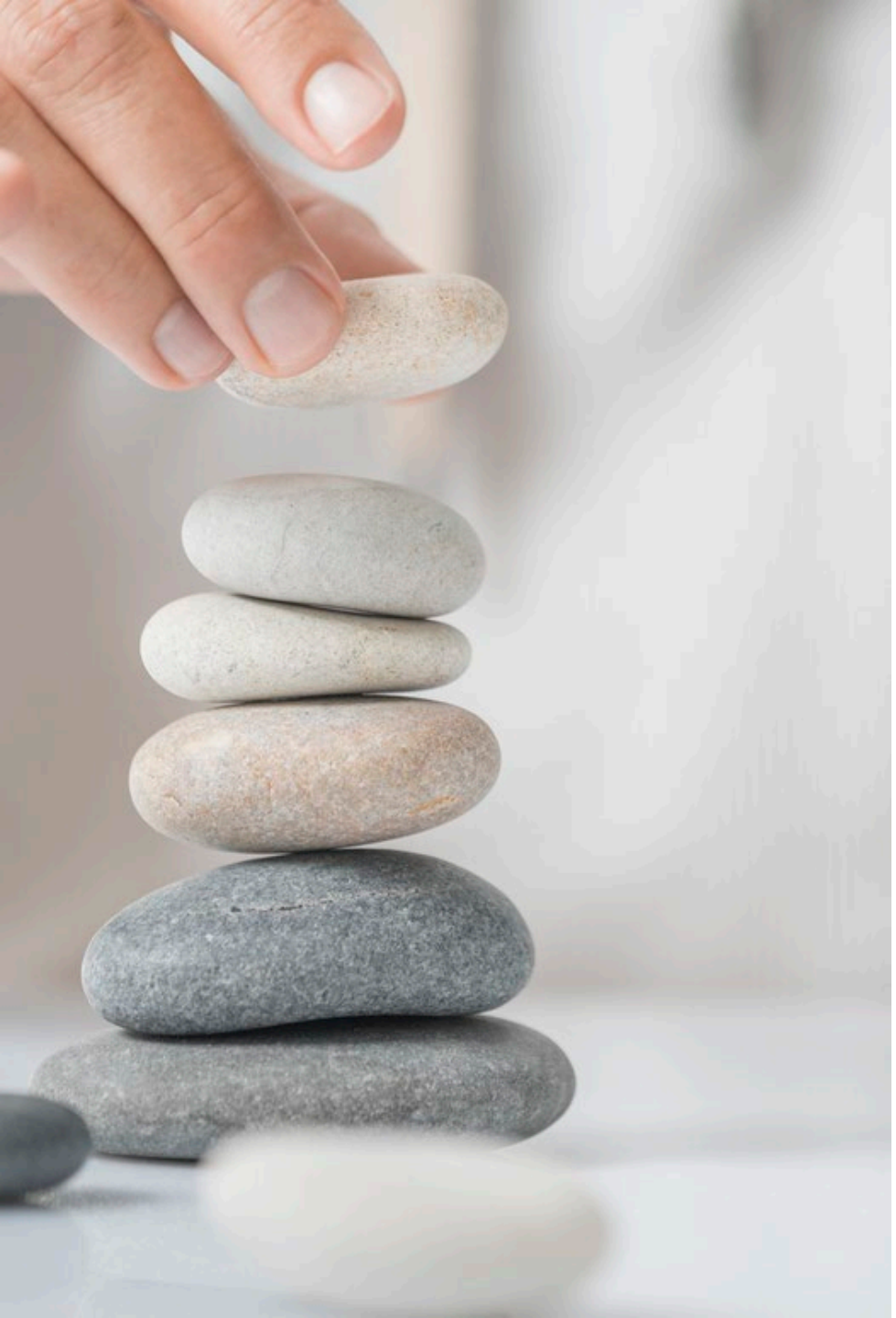
Naloxone is the Preferred treatment to reverse opioid overdose

ACMT | American College of Medical Toxicology

AACT American Academy of Clinical Toxicology

ACMT & AACT Joint Position Statement: Nalmefene Should Not Replace Naloxone as the Primary Opioid Antidote at This Time

September 28, 2023



Assessing Risk and Addressing Potential Harms of Opioid Use

Recommendation #9:

- When prescribing initial opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for chronic pain, clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or combinations that put the patient at high risk for overdose

dhec
S.C. Department of Health and Environmental Control

2023 Annual Report

South Carolina Prescription Monitoring Program

SC Chronology of Regulations/Laws and Controlled Substances:

February 2008: SCRIPTS PDMP launched

May 2017: Mandated prescriber use of PMP; prescribers must check the PMP prior to issuing any CII prescriptions greater than a 5 day supply. (S.C. Code Ann. § 44 53-1645)

Assessing Risk and Addressing Potential Harms of Opioid Use

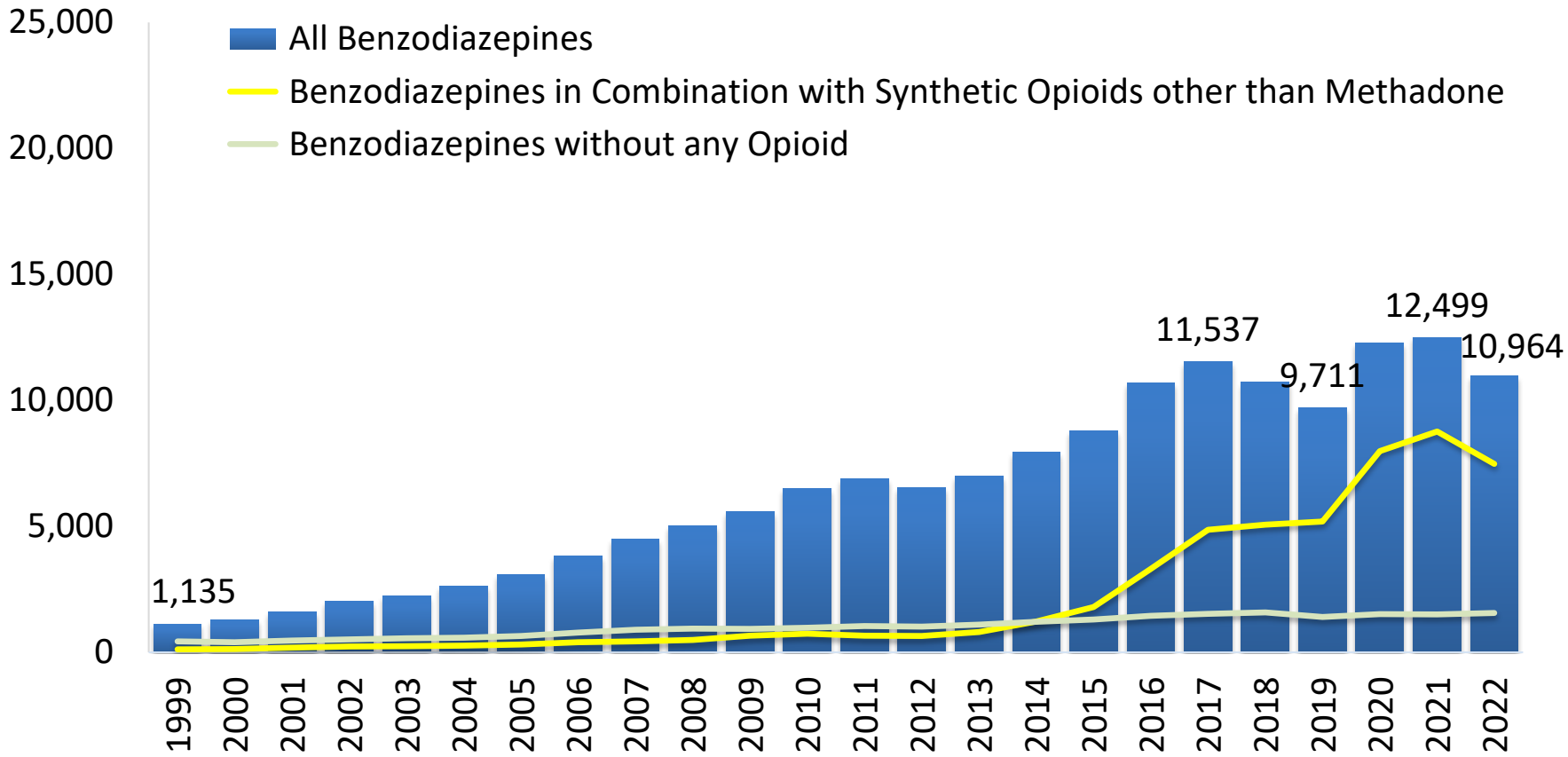
Recommendation #10:

- When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances

Recommendation #11:

- Clinicians should use particular caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants

Figure 9. National Drug Overdose Deaths Involving Benzodiazepines*, by Opioid Involvement, Number Among All Ages, 1999-2022



*Among deaths with drug overdose as the underlying cause, the benzodiazepine category was determined by the T42.4 ICD-10 multiple cause-of-death code. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2022 on CDC WONDER Online Database, released 4/2024.

Assessing Risk and Addressing Potential Harms of Opioid Use

Recommendation #12:

- Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder. Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death

ASAM American Society of Addiction Medicine

The Definition (latest rendition):

Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.

Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases.

DSM-V Criteria for Substance Use Disorder

- Impaired Control
- Social Problems
- Tolerance and Withdrawal
- Risky Use

11 Criteria under the above Categories

- Mild: 2-3 criteria met
- Moderate: 4-5
- Severe: 6 or greater

Withdrawal Symptom Management

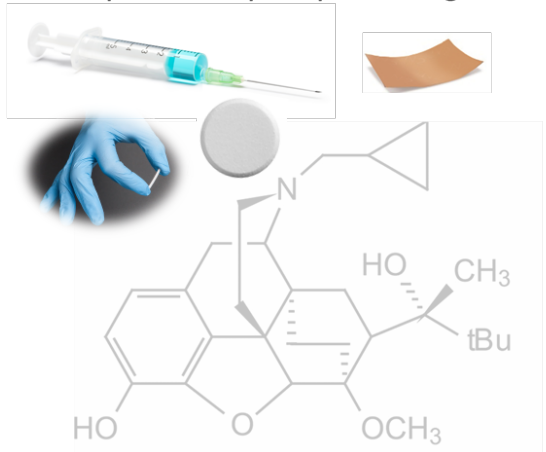
Noradrenergic/Anxiety/Irritability	Gastrointestinal	Pain
• Clonidine • Lofexidine • Trazodone • Gabapentin (off label) • Antihistamine (hydroxyzine, diphenhydramine)	• Dicyclomine • Loperamide • Ondansetron • Metoclopramide	• NSAIDs • Acetaminophen • Gabapentin (off label)

Treatment Improvement Protocol (TIP) 63: **Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families.**

Medications for Opioid Use Disorder: FDA-Approved Medications

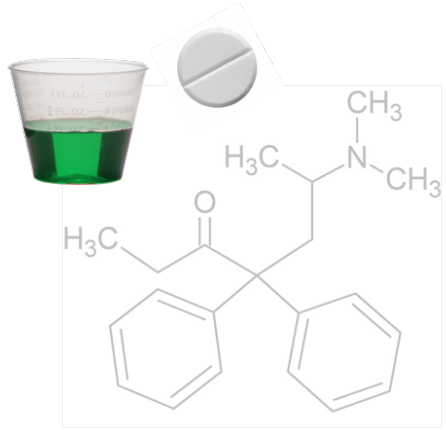
Buprenorphine

mu-opioid receptor partial agonist



Methadone

mu-opioid receptor full agonist



Naltrexone

mu-opioid receptor antagonist

Evidence Based Practice: Medications for Opioid Use Disorder

Methadone

- Full opioid agonist
- Available since 1970s
- In US only available in certified OTP programs with strict regulations around administration
- Strong evidence base- increases retention in treatment and reduces mortality

Buprenorphine (Suboxone®, Bunavail™, Zubsolv®, Subutex, Sublocade injection)

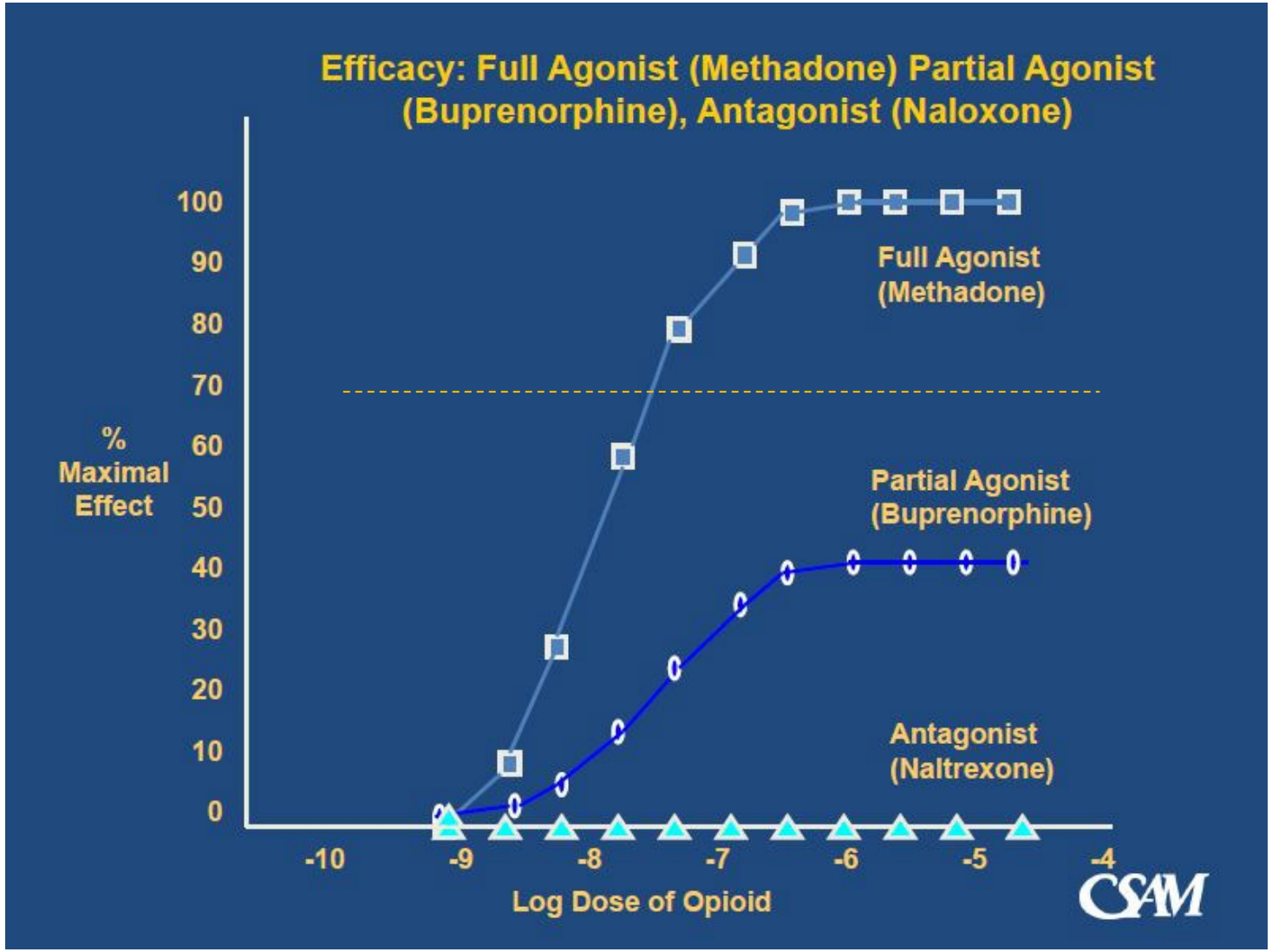
- Partial opioid agonist
- FDA approved for OUD since 2002 and able to be prescribed in outpatient settings with DATA waiver (X-Waiver removed late December 2022)
- Strong evidence- increases retention in treatment and reduces mortality

Injectable Extended Release (ER) Naltrexone (Vivitrol®)

- Opioid antagonist
- FDA approved in 2010
- Evidence not as robust for OUD- increases retention in treatment; difficulty in initiation

from *Treating Addiction in the Chronic Care Model: The Value of Hub and Spoke.*
Elizabeth Salisbury-Afshar, MD

Graph of dose-response curve & ceiling effect



Example of Apneic level

Ceiling Effect of Bup Below Apneic level

Buprenorphine Pharmacology

- Partial agonist at mu opioid receptor
- Long half-life: 24 - 42 hours
- High affinity for mu receptor
- Can displace full opiate agonist such as oxycodone, heroin, methadone, fentanyl
- Ceiling Effect: avoids apneic respiratory depression

Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies

Luis Sordo,[1,2,3] Gregorio Barrio,[4] Maria J Bravo,[1,2] B Iciar Indave,[1,2] Louisa Degenhardt,[5,6] Lucas Wiessing,[7] Marica Ferri,[7] Roberto Pastor-Barriuso[1,2]

- 19 cohorts: 122,885 Methadone patients and 15,831 Buprenorphine patients
- Objective: compare risk of All Cause and OD mortality in patients with OUD on MAT in and out of treatment.
- MAT: included Methadone and Buprenorphine
- Conclusion: (rates per 1000 person years in-treatment vs. out-of-treatment)
  1. Methadone- All Cause 11.3 vs 36.1; OD 2.6 vs 12.7
  2. Buprenorphine- All Cause 4.3 vs. 9.5; OD 1.4 vs. 4.6
  3. Retention in methadone and buprenorphine treatment is associated with substantial reductions in the risk of All Cause and Overdose mortality.

BMJ 2017;357:j1550 | doi: 10.1136/bmj.j1550

Annals of Internal Medicine ORIGINAL RESEARCH

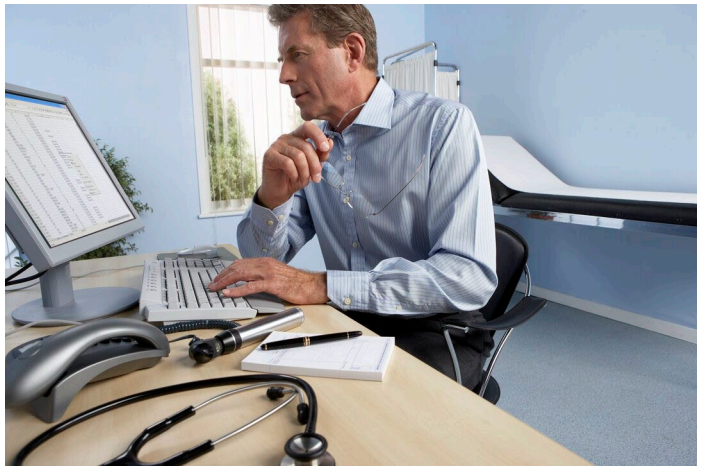
Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality

A Cohort Study

Marc R. Larochelle, MD, MPH; Dana Bernson, MPH; Thomas Land, PhD; Thomas J. Stopka, PhD, MHS; Na Wang, MA; Ziming Xuan, ScD, SM; Sarah M. Bagley, MD, MSc; Jane M. Liebschutz, MD, MPH; and Alexander Y. Walley, MD, MSc

- 17,568 adults who survived Opioid overdose 2012-2014
- Objective: to identify use of medication treatment for OUD after overdose and its effect on mortality in the 12 months post-OD
- MAT: included methadone, buprenorphine, and naltrexone
- Conclusion:
  1. Methadone- reduced all-cause mortality by 53% and opioid-related mortality by 59%
  2. Buprenorphine- reduced all-cause mortality by 37% and opioid-related mortality by 38%
  3. Naltrexone- no statistical correlation (low number of patients)
  4. Only 1/3 of patients received any MAT in the year post-OD

Ann Intern Med. 10.7326/M17-3107. June 19, 2018



Importance of documentation

Federal controlled substance laws are designed to function in tandem with state-controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice.

DEA Practitioner's Manual, 2023

Get more information and find resources for free training, mentoring, and other details so you can start diagnosing opioid use disorder and prescribing medications used to treat this disorder today.

www.fda.gov/prescribewithconfidence

MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES[4]

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Questions?

The Head Ache. By George Cruickshank. 1835. in The MET