Adventures
In Pain Management!

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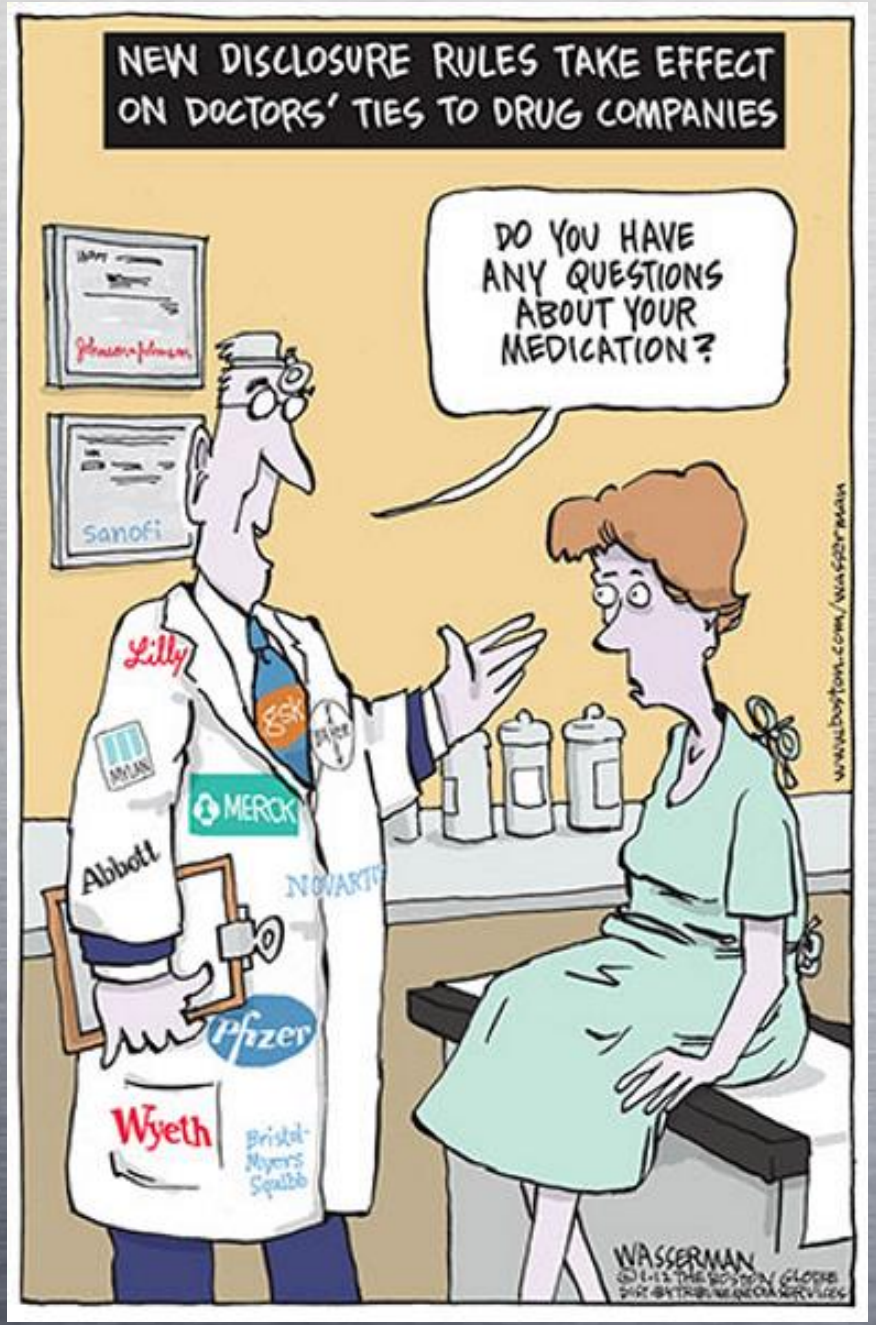
Neurology and Anesthesiology

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Knowledge that will change your world



Disclosures

Dr. Bailey has no relevant financial conflicts of interest or disclosures.

Objectives

- **Review current issues in pain management**
- **Consider how regulations impact how we practice**
- **Consider current pain management guidelines and how well are they achieving the goal of reducing overdose deaths**
- **Review TN specific regulations on pain management issues**
- **Ponder future directions and how we need to adapt**

Pain Epidemiology

Prevalence 2016

- In 2016, an estimated 20.4% of U.S. adults (50.0 million) had chronic pain and 8.0% of U.S. adults (19.6 million) had high-impact chronic pain with higher prevalence associated with advancing age.
- Age-adjusted prevalence of both chronic pain and high-impact chronic pain were significantly higher among women, adults who had worked previously but were not currently employed, adults living in or near poverty, and rural residents.
- In addition, the age-adjusted prevalence of chronic pain and high-impact chronic pain were significantly lower among adults with at least a bachelor's degree compared with all other education levels.

Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006.

Costs of Chronic Pain

The total annual cost of health care due to chronic pain ranges from $560 billion to $635 billion which combines the medical costs of pain care and the economic costs related to disability days and lost wages and productivity.

Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research. The National Academies Press, 2011.

COST OF CHRONIC PAIN CARE AT $32,000 PER PATIENT ANNUALLY

A study published online last month in *Pain Practice* offers a fresh assessment of the burden to the healthcare system imposed by chronic pain conditions. Researchers from Pfizer Inc. examined medical records and claims from 12,165 patients at the Henry Ford Health Care System to assess the overall cost and demand for resources triggered by 24 different chronic pain conditions during calendar year 2010. The summary conclusion of the study: treating chronic pain costs some $32,000 per patient per year.

Except for pharmacy visits, the most used resource were outpatient visits, at a mean 18.8 visits per patient. Of these 59% represented specialty consultations. Chronic pain complaints resulted in a mean of 5.2 discrete imaging tests per patient. Almost 39% of patients were prescribed opioid medication for their condition. Musculoskeletal conditions were associated with the highest overall costs. The study team concluded, "This type of research supports integrated delivery systems as a source for assessing opportunities to improve patient outcomes and lower the costs for chronic pain patients."

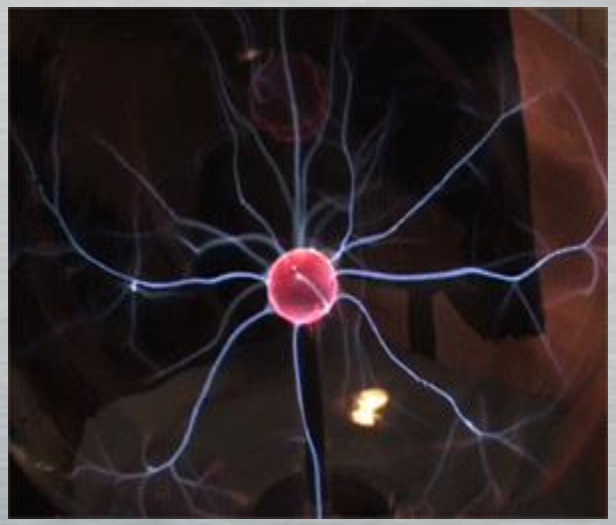
Access the large painweek.org library of chronic pain related articles, **here**.

A news story, with link to the journal abstract, may be read **here**.

Posted on November 6, 2015

Pain

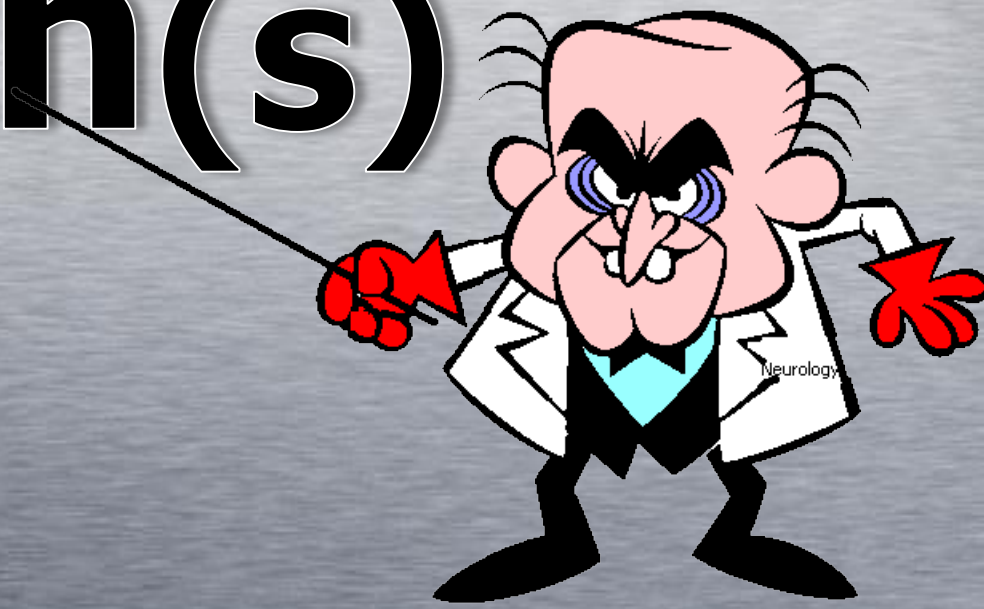
- **#1 reason people seek medical attention**
- **Is an Experience**
- **Multifactorial**
  - Nociceptive / physical
  - Psychological / mood



Definitions

- Chronic pain – lasting over one month
- Acute pain – lasting less than a week
- Morphine Equivalent Dosage (MEQ) – the mg of drug your patient takes / day converted to equianalgesic morphine dosage
- Opioid Risk – how likely your patient is to use opioids in a non-prescribed manner or for a non-medical purpose.

The Harsh Truth(s)



It's a bad time to be a Chronic Pain Patient

- Many physicians don't want to (or are afraid to) write pain medications.
- It's very hard to see a pain specialist.
- Pharmacies often don't want to carry opioids – especially the higher dosages
- You could be robbed for your pain meds
- Less pain medications available in 2017
- Treatment options are often not covered by insurance

It's a bad time to be a Physician with chronic pain patients

- There are many guidelines, recommendations, and laws
- Proper documentation and PDMP use is time-consuming
- You don't want to be seen as the 'candyman' in your community
- You see in the news almost daily about a physician being jailed or fined for improper prescribing
- Naloxone, abuse-deterrent opioids, and many non-opioid choices are often not covered by insurance (while most opioids are)

DEA mandates reduction in opioid manufacturing for 2018

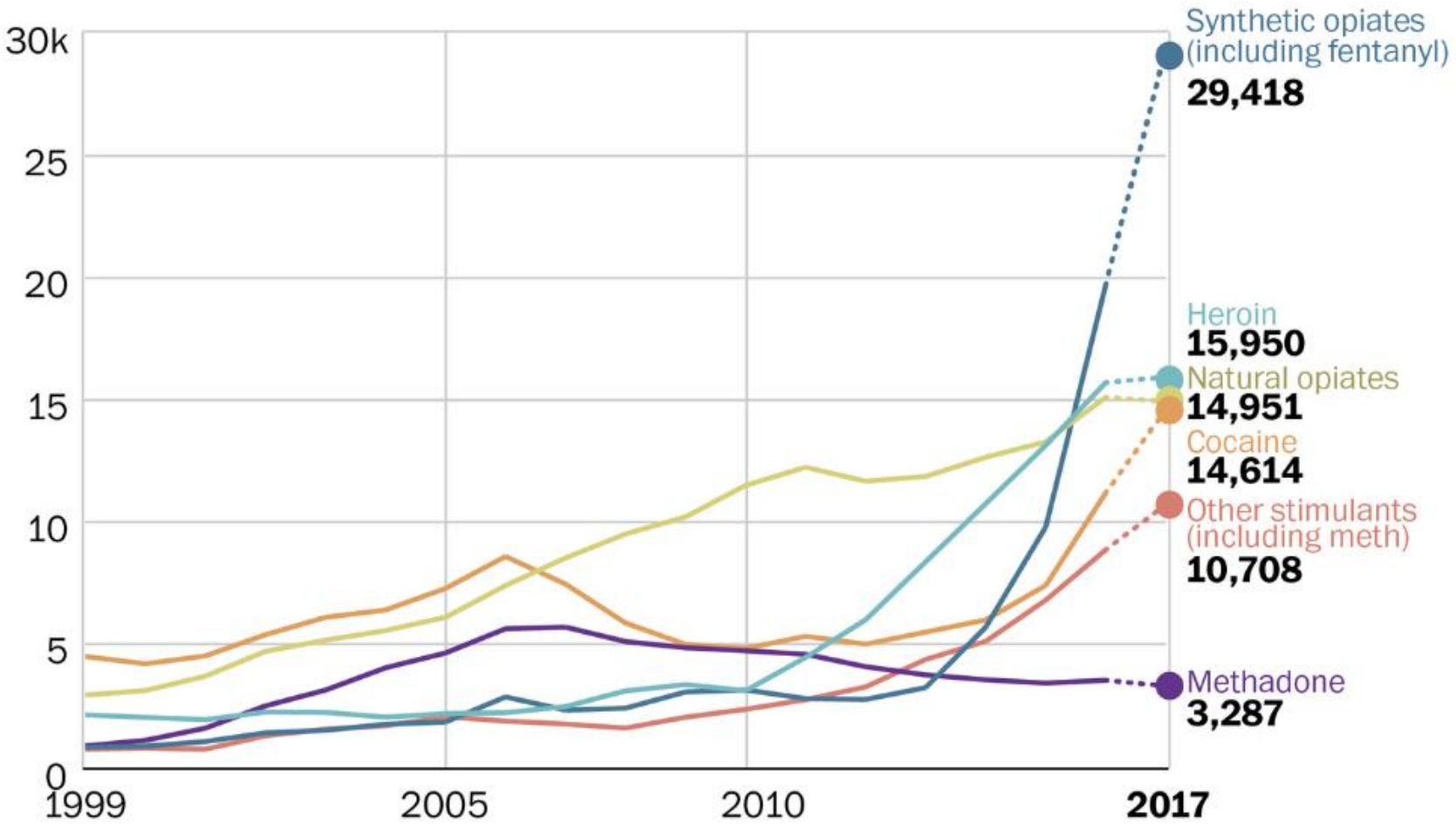
- DEA's finalized annual aggregate production quotas (APQs) for 2018 mandate a 20% reduction in the amount of opiate and opioid medication—including oxycodone, hydrocodone, oxymorphone, hydromorphone, morphine, codeine, meperidine, and fentanyl—that may be manufactured in 2018. Quotas are aimed at preventing a diversion while simultaneously satisfying annual needs.
- APQs establish the total amount of opioids and other controlled substances necessary to meet the estimated medical, scientific, research, industrial, and export needs for 2018 and to maintain adequate reserve stocks. DEA says 2018's cuts are a response to reduced demand.

More Harsh Truths

- We have an opioid overdose epidemic in the USA with a 33% overall increase in the last 5 years (per CDC)
- Deaths from synthetic opioids like illicit fentanyl are up 73% while oxycodone and hydrocodone are up 4%.
- Heroin related deaths are up 50%
- US citizens are about 5% of the worlds population, yet use 80% of the global supply of opioids
- Our patients want a pill for everything and seem minimally willing to participate in their own health care – other than take pills

Synthetic opiate deaths continue to surge

Annual overdose deaths involving selected drugs



Note: 2017 figures are provisional. Many overdose deaths involve multiple drugs.

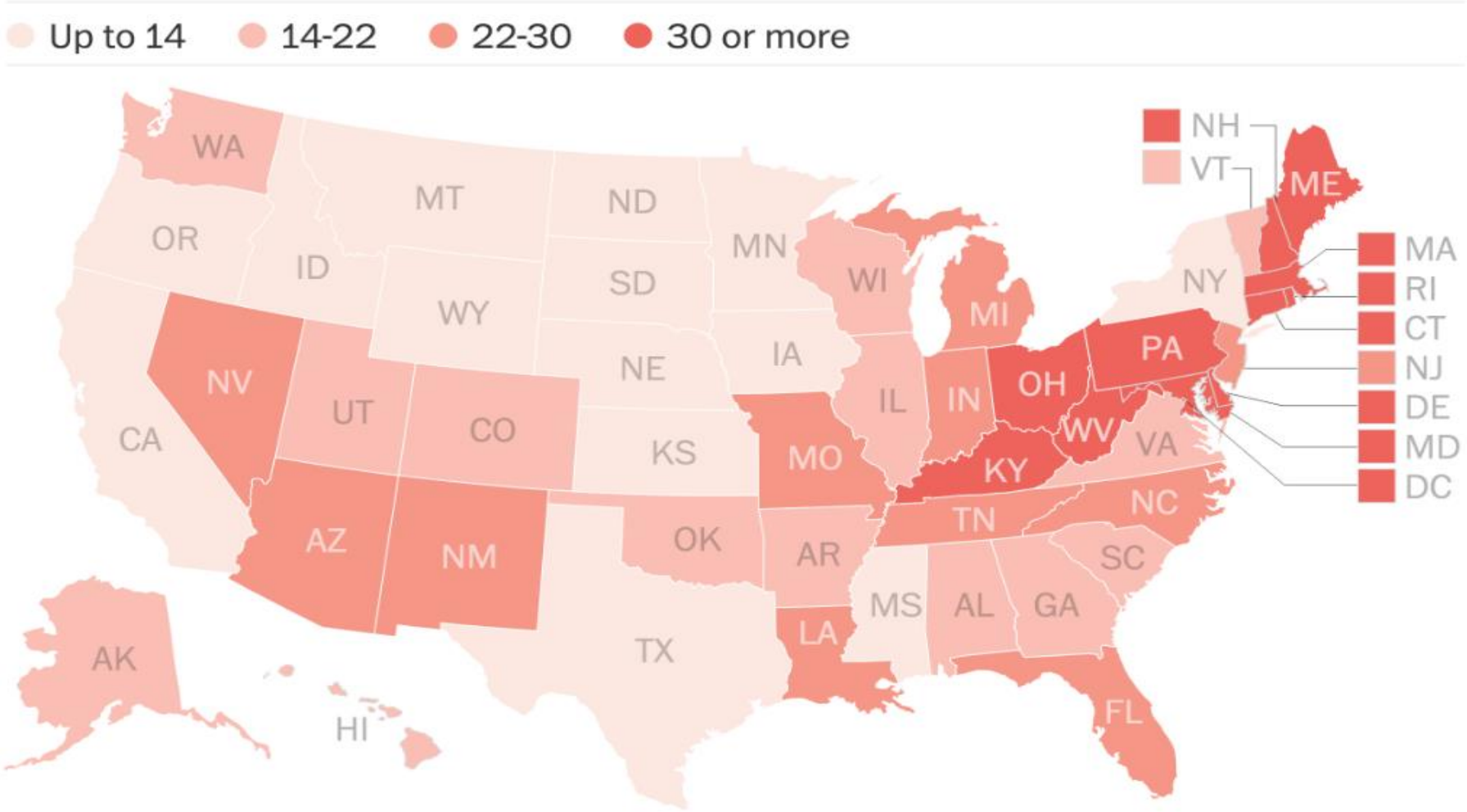
Source: Centers for Disease Control and Prevention

WAPO.ST/WONKBLOG

Overdose estimates for selected drug types in 2017.

The geography of overdose deaths

Drug overdose deaths per 100,000 in 2017

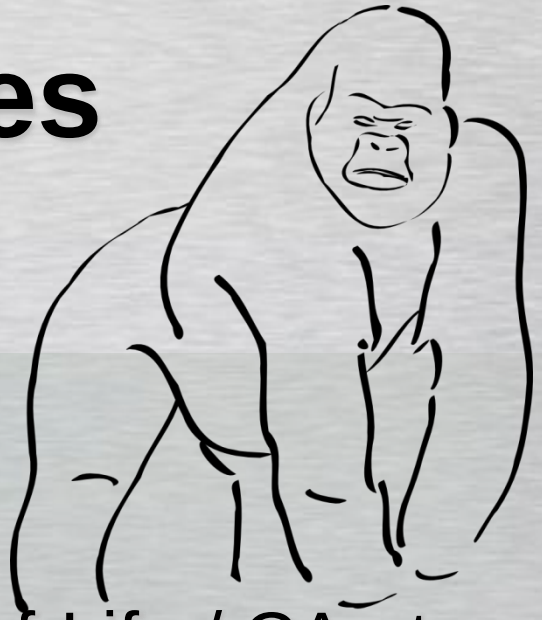


Estimates are preliminary and subject to revision

Source: CDC

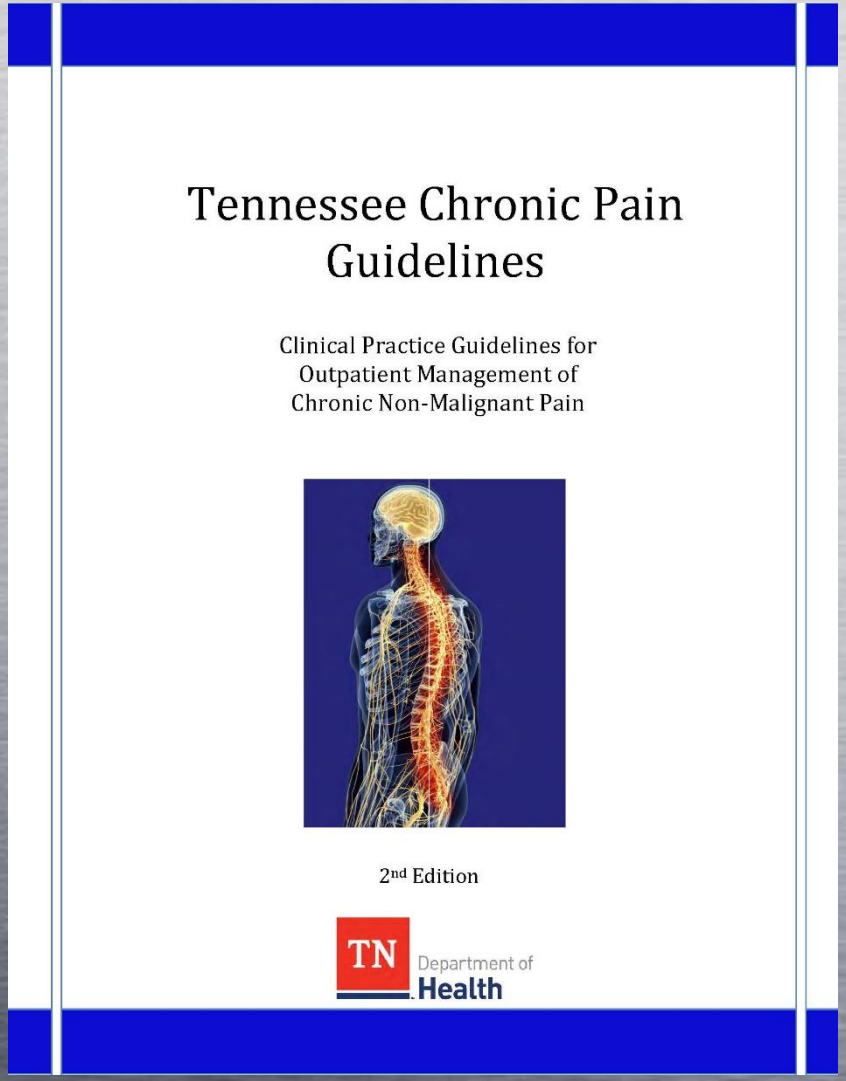
WAPO.ST/WONKBLOG

Guidelines



- **CDC**
  - March 18th, 2016
  - Excludes Palliative / End-of-Life / CA pts
- **Federation of State Medical Boards**
  - Revised Spring 2017
- **State level recommendations and laws**

2017 TN Chronic Pain Guidelines



https://www.tn.gov/content/dam/tn/health/healthprofboards/ChronicPainGuidelines.pdf

Opioid Prescribing Rates & Overdose Deaths

Prescribing Rates (per 100 people)

	2012	2014	2016
TN	136	121	108

Opioid Overdose Deaths

TN 2016	1186	US 2017	47,872

https://www.cdc.gov/drugoverdose
https://www.kff.org/state-category/health-status/opioids/

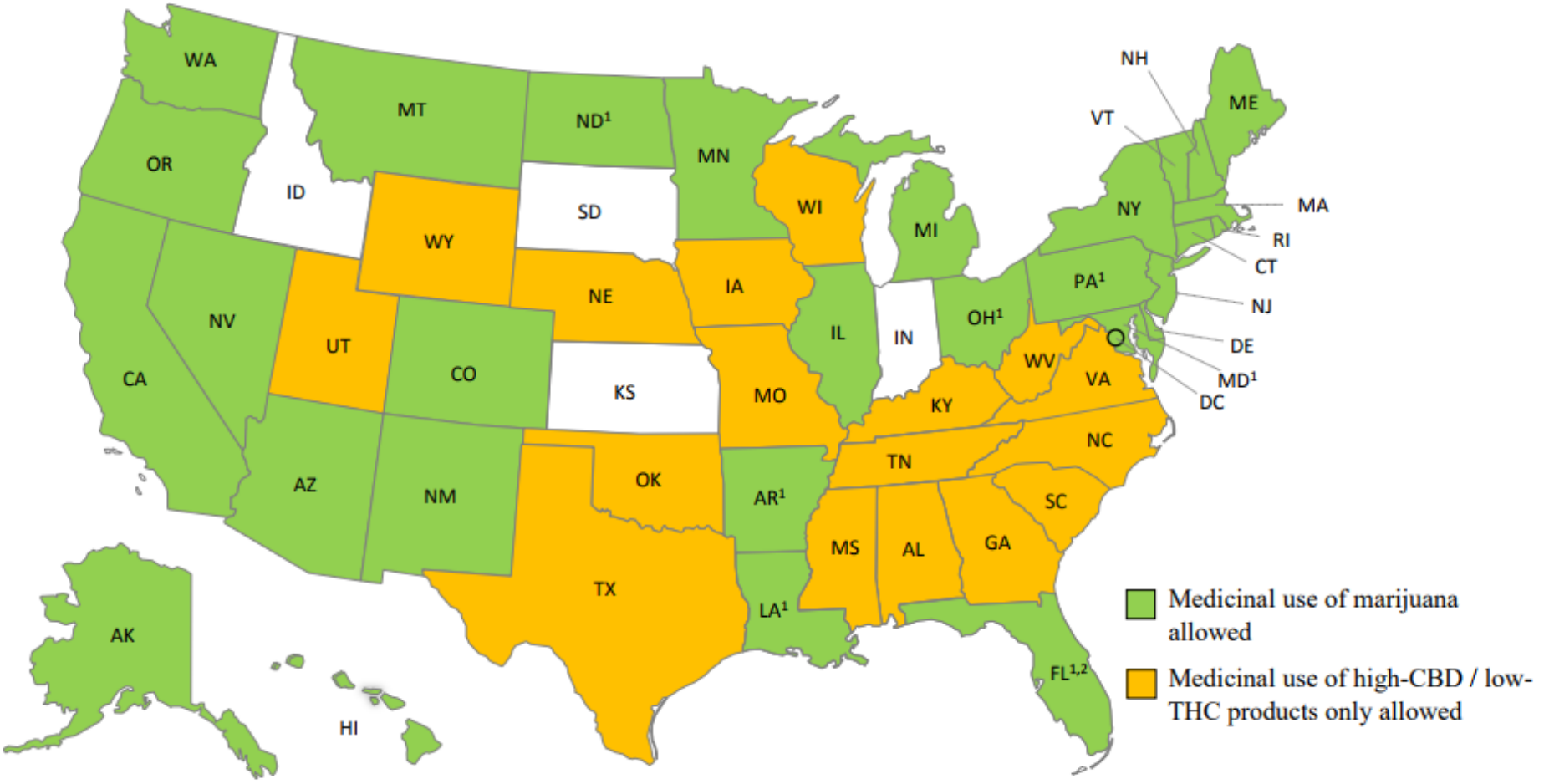
PDMP: Prescription Drug Monitoring Program

General	• **TN Controlled Substances Monitoring Database Program** www.tncsmd.com • Administered by **Department of Health** • **Schedule II-V** are monitored • **Dispensers and prescribers are required** to register and input data • Before prescribing, there **is an obligation** to review under certain circumstances • Prescribers **can authorize** a registered delegate
Reporting	• Must be entered into PDMP within **24 hours** after dispensing • Unsolicited reports/alerts **are sent** to prescribers, dispensers, licensing boards, law enforcement • Tennessee **does share** data with other states' PDMP • Out-of-state pharmacies **are required** to report to the patient's home state • Patient **will not be notified** if their record has been accessed

http://www.namsdl.org/prescription-drug-monitoring-programs-maps.cfm Jan. 2018
http://www.pdmpassist.org/content/pdmp-maps-and-tables Aug. 2018

Marijuana Status

Medical



Recreational

Not legal for recreational use in Tennessee

2017 TN Chronic Pain Guidelines

SECTION I: Prior to initiating opioid therapy for chronic non-malignant pain

- *No treatment by the use of controlled substances through telemedicine.*
- *The patient should be counseled that the goal of chronic opioid therapy is to increase function and reduce pain, not to eliminate pain. Documentation of this discussion shall be included in the medical record.*

SECTION II: Initiating Opioid Therapy for Chronic Non-Malignant Pain

- *An unannounced UDT (or a comparable oral fluids test) should be done twice a year at a minimum.*
- *The practitioner should obtain a signature indicating that any woman who wishes to become or is at risk to become pregnant has been educated about the risks and benefits of opioid treatment during her pregnancy.*

https://www.tn.gov/content/dam/tn/health/healthprofboards/ChronicPainGuidelines.pdf

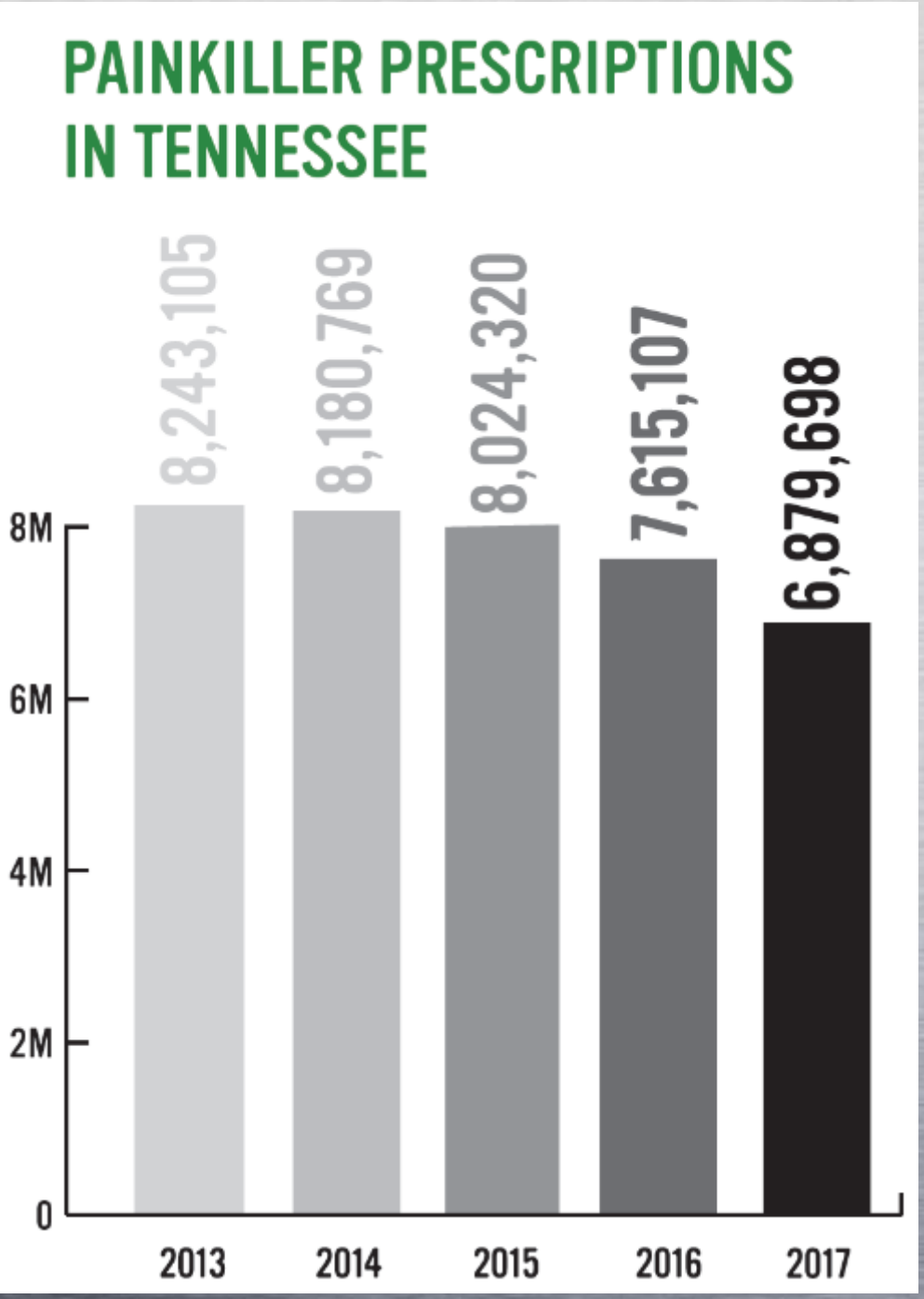
2017 TN Chronic Pain Guidelines

SECTION III: Ongoing Opioid Therapy for Chronic Non-Malignant Pain

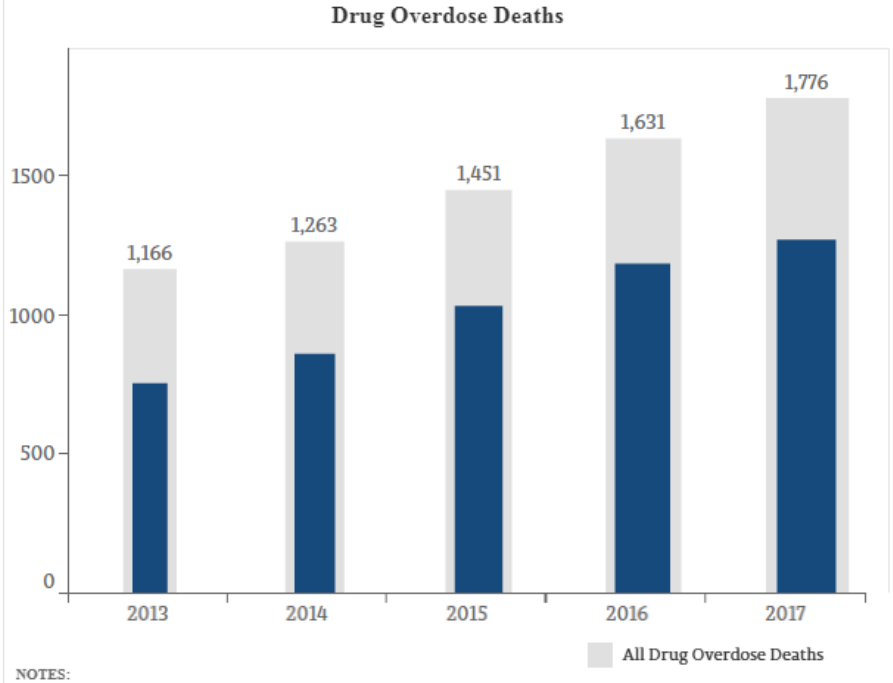
- *Documentation of the discussion of the five A's (analgesia, activities of daily living, adverse side effects, aberrant drug-taking behaviors and affect) at initiation of chronic opioid therapy and at follow up visits shall be included in the medical record.*
- *Patients on opioid doses of 120mg MEDD or greater should be referred to a pain specialist for a consultation and/or management. If a provider cannot make the required consultation as outlined above, then he/she shall clearly document why not.*
- *All providers prescribing 120MEDD for ≥ 6 months in any calendar year) shall obtain at least one annual consultation with a Pain Medicine Specialist.*
- *If a woman of child-bearing potential on opioids become pregnant, she shall be referred to an obstetrician.*

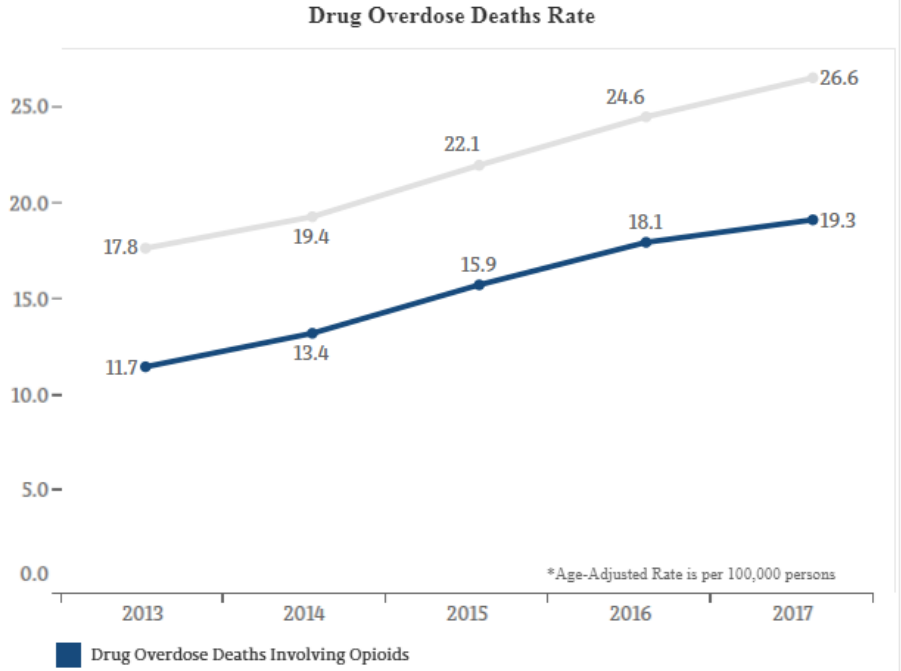
https://www.tn.gov/content/dam/tn/health/healthprofboards/ChronicPainGuidelines.pdf

PAINKILLER PRESCRIPTIONS IN TENNESSEE



TN Overdose Deaths





NOTES:

Tennessee Department of Health, Office of Policy, Planning, and Assessment.

Hospital Discharge (2012-16) and Death Data file (2013-17).

Controlled Substance Monitoring Database (2013-17)

State | Region | County

http://tn.gov/health/topic/pdo-data-dashboard

PDMP: Prescription Drug Monitoring Program

General	• **TN Controlled Substances Monitoring Database Program** www.tncsmd.com • Administered by **Department of Health** • **Schedule II-V** are monitored • **Dispensers and Prescribers are required** to register and input data • Before prescribing, there is **an obligation** to review under certain circumstances
Access	• **Prescribers, dispensers; county medical examiner; law enforcement/judicial; licensing boards; inspector general, the Medicaid fraud control unit, and the bureau of TennCare related to participants in TennCare; chief pharmacist, the state opioid treatment authority, and the medical director of the department of mental health and substance abuse services; quality improvement committee of hospital; patient; third party with signed consent form** • Prescribers **can authorize** a registered delegate
Reporting	• Must be entered into PDMP **24 hours** after dispensing • Unsolicited reports/alerts **are sent** to prescribers, dispensers, licensing boards, law enforcement • Tennessee **does share** data with other states' PDMP • Out-of-state pharmacies **are required** to report to the patient's home state • Patient **will not be notified** if their record has been accessed

http://www.namsdl.org/prescription-drug-monitoring-programs-maps.cfm June 2017

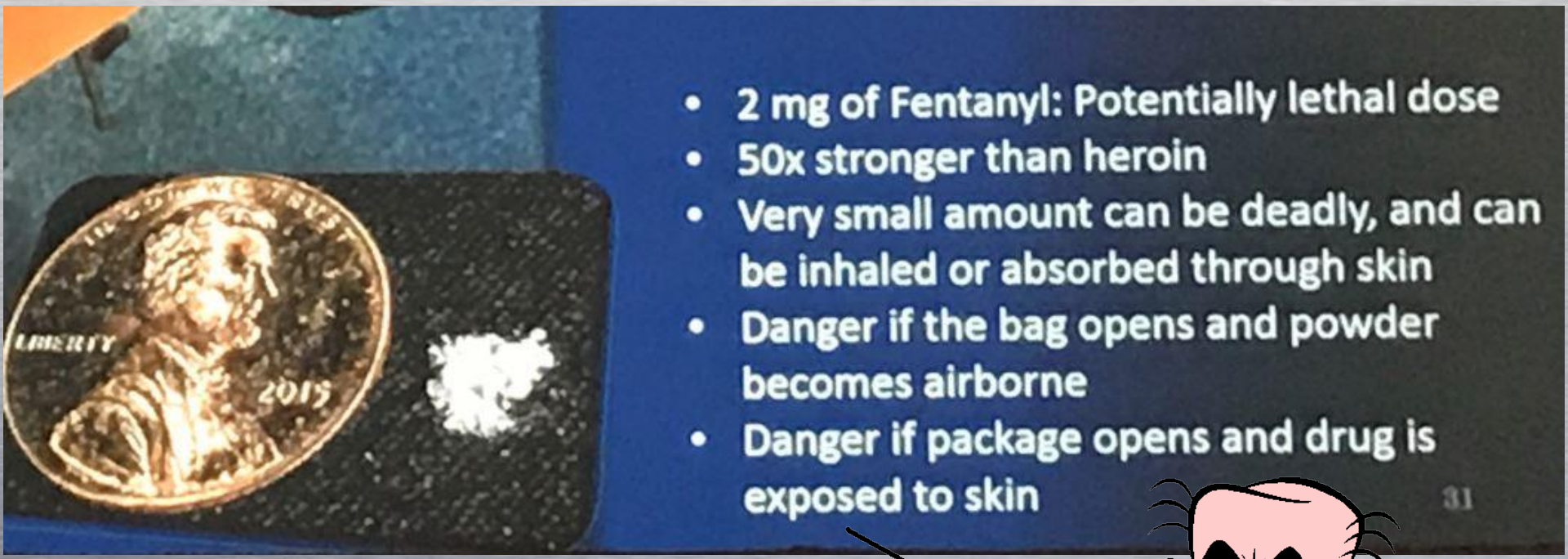
Medical and Recreational Marijuana Status

- It **is not legal** to prescribe
- It **is not legal** for recreational use
  http://lawatlas.org/query?dataset=medical-marijuana-patient-related-laws
  http://www.namsdl.org/controlled-substances-and-prescription-drugs-maps.cfm Jan. 2017

Patient Prescriber Agreement and Treatment Programs

- A Patient Prescriber Agreement (PPA) **is recommended or required**
  http://www.namsdl.org/library/7440DB2D-FE8C-5D71-83963097CEEE4A1F/ Jan. 2016
- For a list of treatment programs in this state:
  https://findtreatment.samhsa.gov/locator/home

Fentanyl


LIBERTY
2015
• 2 mg of Fentanyl: Potentially lethal dose
• 50x stronger than heroin
• Very small amount can be deadly, and can be inhaled or absorbed through skin
• Danger if the bag opens and powder becomes airborne
• Danger if package opens and drug is exposed to skin
31


Neurology

Naloxone Use

(Photo: Josh Mitchell)

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ATLANTA — The U.S. Surgeon General issued an advisory Thursday urging more Americans to carry naloxone, which can reverse the opioid overdoses that kill a person every 12½ minutes in this country.

Dr. Jerome Adams said people at risk of an opioid overdose, as well as their family and friends, should keep the antidote on hand. Many police officers and emergency medical technicians already carry it.

This is the first surgeon general advisory in 13 years. The last, in 2005, dealt with alcohol use during pregnancy.

Laura Ungar, USATodayPublished 1:17 a.m. ET April 5, 2018

Naloxone Regulation

Effective date	• **July 2015**
Criminal Immunity	• Prescribers: **No** • Dispensers: **No** • Lay People: **No**
Also Available	• Without Prescription: **Yes** • To 3rd Party: **Yes** • By Standing Order: **Yes**
Carried by First Responders	• **Yes**

https://www.networkforphl.org/_asset/qz5pvn/legal-interventions-to-reduce-overdose.pdf July 2017
www.pdaps.org

Success with Regulations

Less Doctor Shopping

Less Oxycodone Overdose Deaths

Less Doctor Shopping

FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning

The FDA has issued new information about the combined use of medication-assisted treatment (MAT) drugs with benzodiazepines or other central nervous system depressants. See the **FDA Drug Safety Communication** issued on 9-20-2017.

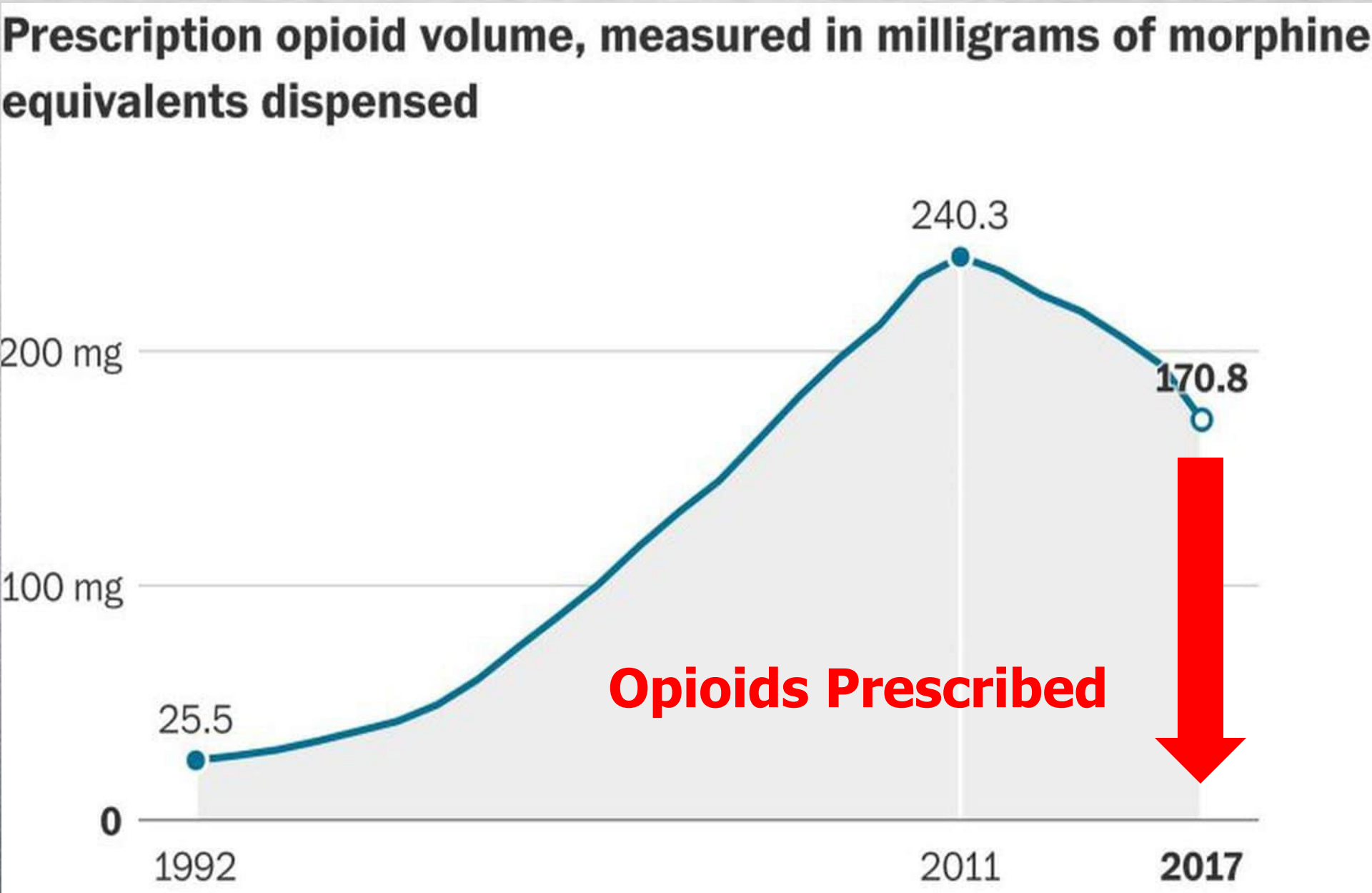
Safety Announcement

[8-31-2016] A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding *Boxed Warnings*, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.

Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study.

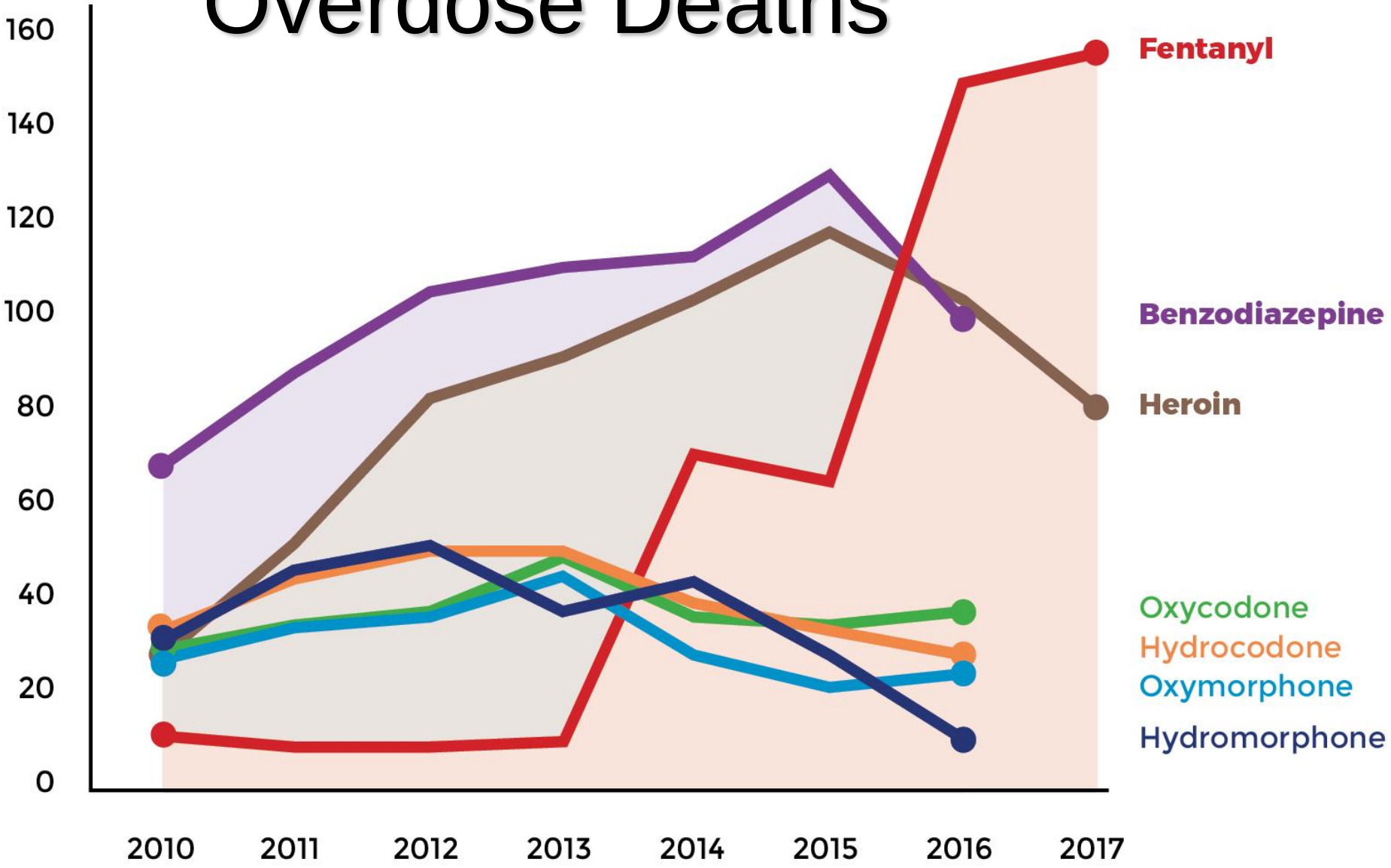
- **CONCLUSIONS:** In this study we found that among patients receiving prescription opioids, **concomitant treatment with gabapentin was associated with a substantial increase (nearly 60%) in the risk of opioid-related death.** Clinicians should consider carefully whether to continue prescribing this combination of products and, when the combination is deemed necessary, should closely monitor their patients and adjust opioid dose accordingly. Future research should investigate whether a similar interaction exists between pregabalin and opioids.

PLoS Med. 2017 Oct 3;14(10):e1002396:



Alabama decreased opioid prescribing by 23.3% in the last 5 years

Overdose Deaths



Opioid Risk Tool (ORT)

Mark each box that applies	Female	Male
1. Family history of substance abuse		
• Alcohol	❑ 1	❑ 3
• Illegal drugs	❑ 2	❑ 3
• Prescription drugs	❑ 4	❑ 4
2. Personal history of substance abuse	❑ 3	❑ 3
• Alcohol	❑ 4	❑ 4
• Illegal drugs	❑ 5	❑ 5
• Prescription drugs		
3. Age (mark box if 16-45 years)	❑ 1	❑ 1
4. History of preadolescent sexual abuse	❑ 3	❑ 0
5. Psychological disease		
• ADD, OCD, bipolar, schizophrenia	❑ 2	❑ 2
• Depression	❑ 1	❑ 1

- Exhibits high degree of sensitivity and specificity
- 94% of low-risk patients did not display an aberrant behavior
- 91% of high-risk patients did display an aberrant behavior

Risk Level Scoring	
0 - 3	Low
4 - 7	Moderate
> 8	High

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

Risk Assessment, Office visits, and Drug Screens – per Bailey

- **Risk Assessment - ORT for baseline risk**
- **Adjusted upwards by one risk factor category for each of the following:**
  - Concurrent benzodiazepine use
  - MME > 90
  - Respiratory compromise (OSA / COPD)
  - Concurrent use of hypnotics
  - Concurrent use of carisoprodol
  - Methadone as analgesic
  - History of aberrant behaviors
  - Drug screens positive for marijuana or alcohol in the past
  - Physician Discretion

How often RTC?
(per Bailey)

- **High Risk**
  - Drug screen - Q3 months
  - Office visit – Q month
  - Must have Rx for Narcan Nose Spray and Instructions documented
- **Moderate Risk**
  - Drug screen Q 6 months
  - Office visit – Q 3 months (if stable)
- **Low Risk**
  - Drug screen Q 12 months
  - Office visit – Q 3 months (if stable)

ALL patients:

- **Drug screened on their initial visit and after change in analgesic**
- **Sign all consents / medication management agreements**
- **Have current ORT in chart**
- **PDMP checked on each office visit**
- **Must have current / working contact information in chart**

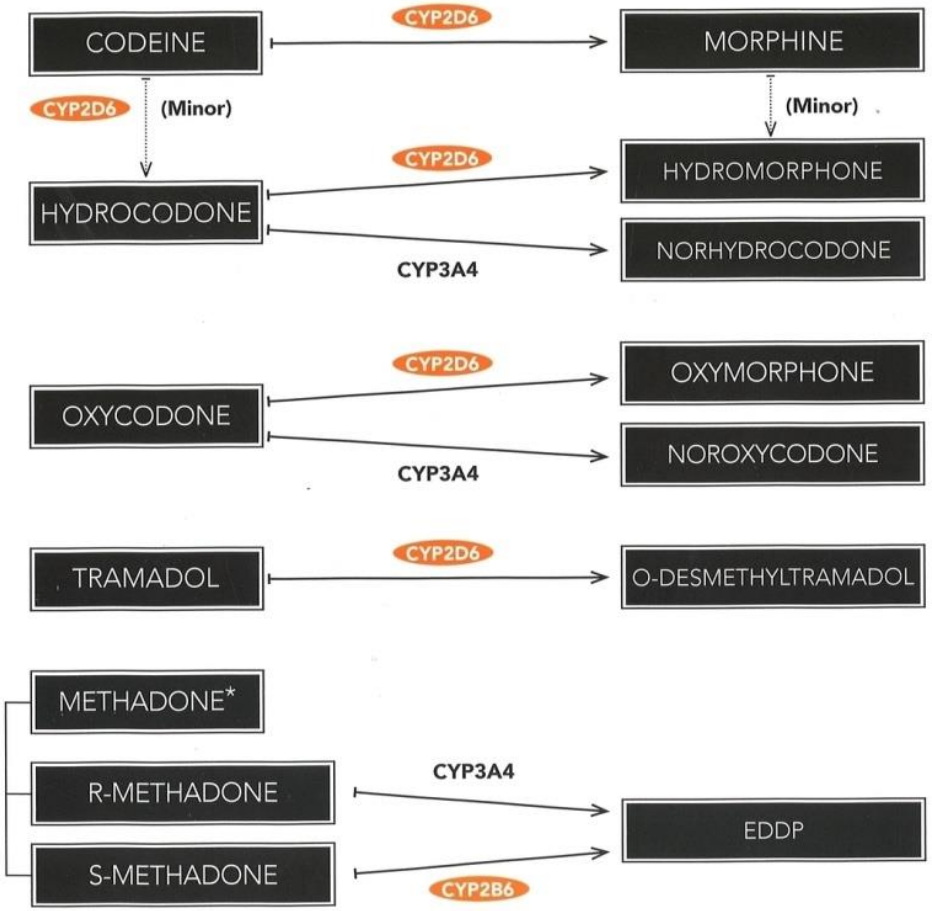
Drug Screen Detection Times

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

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

Opioid Metabolism

PRIMARY OPIOID METABOLIC PATHWAYS[2,3]



*Lesser metabolic pathways for methadone also mediated by 2D6, 2C9, 2C19 to varying degrees

→ Major metabolic pathway
⇢ Minor metabolic pathway
⬭ = Tested by Millennium PGT

CYP = cytochrome P450
EDDP = 2-Ethylidene-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine

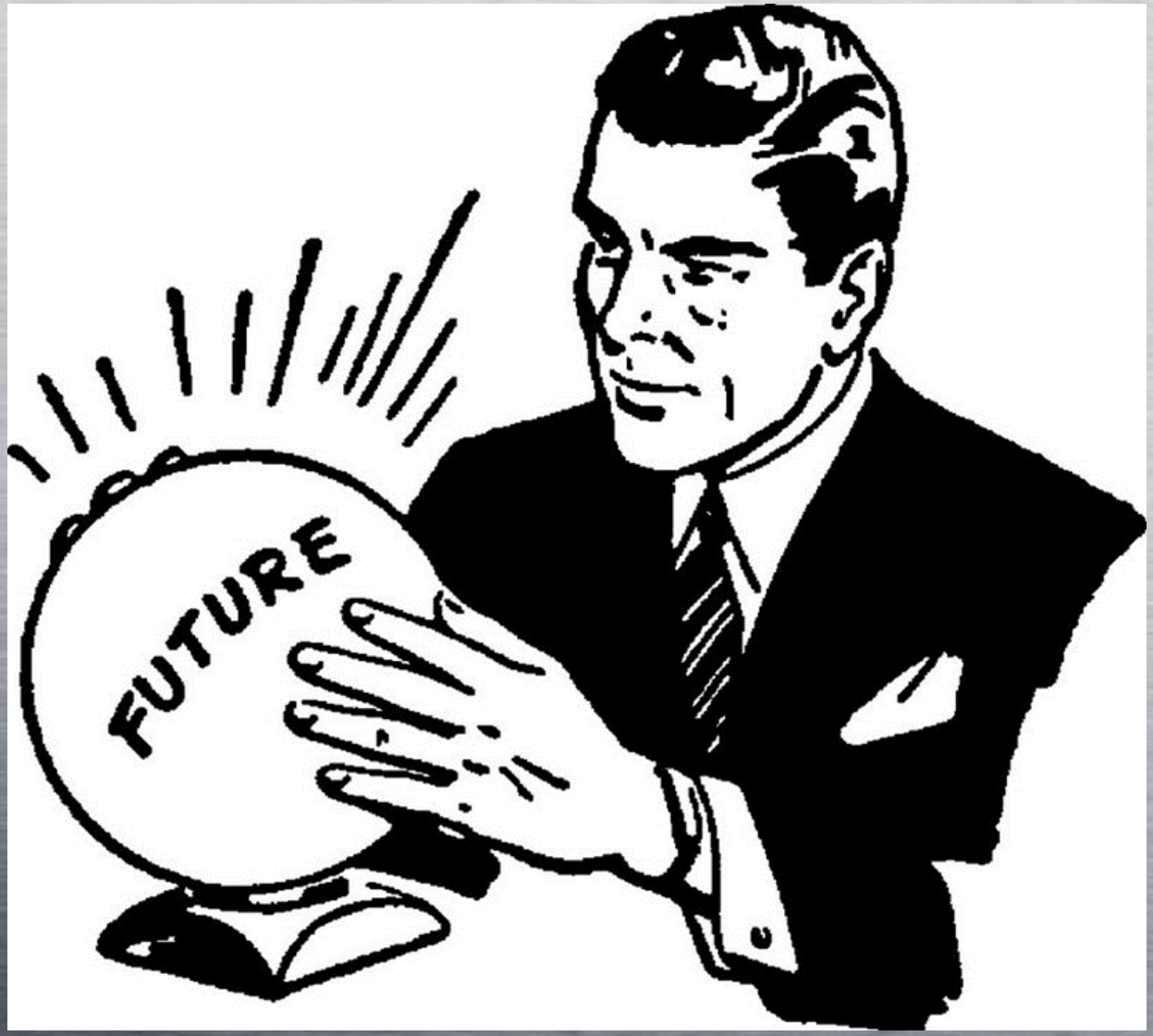
PARENT DRUG	PRIMARY METABOLITES
CODEINE	Morphine, Hydrocodone (minor)
HYDROCODONE	Hydromorphone; Norhydrocodone
OXYCODONE	Oxymorphone, Noroxycodone
TRAMADOL	O-Desmethyltramadol
METHADONE (R- AND S-ISOMERS)	EDDP

(2) Adapted from Smith HS. Opioid Metabolism. *Mayo Clin Proc.* 2009; 84(7):613-624.
(3) Adapted from Trescot AM, et al. Opioid Pharmacology. *Pain Physician.* 2008;11(suppl):135S-153S.

SUBSTANCE FALSELY IDENTIFIED ON TEST	ACTUAL SUBSTANCE	TYPE OF STUDY	NOTES
Amphetamine and methamphetamine	Selegiline	Single case report[1,2]	L-stereoisomer only detected (D-stereoisomer present in illicit drugs)
Amphetamine and methamphetamine	Vicks Inhaler	Several case reports, controlled-exposure studies[1-3]	L-stereoisomer only detected; most positives noted with twice recommended dosage
Barbiturate	NSAIDs (ibuprofen, naproxen)	Controlled-exposure study of 60 subjects (510 specimens)[4]	0.4% false-positive rate
Benzodiazepine	Oxaprozin	Controlled-exposure study of 12 patients (36 specimens)[5]	100% false-positive rate, some cases lack controls
Cannabinoid	NSAIDs (ibuprofen, naproxen)	Controlled-exposure study of 60 subjects (510 specimens)[4]	0.4% false-positive rate
Opiate	Fluoroquinolone*	Controlled-exposure studies (8 subjects) and case series (9 subjects)[6]	Most levels detected were below new 1998 threshold (2000 ng/mL)
Opiate	Rifampin	3 case reports[7]	
Phencyclidine	Venlafaxine	1case report[8]	Confirmed by GC-MS (7200 mg intentionally ingested)
Phencyclidine	Dextromethorphan	1case report[9]	(500 mg ingested)

*Ofloxacin and levofloxacin most likely to cause false positive.

Prognostications



In My Opinion

- **Pain management is hard now and is going to get harder.**
- **Non-opioid treatment is going to have to assume a much more prominent role in chronic pain management – and our patients are going to have to buy into this.**
- **Both patients and physicians are going to have to get past the 'pill for every symptom' mentality**
- **Patients are going to have to become more active participants in their own health care**
- **Naloxone rescue is standard of care**
- **Methadone use in the treatment of chronic pain will diminish markedly**

My Advice

- Apply the concept of risk assessment to your pain patients
- Avoid use of high-dose opioids (whatever that is) and document an effort to decrease dosage whenever possible
- Extreme caution with:
  - Prescribing opioids and benzos
  - Prescribing opioids to anyone who is compromised from a respiratory standpoint (COPD…)
- Encourage the use of Narcan Nasal Spray and abuse-deterrent formulations of opioids
- See your pain patients at no less than 90 day intervals
- Refer for addiction evaluation at the first concern
- Pressure carriers to pay for the non-opioid treatments that our guidelines advise (but presently don't cover)
- Know at least the basics of your own state's laws concerning pain management
- Be willing to work with your pharmacist colleagues

Contact Information

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