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Understanding the Opioid Epidemic: Providers' Role in the Treatment of Opioid Use Disorder

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University of Maryland School of Medicine

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DACS provides support to primary care and specialty prescribers in addressing the needs of their patients with substance use disorders and chronic pain management.

All Services are FREE

- Phone consultation for clinical questions provided by expert addiction medicine specialists
- Education and training opportunities related to substance use disorders and chronic pain management
- Assistance in the identification of substance use and behavioral health resources and referrals that meet the needs of the patients in your community

Funding for DACS is provided by The District of Columbia Government, DC Health, Health Regulation and Licensing Administration (HRLA), Pharmaceutical Control Division (PCD). DACS is administered by the University of Maryland School of Medicine staff and faculty.

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Learning Objectives:

1. To understand the basic concepts of addiction
2. To understand the current extent and severity of the opioid epidemic in the United States
3. Describe the factors responsible for initiating and maintaining the crisis
4. Outline available effective evidenced-based treatments and interventions for individuals with opioid use disorder

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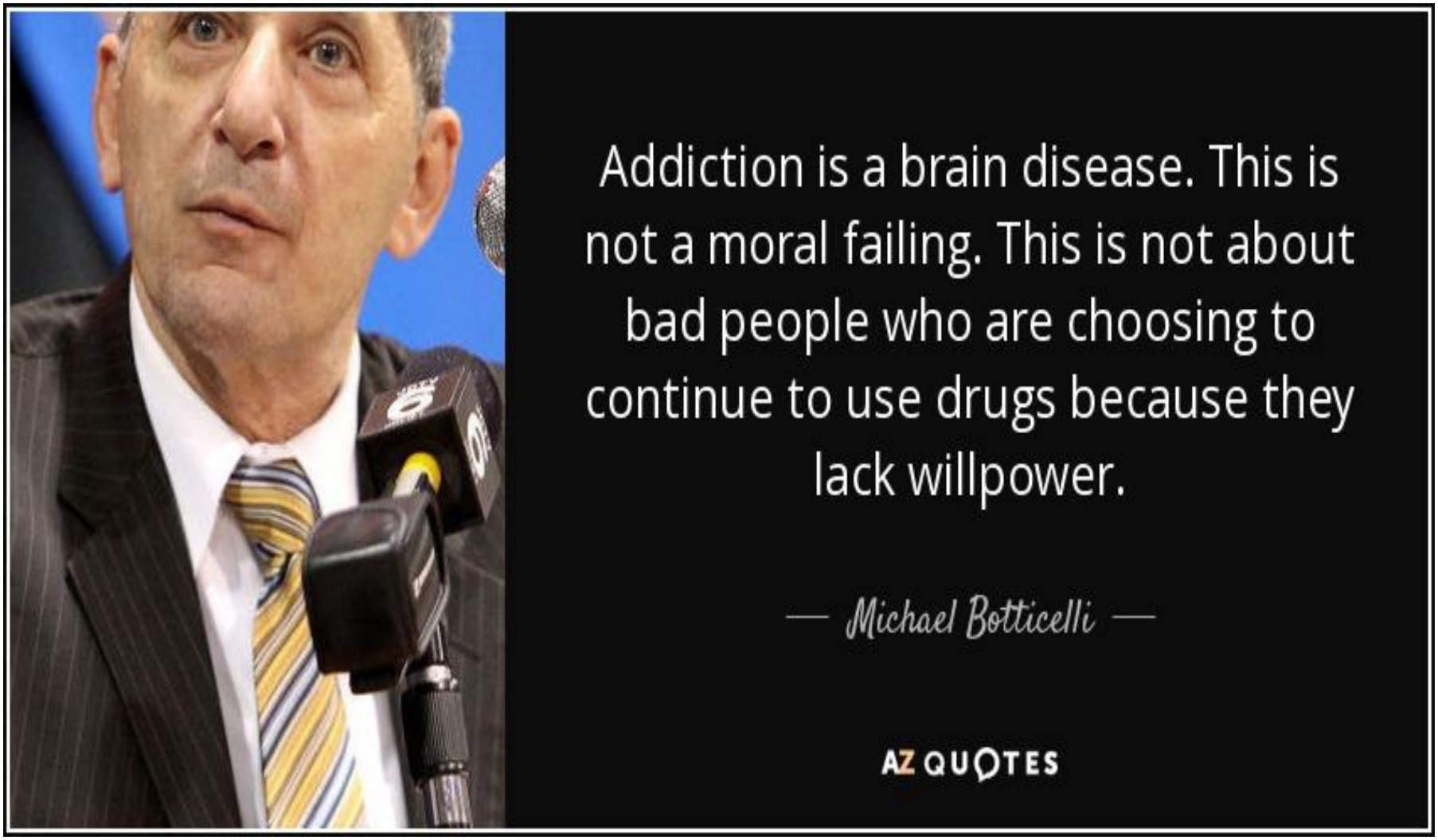

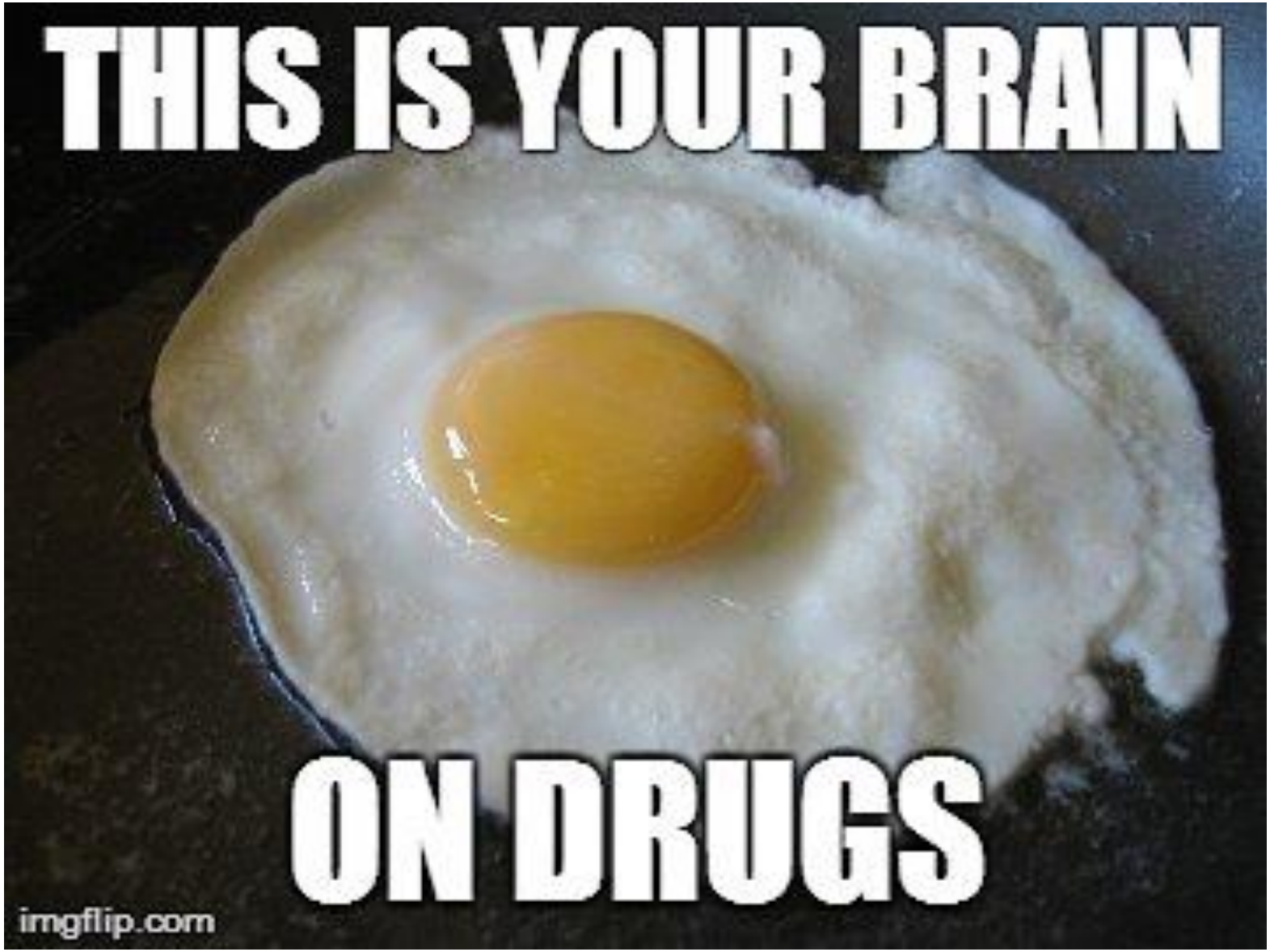
THIS IS YOUR BRAIN
ON DRUGS
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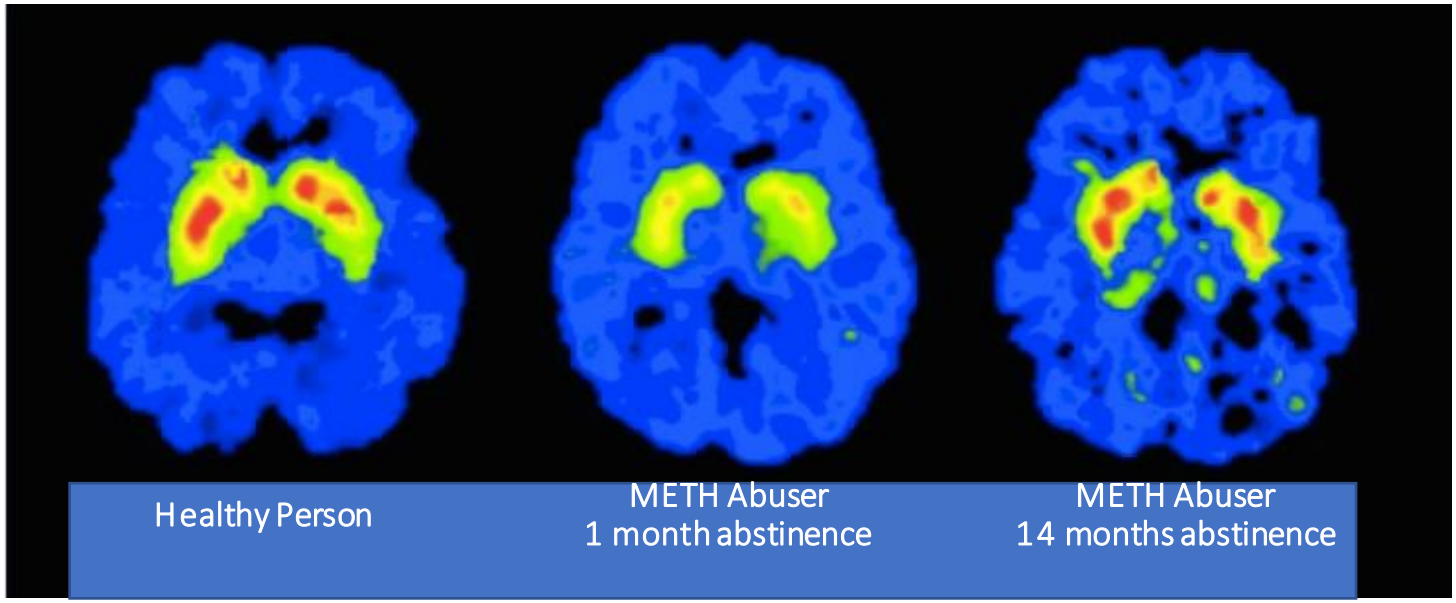
Brain Recovery With Prolonged Abstinence



Volkow ND, et al. *J Neurosci*. 2001;21:9414-18.

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ASAM Definition of Addiction

Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. **Like other chronic diseases, addiction often involves cycles of relapse and remission**. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

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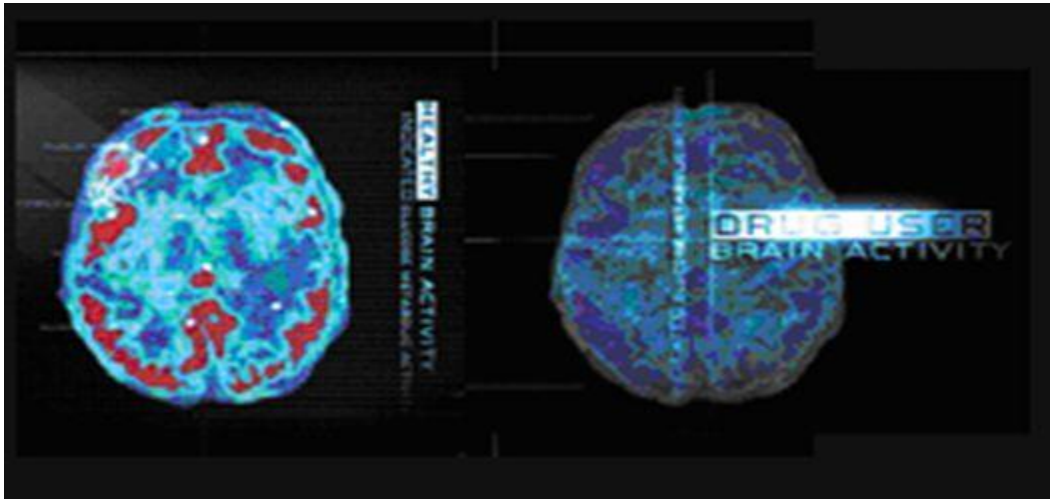
What is Addiction? Addiction is A Brain Disease



Compulsive Behavior

Continued abuse of drugs despite negative consequences NIDA

Persistent changes in the brain's structure and function

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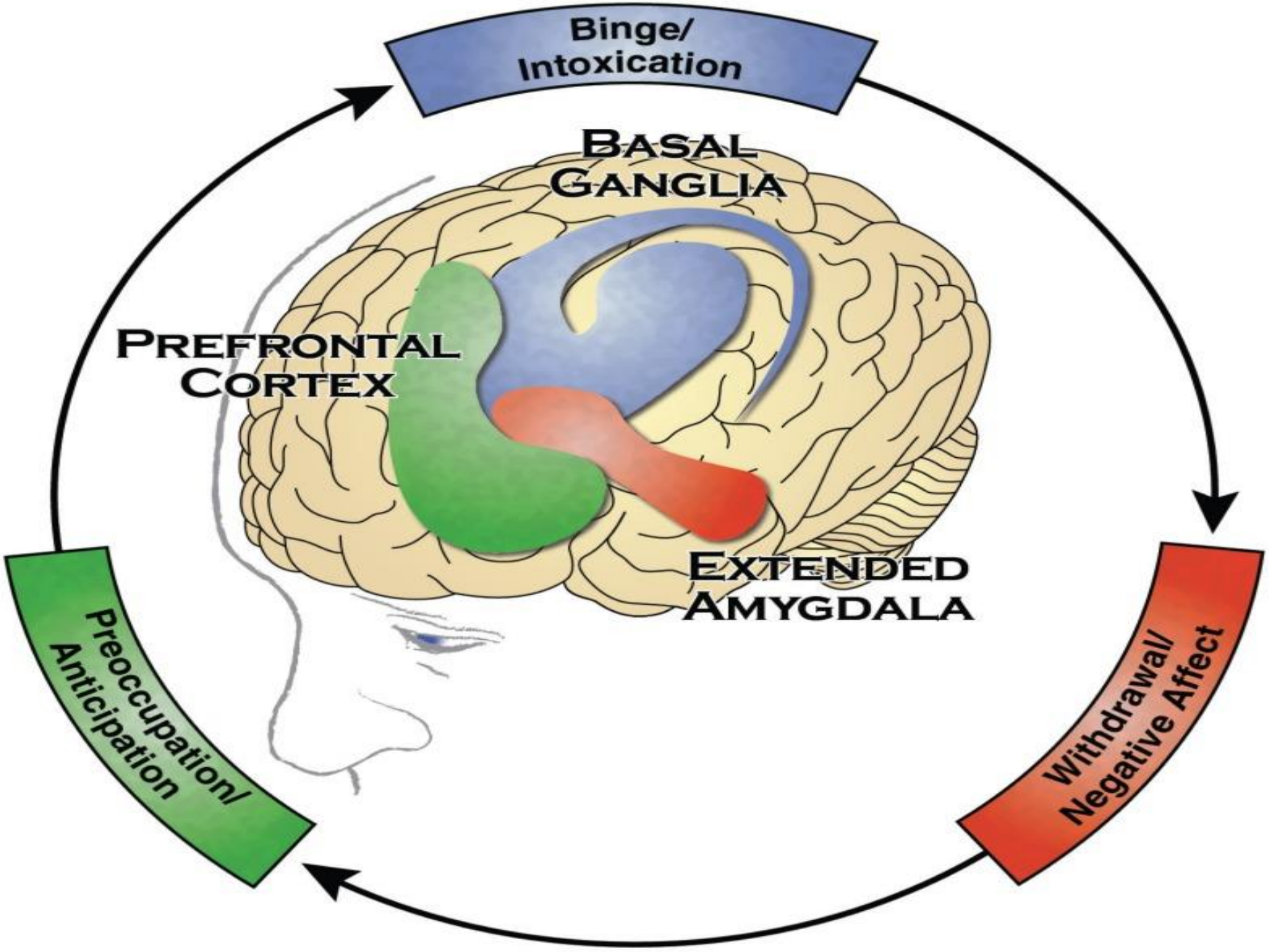
Science Has Generated Much Evidence Showing That…

Prolonged Drug Use Changes the Brain In Fundamental and Long-Lasting Ways


Binge/
Intoxication
Basal
Ganglia
Prefrontal
Cortex
Extended
Amygdala
Preoccupation/
Anticipation
Withdrawal/
Negative Affect

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Addiction is Similar to Other Chronic Illnesses Because:

- It has biological and behavioral components, both of which must be addressed during treatment.
- Recovery from it--protracted abstinence and restored functioning--is often a long-term process requiring repeated episodes of treatment.
- Relapses can occur during or after treatment, and signal a need for treatment adjustment or reinstatement.
- Participation in support programs during and following treatment can be helpful in sustaining long-term recovery

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PHYSIOLOGIC DEPENDENCE

- The state of the body as a result of the ongoing exposure to a substance.

- It is present if the person displays tolerance and/or withdrawal.

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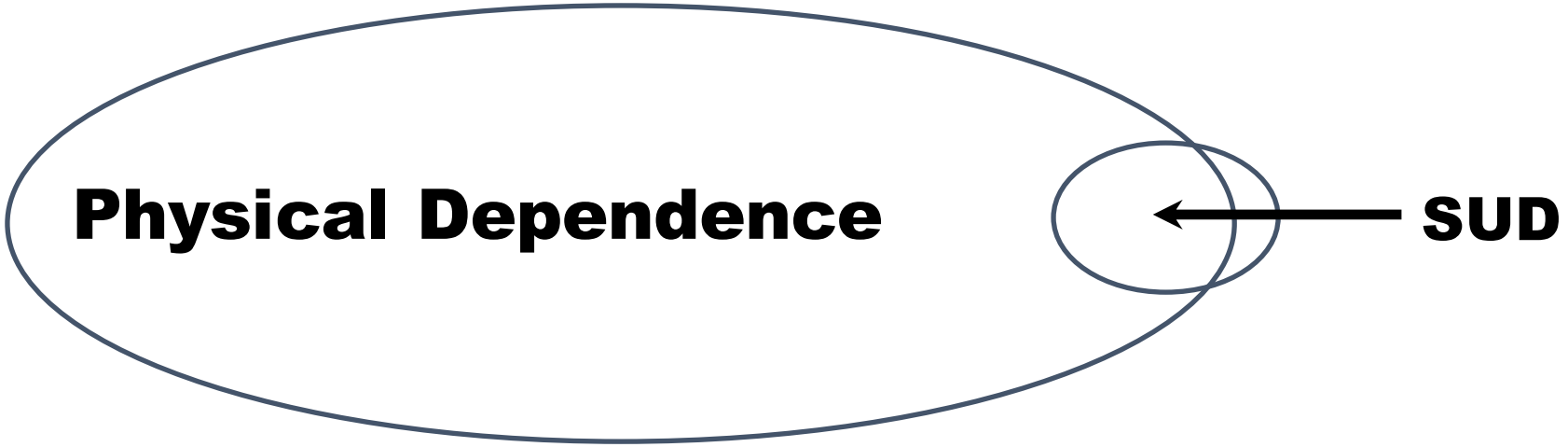
PHYSICAL DEPENDENCE & SUBSTANCE USE DISORDER



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TOLERANCE

- A diminished biological or behavioral response to repeated administration of the same amount of a substance

or

- The need for increasing amounts of a substance to achieve the same effect.

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WITHDRAWAL

The physical and/or psychological disturbances that occur after the cessation of use of a substance to which the body has developed tolerance

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Cardinal Signs of Addiction

- Craving for the drug
- Obsessive thinking about the drug
- Decrease in inhibitory control in efforts to not use the drug
- Compulsive behavior in regards to drug taking
- Persistent changes in the brain's structure and function in the reward, inhibitory, and emotional circuits of the brain

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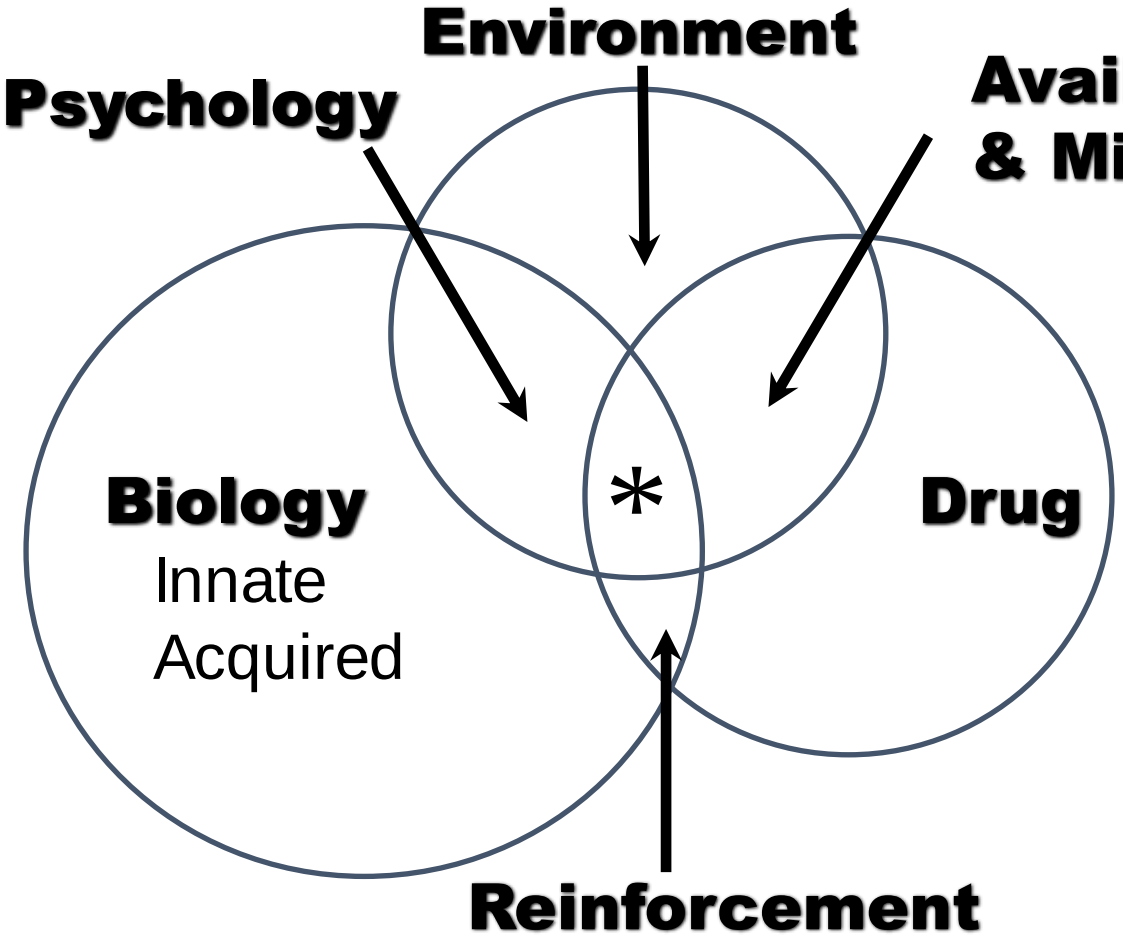
OPIOID USE DISORDER: A MULTI-FACTORIAL DISORDER



*Manifestation of the disease of addiction

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Opioid Overdose Deaths

Opioid overdose deaths have increased six-fold since 1999

2018 overdose deaths dropped from 5% from 72,000 to 68,500 in 2017

2019 rates increased by 4.6 percent

Approximately135 deaths per day from an opioid overdose

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Deaths from Other Causes

- Approximately 58,000 soldiers died in Vietnam War
- 55,000 died in car crashes at peak in 1972
- 43,000 died of HIV/AIDS at height of epidemic in 1995
- 40,000 individuals died of gun violence in peak year of 1993

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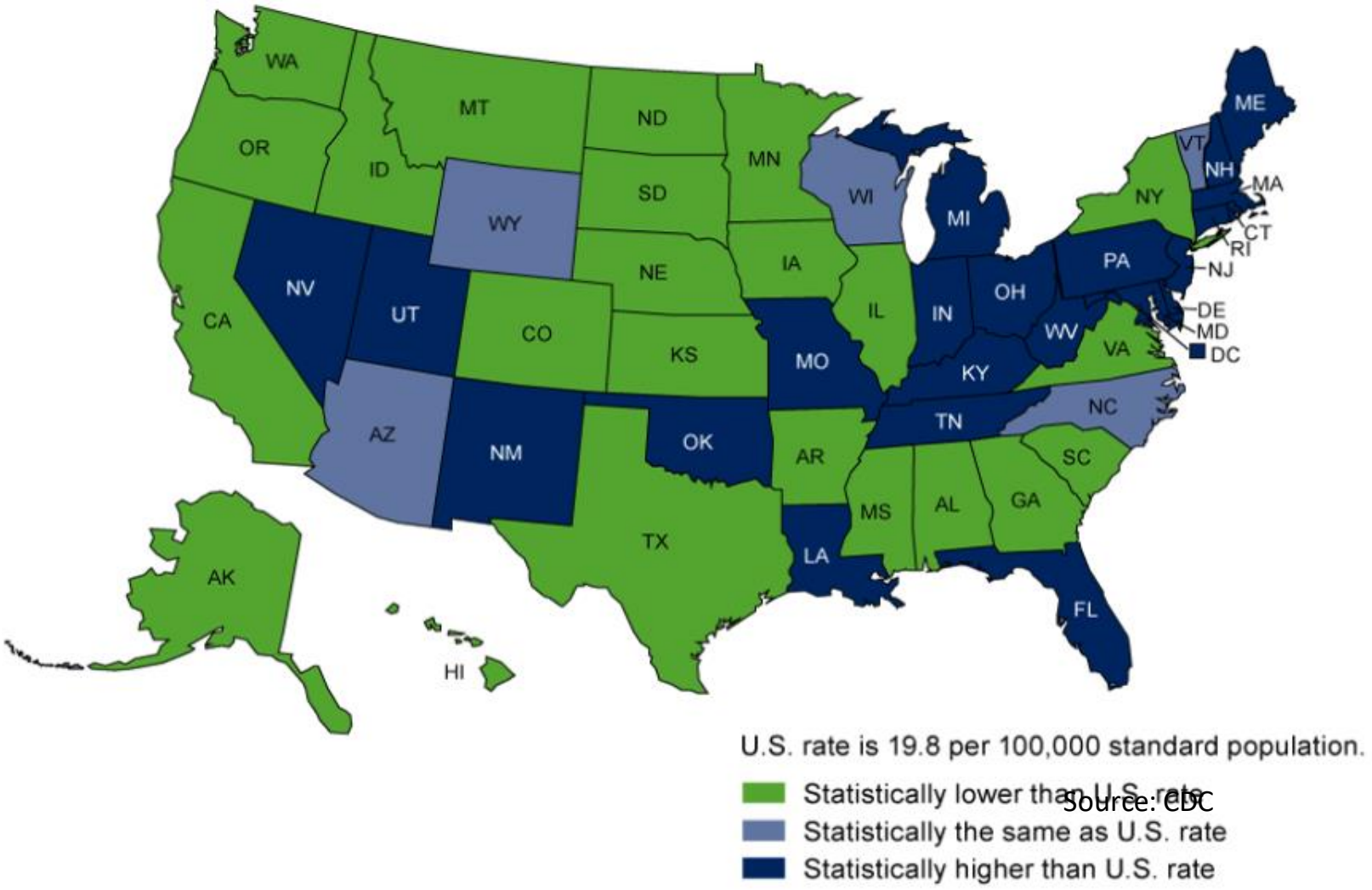
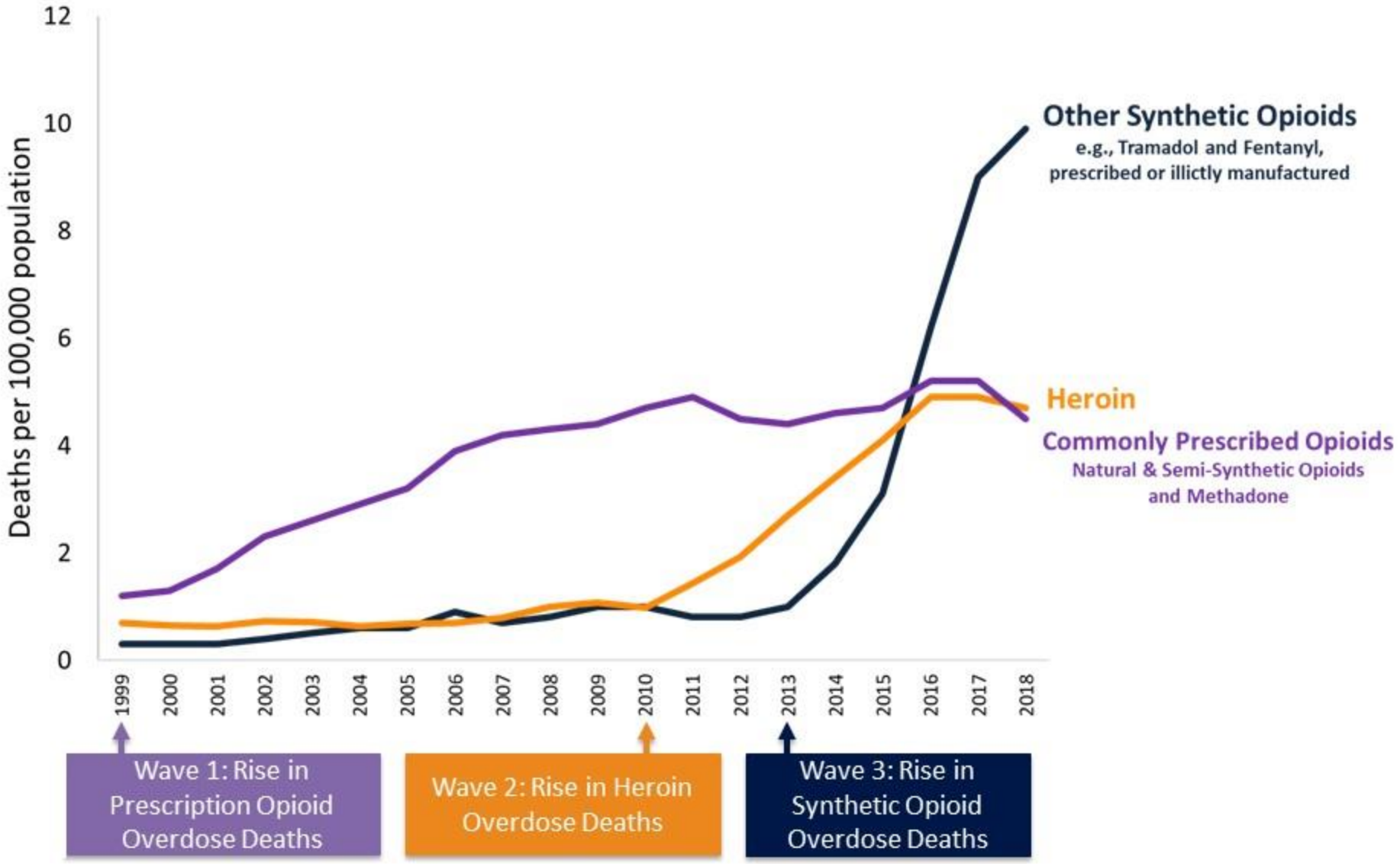


Source: CDC

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

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Prescription Opioids

- In 2012, 259 million prescriptions were written for opioids, enough for one bottle for each adult in US

- 80% of all opioids are prescribed in the US (4.6% of the worlds population)

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Rise In Opioid Prescribing

- 1980 NEJM Letter to Editor
- Russell Portnoy MD
- Pain is the fifth vital sign
- Use of opioids to treat non malignant pain
- Long acting opioids non-addictive
- Big Pharma
- OxyContin
- Patient satisfaction

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Addiction Rare in Patients Treated with Narcotics

N Engl J Med 1980; 302:123January 10, 1980DOI: 10.1056/NEJM198001103020221

Share:

To the Editor:

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients1 who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,2 Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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Hershel Jick, M.D.
Boston Collaborative Drug Surveillance Program Boston University Medical Center, Waltham, MA 02154

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OxyContin

- OxyContin/Purdue Pharmaceuticals 1996
- Aggressively Marketed/Highly Promoted
- Sales from 48 million to 1.1billion from 1996-2001
- Focus on high prescribers of opioids and PCP's
- Free time limited prescriptions
- Non-malignant pain/86% of pain market in 2000
- Minimized risk of addiction at 1%
- Highly abused/new formulation 2010

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Heroin

- Users of heroin have approximately doubled since 2008
- Price of heroin has decreased dramatically since the 1980's and continues to drop (halved again between 2010-14)
- Supply has increased/seizures were up close to 150% between 2010-15
- Source has changed and now 80% of US heroin is being imported from Mexico
- Potency of heroin has increased significantly

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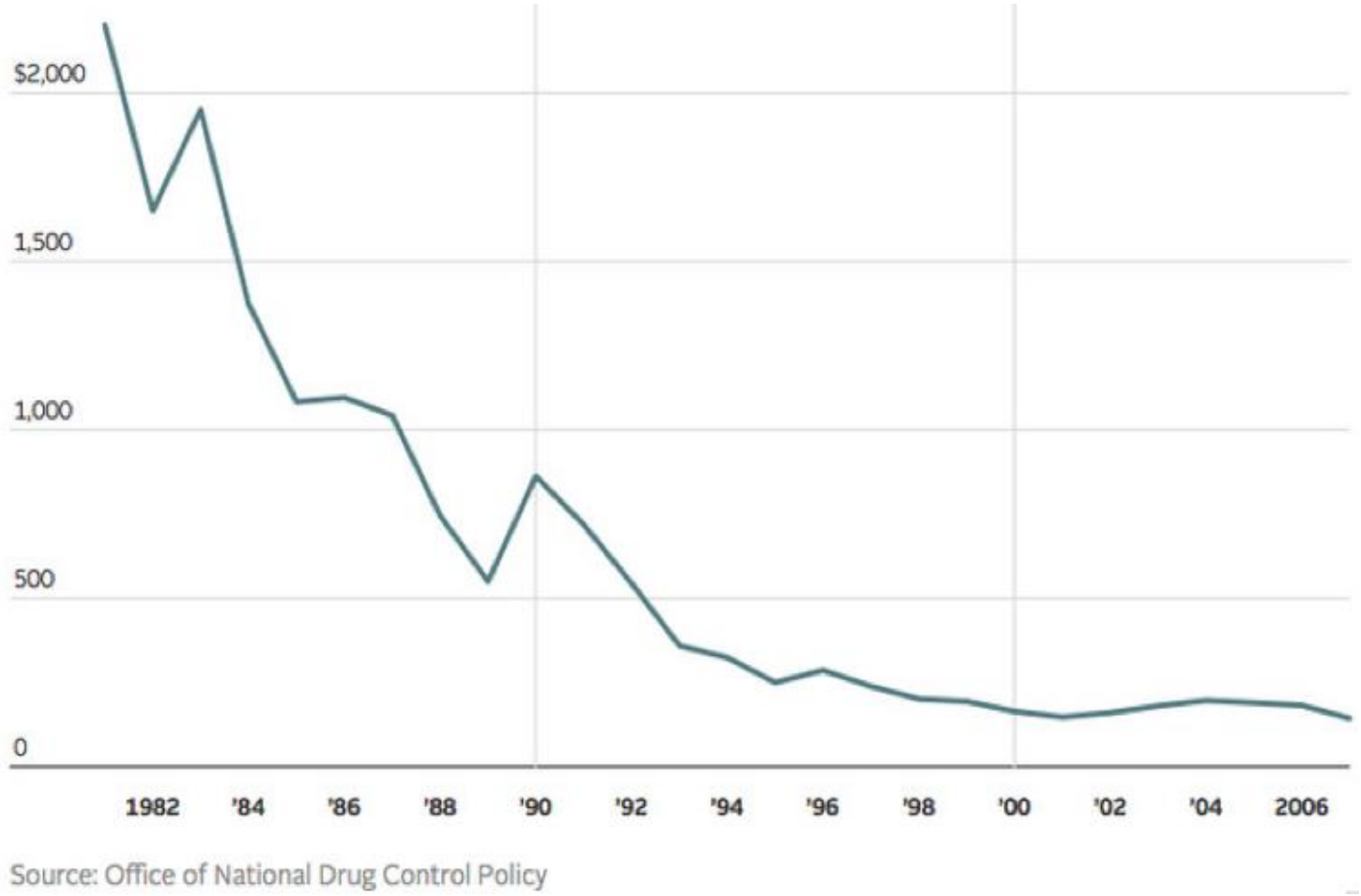

Source: Office of National Drug Control Policy

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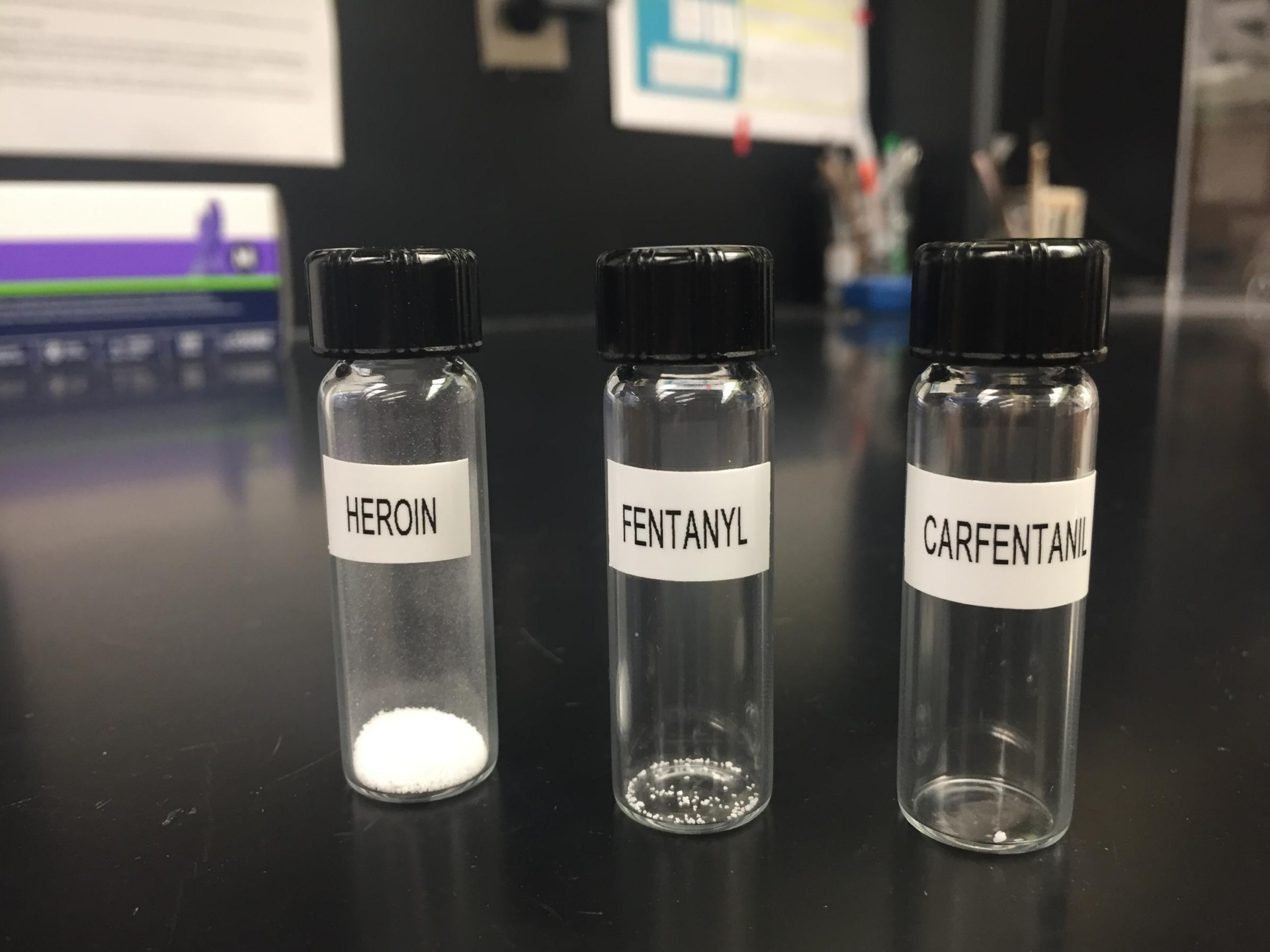
Prescription Opioid/Heroin Use Link

- During the 60's heroin epidemic most users often chose heroin as their first drug
- Currently most heroin users/80% start with the non-medical use of prescription opioids before switching to heroin
- Most current heroin users started with other drugs as adolescents before trying prescription opioids


HEROIN
FENTANYL
CARFENTANIL

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Impact of Epidemic

- Acute care medical costs
- Children and families of overdose victims
- Pregnant addicted women
- Significant increase in rates of Hepatitis
- Increasing rates of HIV

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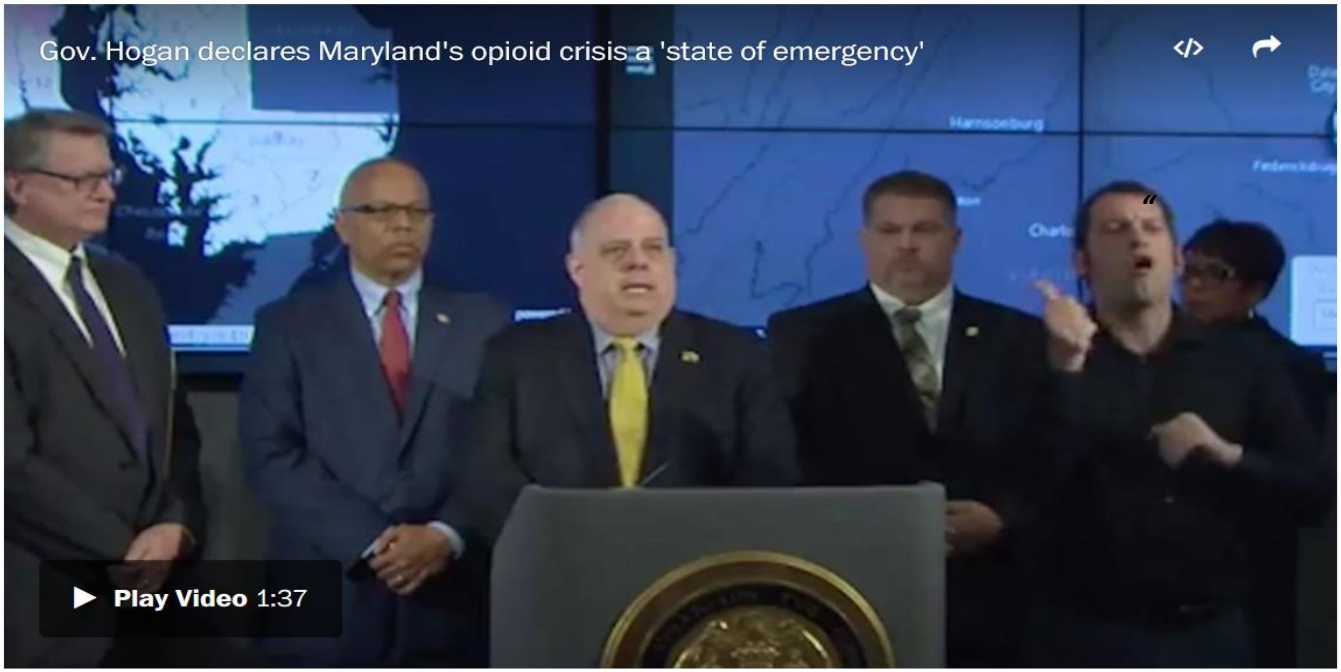
The Washington Post

Maryland Politics

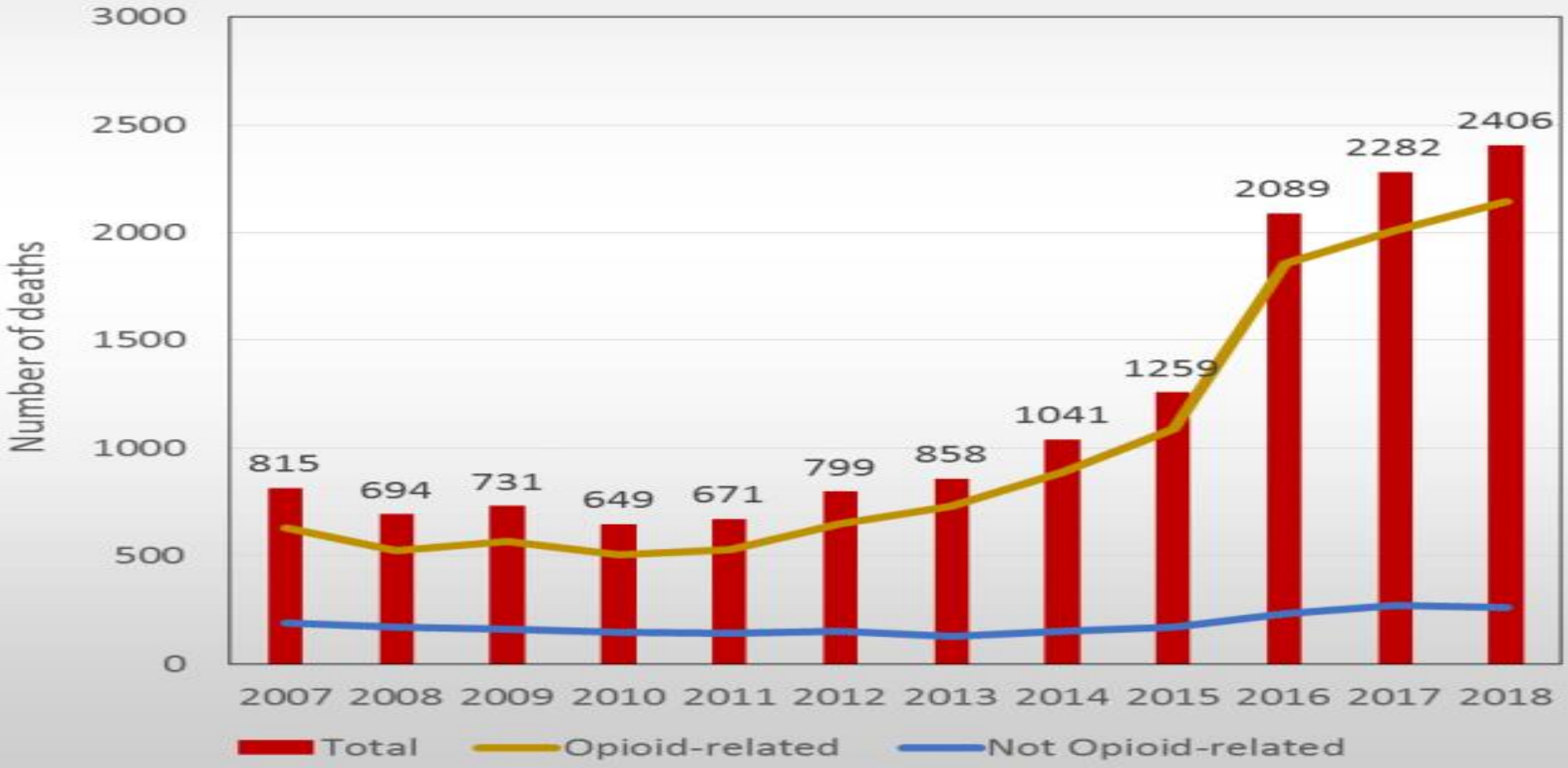
Maryland governor declares state of emergency for opioid crisis



At a news conference on March 1, Maryland Gov. Larry Hogan (R) said he will sign an executive order to declare the state's opioid crisis a "state of emergency," a legal step that will allow state agencies to better coordinate their response to the growing opioid addiction crisis. (Facebook/larryhoganmd)

By Bill Turque March 1

Unintentional Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2018



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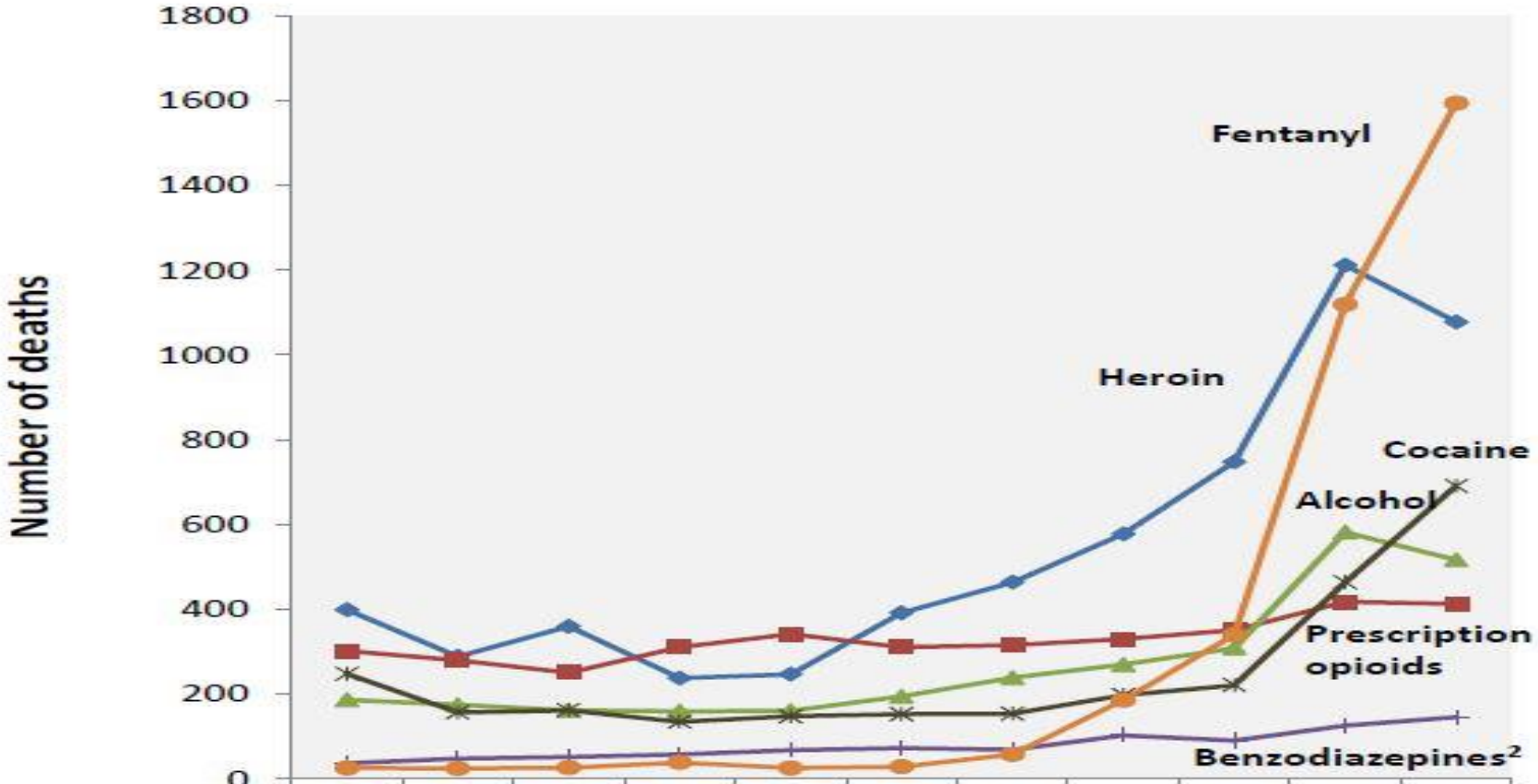
Maryland Overdose Deaths 2019-2020

- Approximately 5 % in decrease in overdose deaths in 2019
- First decrease after seven consecutive years of increases
- Through the first 2 quarters of 2020 there has been a 9.1 % increase in intoxication deaths with 89.5 % being related to opioids and 83 % secondary to fentanyl

Figure 5. Total Number of Drug- and Alcohol-Related Intoxication Deaths by Selected Substances[1], Maryland, 2007-2017.



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Heroin	399	289	360	238	247	392	464	578	748	1212	1078
Prescription opioids	302	280	251	311	342	311	316	330	351	418	413
Alcohol	187	175	162	160	161	195	239	270	309	582	517
Benzodiazepines	37	48	52	58	68	73	69	103	91	126	146
Cocaine	248	157	162	135	148	153	154	198	221	464	691
Fentanyl	26	25	27	39	26	29	58	186	340	1119	1594

[1]Since an intoxication death may involve more than one substance, counts of deaths related to specific substances do not sum to the total number of deaths.
[2]Includes deaths caused by benzodiazepines and related drugs with similar sedative effects.

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Opioid Usage Impact in Maryland

- Maryland ranked #1 among all states in 2014 in rate of opioid related inpatient hospital stays

- Maryland ranked # 2 among all states in opioid related Emergency Department visits

*Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project

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Prevention Strategies

- Regulation of pain management "pill mills"
- PDMP
- Prescriber education on treatment of chronic pain
- Use of alternative modalities for pain management
    - physical therapy
    - acupuncture
    - non-narcotic medications

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Prevention Strategies

- Universal prevention strategies in childhood and adolescence
- Development of safer pain medications
- Abuse deterrent formulations
  - Less rewarding
  - Decrease intentional misuse

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Risk Factors

- Genetic
- Early use
- Peers
- Less perceived risk
- Early emotional distress or aggressviness
- Family substance use, conflict, neglect
- Poor school performance
- Lower socioeconomic status
- Drug availability

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Protective Factors

- Resiliency
- Spirituality
- Interpersonal skills
- Attachment to family, school and community
- Family norms
- In a relationship with a partner who doesn't use
- Meaningful, fulfilling extracurricular activities

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Medication Based Treatment

Combination of medications with counseling and behavioral therapies to treat substance use disorders

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Medication Based Treatment

Recommended as treatment for opioid use disorders by the following:

- United States Federal Government
- American Society of Addiction Medicine(ASAM)
- World Health Organization
- United Nations

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Medication Based Treatment

"Access to medication-assisted treatment can mean [the] difference between life or death."

Michael Botticelli, October 23, 2014 Director, White House Office of National Drug Control Policy

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Medication Based Treatment: FDA Approved

- **Methadone** (**Methadose**; Dolophine)
- **Buprenorphine** (Suboxone; Suboxone Film; Subutex; Bunavail; Zubsolv)
- **Naltrexone** (Trexan; Vivitrol)

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Medication Based Treatment

Only 40 percent of the 2.5 million Americans who could benefit from medication-assisted treatment are receiving it

**Substance Abuse and Mental Health Services Administration (SAMHSA).*

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Medication Based Treatment

- Increases retention in treatment
- Decreases illicit opioid use
- Decreases rate of overdoses by up to 50%
- Improves social functioning
- Decreases transmission of infectious diseases
- Decreases criminal activity

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MBTs Impact on Overdose Deaths

- Compared to patients receiving MAT, untreated patients with OUD have at 1 year:
  - >2.5 X all cause mortality
  - > 8 X overdose mortality

Source: Ma J, Bao YP, Wang RJ, et al. **Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis.** *Mol Psychiatry*. 2018 Jun 22. doi: 10.1038/s41380-018-0094-5.

Medication First Model

for the treatment of Opioid Use Disorder

Introduction

The Medication First (or low-barrier maintenance pharmacotherapy) approach to the treatment of Opioid Use Disorders (OUD) is based on a broad scientific consensus that the epidemic of fatal accidental poisoning (overdose) is one of the most urgent public health crises in our lifetimes. Increasing access to buprenorphine and methadone maintenance is the most effective way to reverse the overdose death rate. Increased treatment access will best be achieved by integrating buprenorphine induction, stabilization, maintenance, and referral throughout specialty addiction programs as well as prima care clinics and other medical settings throughout the mainstream healthcare system1.

Parallels to Housing First

Not Treatment as Usual

Maintenance pharmacotherapy with buprenorphine and methadone can reduce fatal opioid overdose rates by 50-70%, reduce illicit drug use, and increase treatment retention 3-4. However, in traditional treatment programs for addiction, the vast majority of patients are offered no ongoing medical treatment. Those who do receive medical care often face intensive psychosocial service requirements that make treatment both burdensome and costly.

4 Principles of the Medication First Model:

1. People with OUD receive pharmacotherapy treatment as quickly as possible, prior to lengthy assessments or treatment planning sessions;
2. Maintenance pharmacotherapy is delivered without arbitrary tapering or time limits;
3. Individualized psychosocial services are continually offered but not required as a condition of pharmacotherapy;
4. Pharmacotherapy is discontinued only if it is worsening the person's condition.

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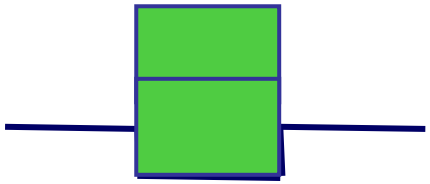
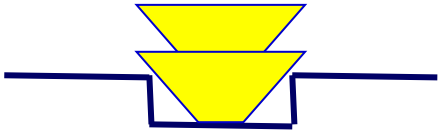
RECEPTOR ACTIVATION



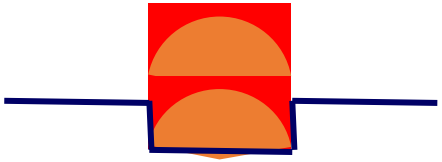
mu receptor site

eg, methadone



mu receptor site

eg, buprenorphine



mu receptor site

eg, naloxone

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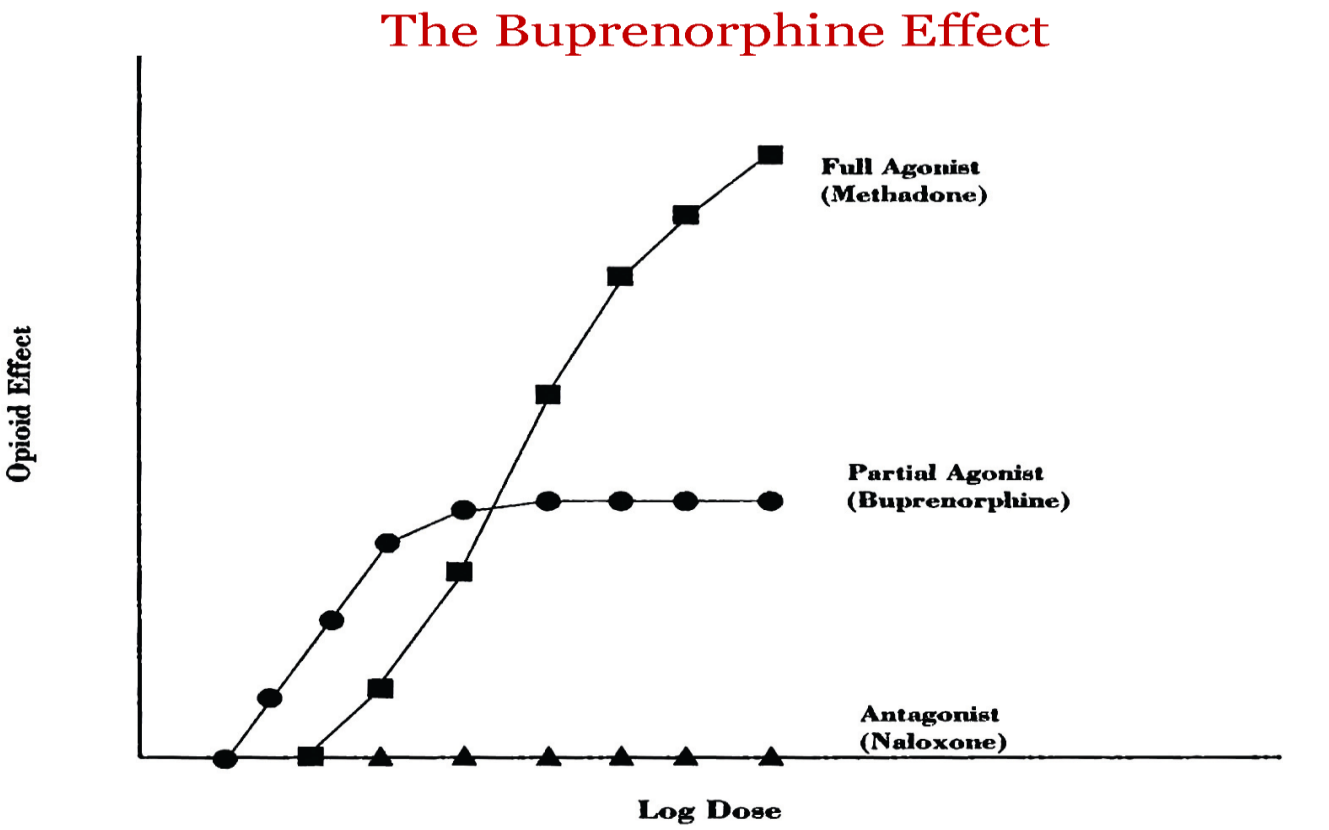
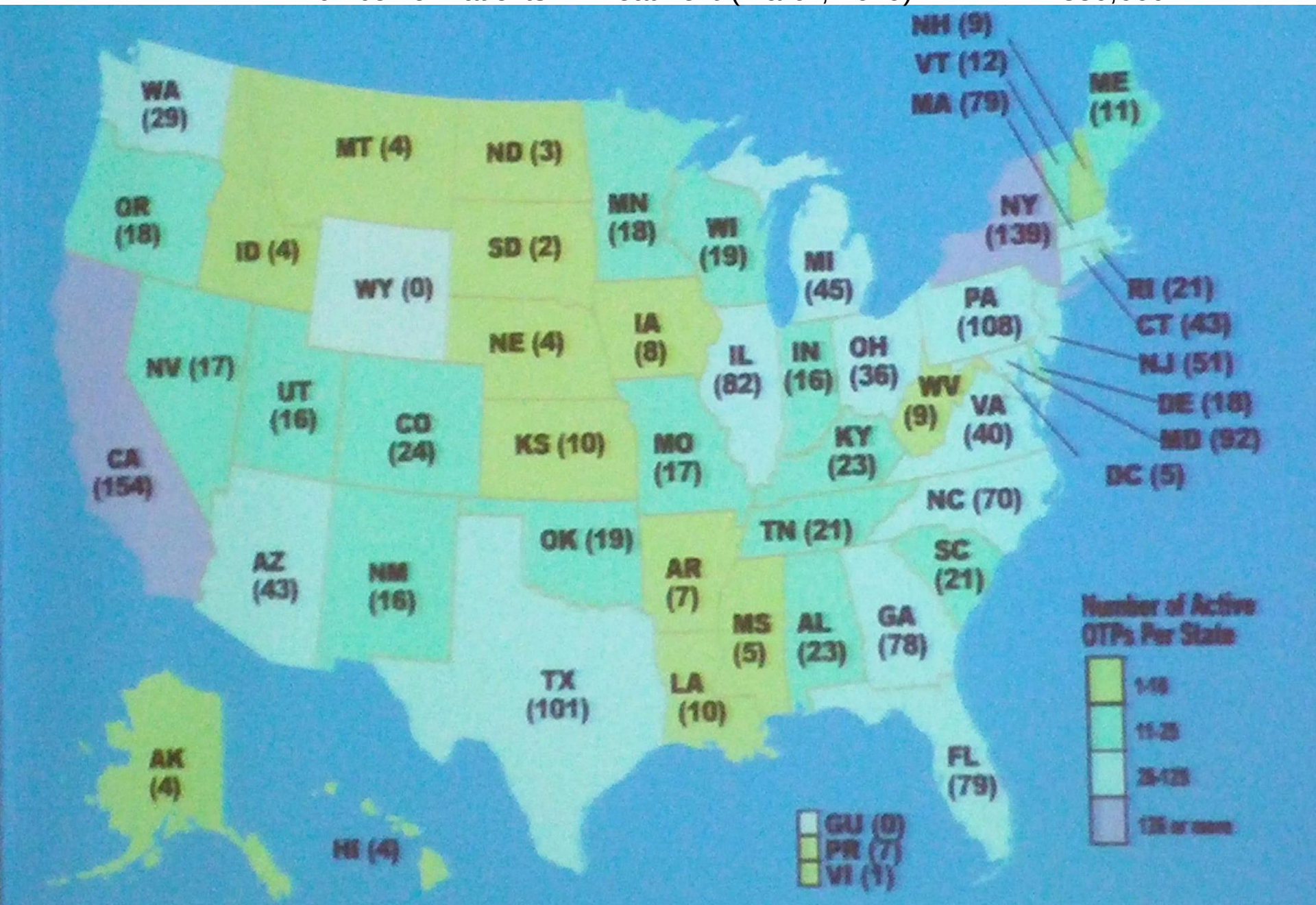
How does buprenorphine differ from methadone?



SAMHSA chart shows how buprenorphine works to ease withdrawal while producing less euphoric opioid effects

Number of Opioid Treatment Programs (March, 2019) >1660
Number of Patients In Treatment (March, 2019) > 350,000



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ADVANTAGES OF METHADONE

- Orally administered
- Gradual onset of action
- Long half-life
- Long duration of action
- Produces complete blockade of effects of heroin
- Minimal chronic problems

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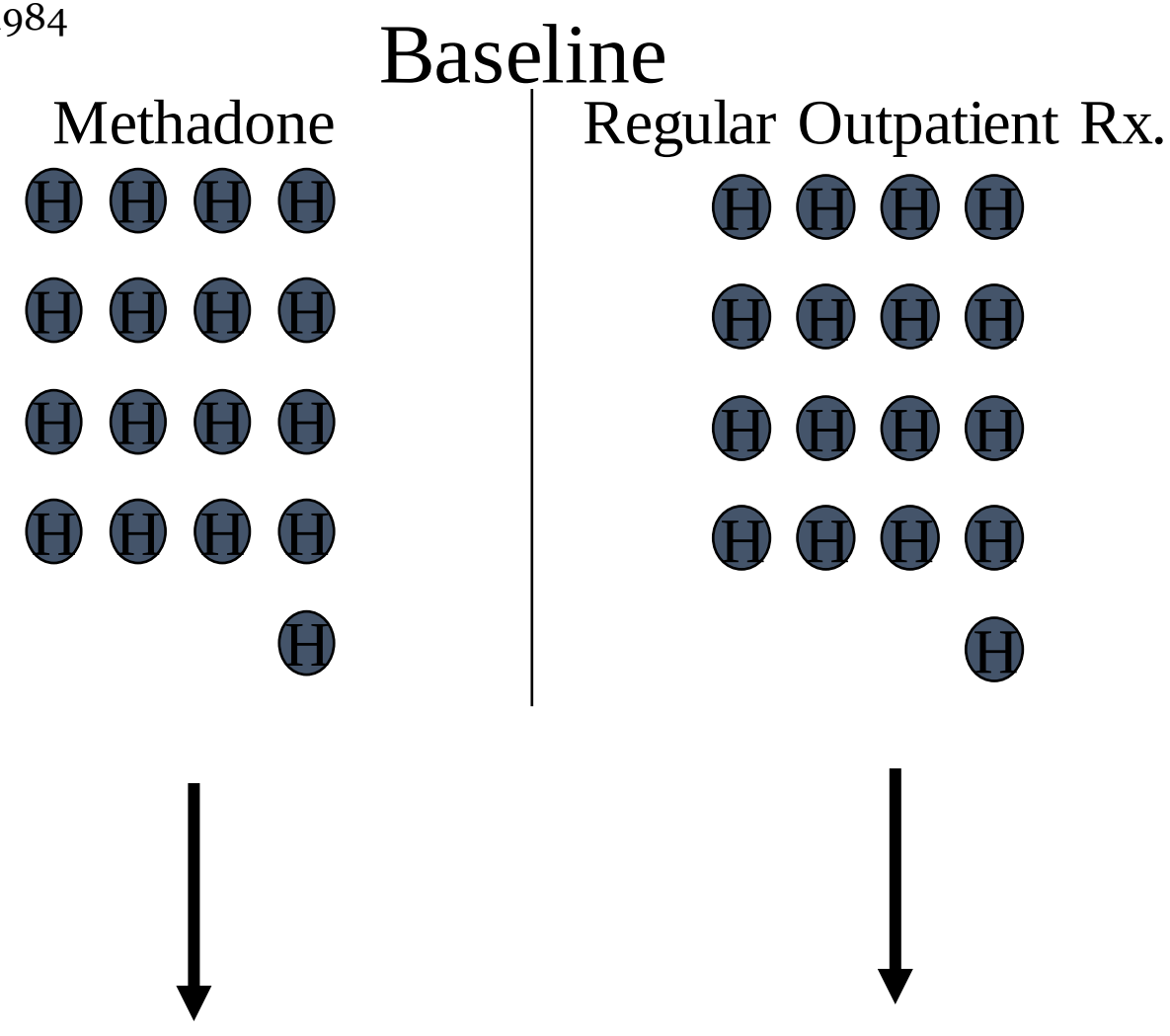
METHADONE EFFECTIVENESS

Gunne & Gronbladh, 1984



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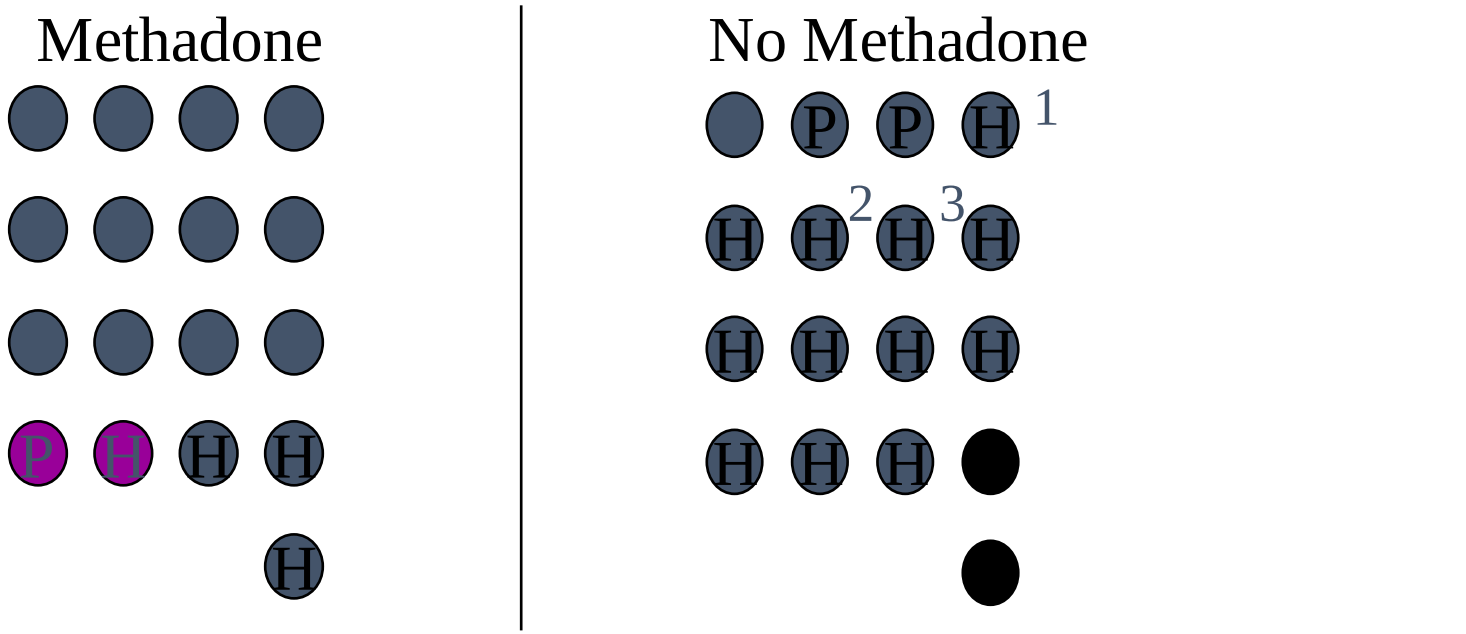
METHADONE EFFECTIVENESS

Gunne & Gronbladh, 1984

After 2 Years



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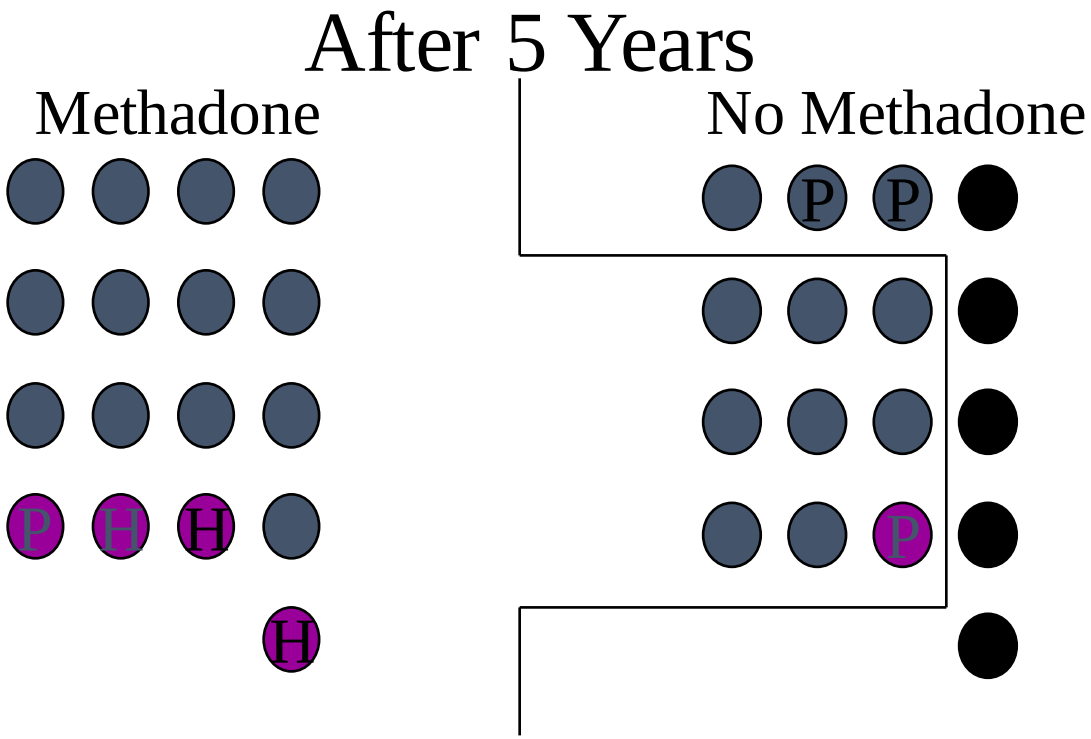
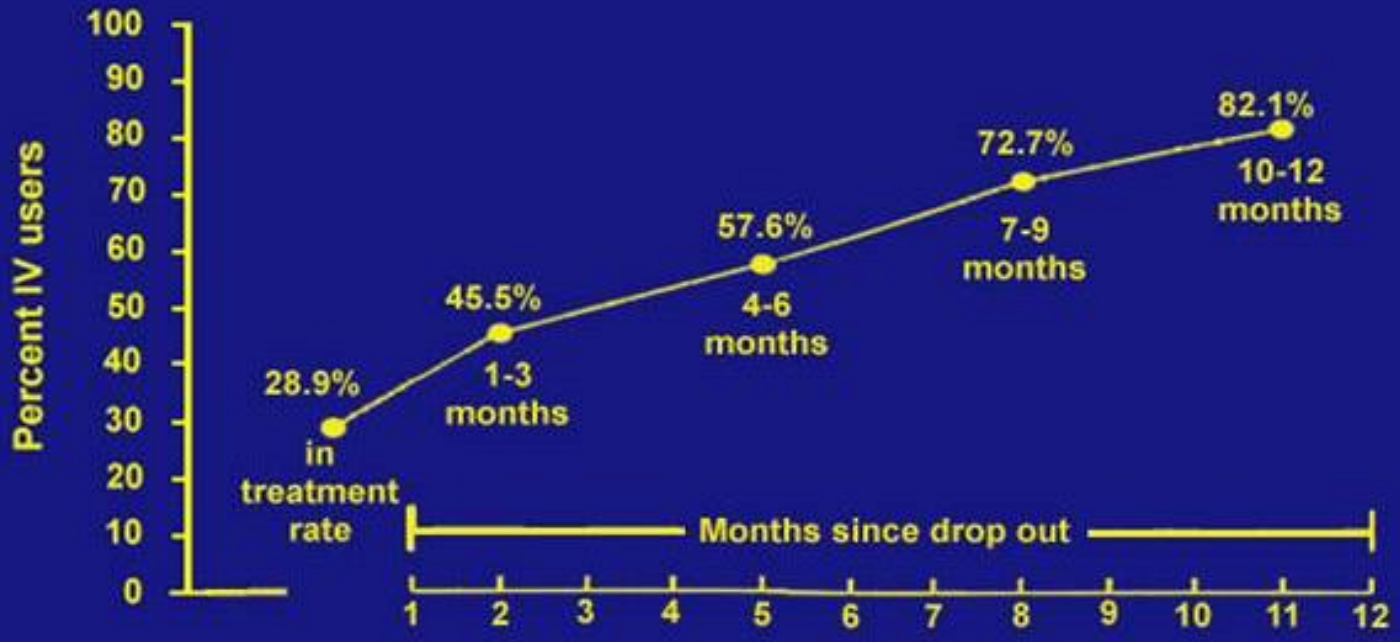
METHADONE EFFECTIVENESS

Gunne & Gronbladh, 1984





Relapse to intravenous drug use after methadone maintenance treatment for 105 male patients who left treatment.

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METHADONE DOSING

- Prevent withdrawal symptoms
  -usually 20-50mg/day
- Reduce drug craving
  -usually 50-70mg/day
- Block the effects of other opioids
  -usually >70mg/day
- Optimal blood levels 150-600ng/ml
- Higher dose (70-100mg/day) more effective than lower (40-60mg/day)

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METHADONE DISADVANTAGES

- Fairly high abuse liability & street value
- Necessitates "take home" doses
- Overdose potential in non-tolerant people
- Detoxification from blocking dose may be difficult
- Poor public acceptability
- Very difficult to expand treatment capacity

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Drug Abuse Treatment Act of 2000 (Data)

Allows: physicians to prescribe (in an office-based setting) & pharmacists to dispense "narcotics", specifically buprenorphine, to treat opioid addiction

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DATA 2000 – Practitioners Requirements

- ✓ Licensed provider with DEA Registration
- ✓ Subspecialty training in addictions or completion of an 8-hour course for MD, 24-hour for NP/PA
- ✓ Registration with SAMHSA and DEA
- ✓ Must affirm the capacity to refer patients for appropriate counseling and ancillary services
- ✓ Must adhere to patient panel size limits
  - 30 during the first year
  - 100 during the second year
  - 275 during the third year

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Relief of Acute Withdrawal Exception

- **The "3-day rule"** provides an exception to the CSA.
- Title 21 C.F.R.§ 1306.07
- allows a physician to "administer (but not prescribe) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. However, the prescriber may not administer more than one day's medication at one time and such treatment may not last for more than 3 days; no renewals or extensions of that period are permitted."

- **Applies in out-patient and Emergency Department settings**

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Incidental Adjunct Exception

- **The "adjunct rule"** provides an exception to the CSA.
- Title 21 C.F.R.§ 1306.07
- allows "a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an **incidental adjunct** to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts."

- **Unclear if this applies in the Emergency Department setting**

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Buprenorphine Characteristics

Partial agonist at mu receptor

- Comparatively minimal respiratory suppression

Long acting

- Half-life ~ 24-36 Hours

High affinity for mu receptor

- *Blocks* other opioids
- *Displaces* other opioids
  - Can precipitate withdrawal

Slow dissociation from mu receptor

- *Stays on receptor for a long time*

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How Does Buprenorphine Work

- High affinity for, and slow dissociation from the mu receptor which leads to:
  - Alleviation of withdrawal symptoms
  - Decreased cravings for opiods
  - Decreased effects of other opioids

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BUPRENORPHINE FORMULATIONS

Buprenex-for pain only

Butrans/Belbuca-for pain only

Subutex-for opioid addiction only

Suboxone-for opioid addiction only

combination pill/film/buccal "patch" w/ naloxone

Probuphine- 6 month sc implant

Sublocade- monthly sc injection


2 mg/0.5 mg
Suboxone
4 mg/1 mg
Suboxone
8 mg/2 mg
Suboxone
Suboxone


Bunavail™
(buprenorphine and naloxone) buccal film
2.1 mg / 0.3 mg
Bunavail™
(buprenorphine and naloxone) buccal film
4.2 mg / 0.7 mg
Bunavail™
(buprenorphine and naloxone) buccal film
6.3 mg / 1 mg


Belbuca™
(buprenorphine hydrochloride)
buccal film
75 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
150 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
300 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
450 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
600 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
750 mcg
Belbuca™
(buprenorphine hydrochloride)
buccal film
900 mcg


8


A
14
2mg/0.5mg
AN
415
8mg/2mg


1·4
1.4mg/0.36mg
5·7
5.7mg/1.4mg


zubsolv
1.4 mg/0.36 mg
zubsolv
5.7 mg/1.4 mg


Sublocade
100 mg
WARNING: SERIOUS HARM OR DEATH
COULD RESULT IF INJECTED INTRAVENOUSLY

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SUBOXONE PHARMACOLOGY

If taken under tongue, predominant buprenorphine effect

If opioid dependent person dissolves and injects, predominant naloxone effect (and precipitated withdrawal)

Naloxone will block buprenorphine's effects by the IV but not the sublingual route

Sublingual absorption:

buprenorphine @ 70%

naloxone @ 10%

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SUBOXONE

- Buprenorphine mono product produces leasurable effects and would likely be purchased by illicit drug users

- Naloxone when combined with buprenorphine attenuates euphoric effect

- Buprenorphine/naloxone should decrease abuse liability in untreated opioid- dependent individuals

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Buprenorphine Safety

- Highly safe medication
- Primary side effects: like other mu agonist opioids but may be less severe
- No evidence of significant disruption in cognitive or psychomotor performance
- No evidence of organ damage with chronic dosing
- Possible mild increase in LFTs for patients with hepatitis

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Precipitated Withdraw

- Because of its high affinity for mu opioid receptors, buprenorphine can displace other agonists (such as heroin, methadone) that are already present and occupying the receptors
- The sudden change from full-agonist to partial-agonist activation of opioid receptors can cause sudden and severe withdrawal symptoms, a condition known as precipitated withdrawal

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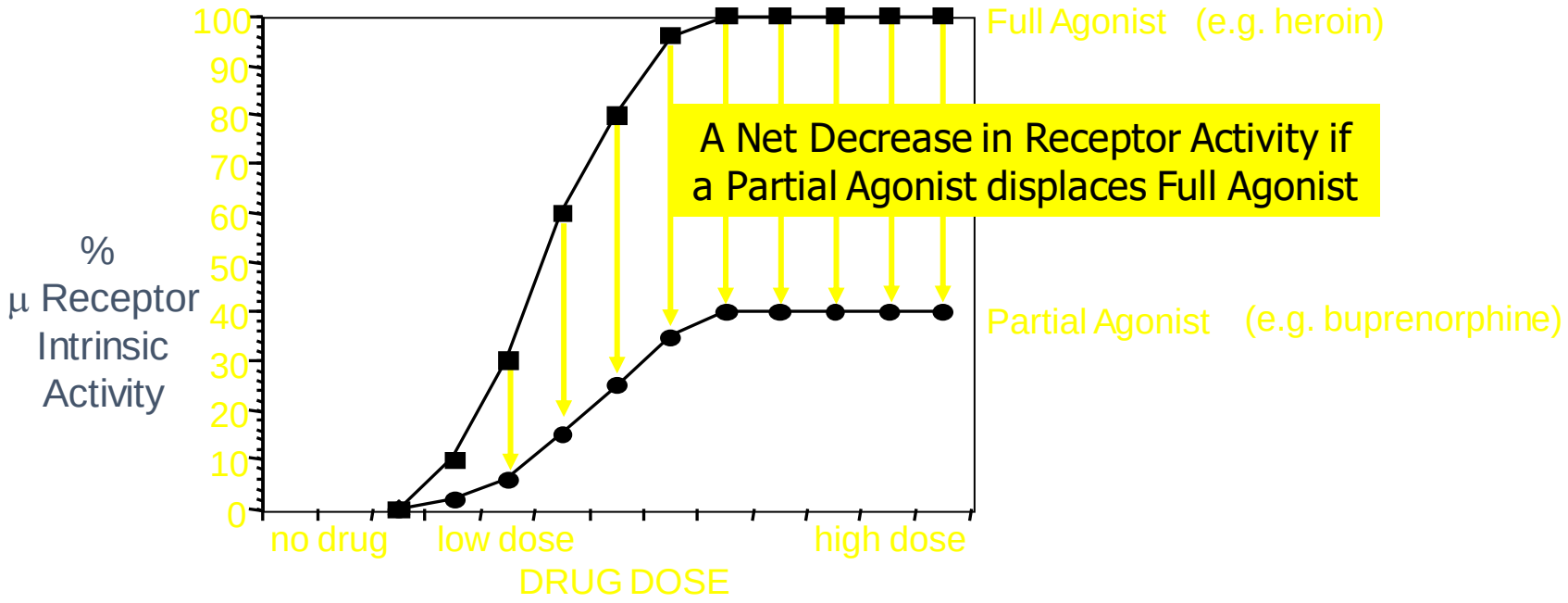
PRECIPTATED WITHDRAWAL

- Displaces full agonist off μ receptors



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Maintenance Treatment Using Buprenorphine

- Numerous outpatient clinical trials comparing efficacy of daily buprenorphine to placebo, and to methadone
- Consistently find:
  - Buprenorphine more effective than placebo in increasing retention in treatment and decreasing illicit opioid use
  - Buprenorphine equally effective as moderate doses of methadone (e.g., 60 mg per day)

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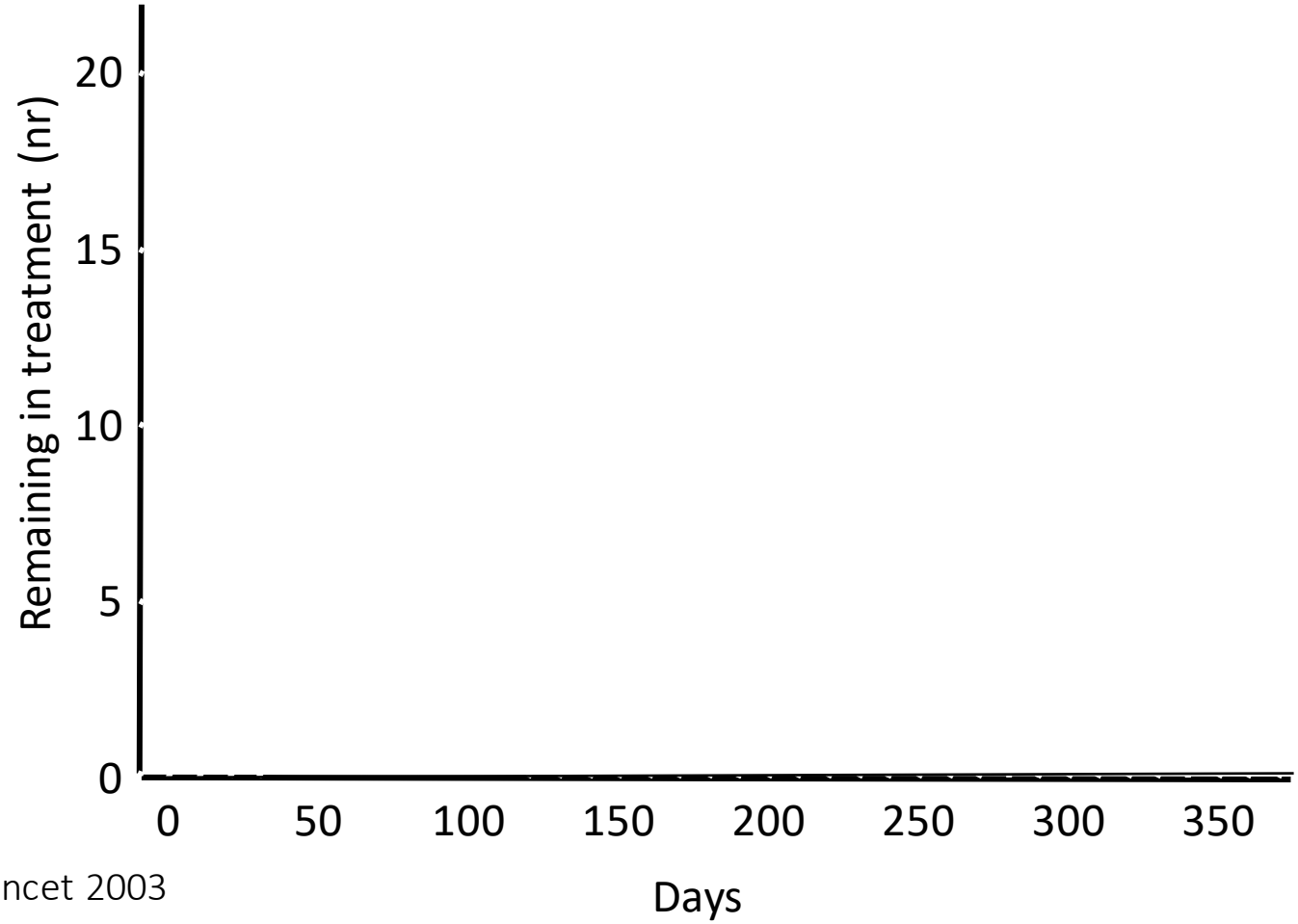
Treatment Retention: Buprenorphine-assisted Detox vs. Maintenance



Kakko, Lancet 2003

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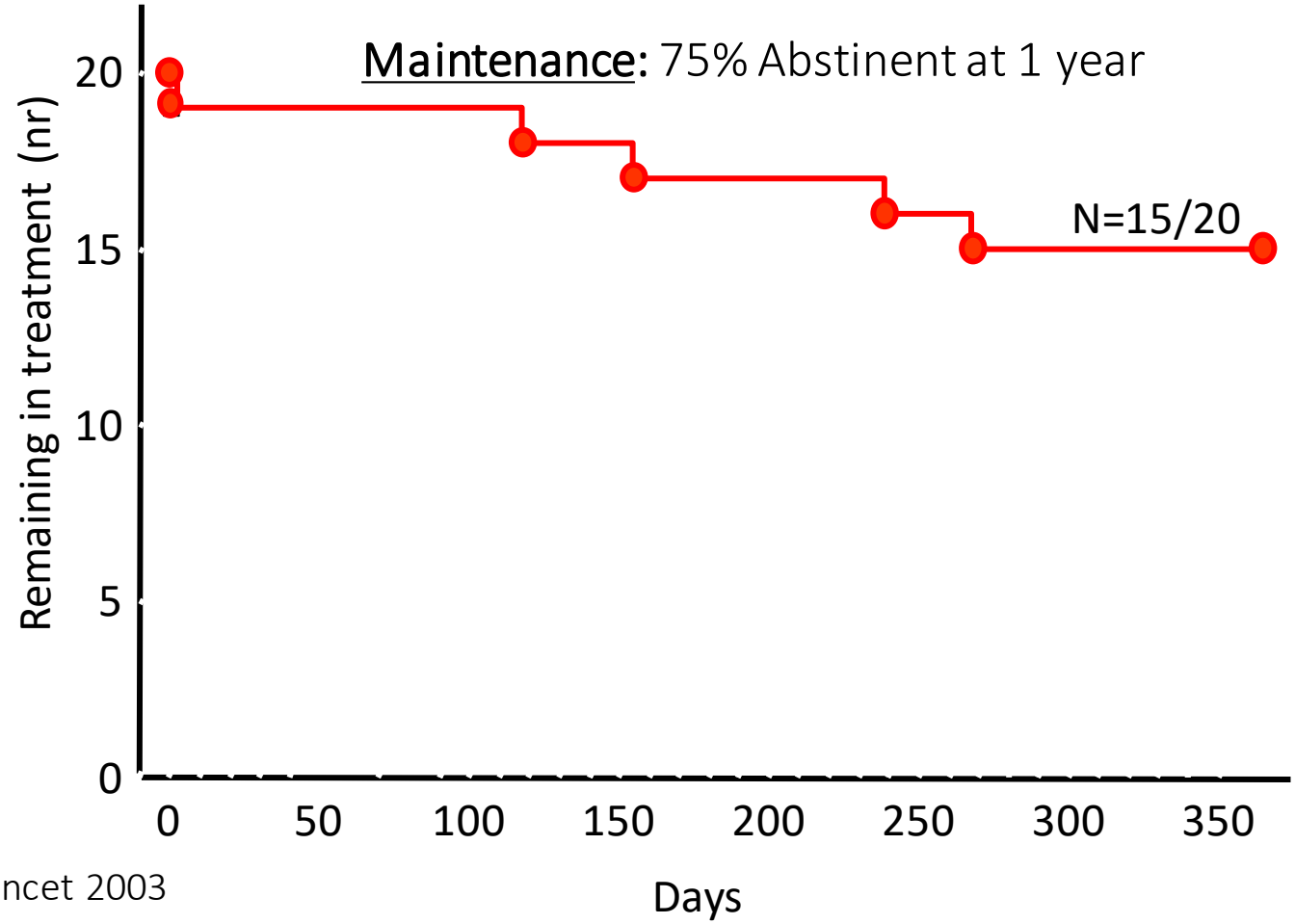
Treatment Retention: Buprenorphine-assisted Detox vs. Maintenance



Kakko, Lancet 2003

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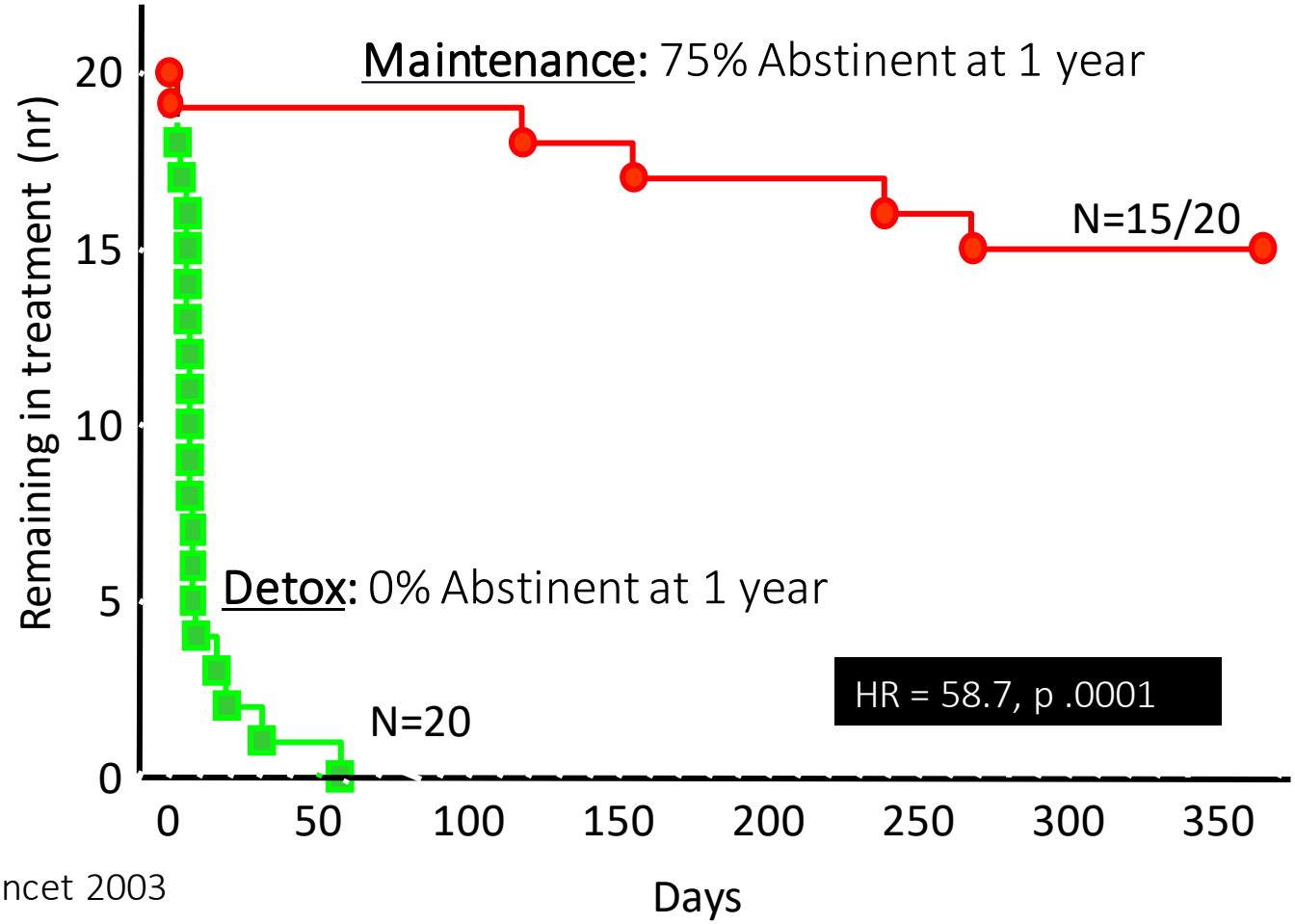
Treatment Retention: Buprenorphine-assisted Detox vs. Maintenance



Kakko, Lancet 2003

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METHADONE BUPRENORPHINE & PREGNANCY

- Less risk to the fetus than heroin
- Less adverse pregnancy outcomes
- Less adverse birth outcomes
- Less chance that mother will contract STDs, endocarditis, cellulitis, etc.
- Less chance that mother will get shot, stabbed, beaten, arrested, etc.
- Neonatal abstinence syndrome (NAS) is relatively easy to manage

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NALTREXONE

- *mu* opioid receptor antagonist
- Only works if you take it!
  - -should be observed
  - -should be dispensed as part of a comprehensive treatment program
  - -works well with professionals & probationers
- Generally very well tolerated
- Allows patient to function without constraints of a clinic
- Long-acting injection now approved for opioid
- No abuse potential

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Barriers to Medication Assisted Treatment

Associated stigma:

- Addicted to another drug
- Covering up the addiction
- Personal bias based on experience
- Adherence to abstinence-based treatment
- Negative attitudes towards individuals with addiction disorders.

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Barriers to Primary Care Physicians

- Lack of administrative support
- Financial issues/reimbursement
- Need of technical assistance
- Time constraints

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Rural America

- Disproportionally impacted
- Higher rates of opioid prescribing
- Demographic, economic and environmental factors
- Higher overdose rates
- Higher rates of neonates in withdrawal
- Physical jobs with more injuries
- Larger social networks

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Barriers to Medication Assisted Treatment in Rural Areas

- Lack of methadone programs/less than 5% in rural areas
- Methadone programs are highly regulated and require frequent attendance
- Geography/ transportation/weather
- Lack of buprenorphine waivered physicians/ less than 2% in rural areas

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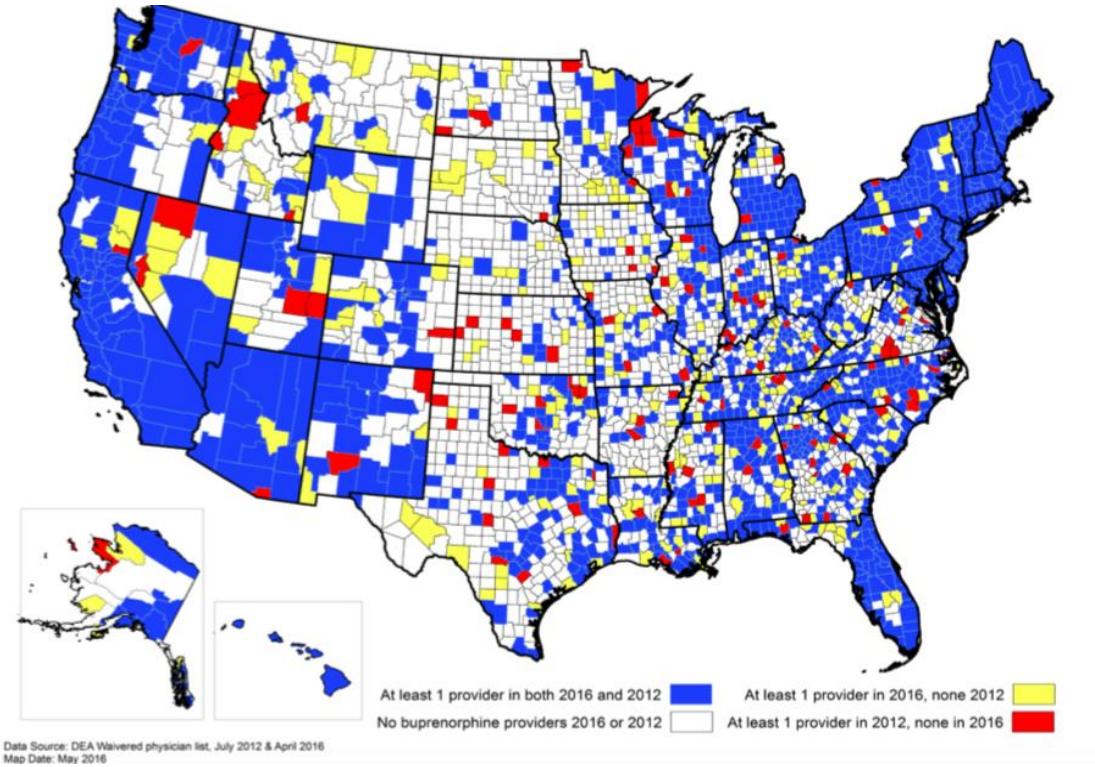
Map of U.S. Buprenorphine Providers



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MONITORING FOR DIVERSION/ADHERANCE

- Checking PDMP
- Random call-backs with pill/strip counts
- Urine toxicology
- Patient Agreements
- COORDINATION OF CARE

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URINE TESTING

Purpose:

Drug abuse & dependence are chronic disorders relapse can occur

Patients may deny or minimize use

Urine testing an integral part of on-going evaluation and treatment planning

Not to punish the patient

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URINE TESTING

Urine toxicology detection time limits

Amphetamine	2-4 days
Benzodiazepines	1-10 days
Cocaine	1-3 days
Heroin/morphine	1-3 days
Methadone	1-4 days
Marijuana	1-30 days
PCP	3-30 days

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INTERPRETATION OF UDT RESULTS

- Immunoassays report each sample as positive or negative for particular drug/class
  - Based on predetermined cutoffs
- Positive UDT results
  - Reflect recent drug use
  - Cannot determine exposure time, dose, or frequency of use

Wolff K, et al. *Addiction*. 1999;94:1279-98.
Vandevenne M, et al. *Acta Clinica Belgica*. 2000;55:323-33.

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Clinical Goals

- Immediate engagement and linkage to treatment
- Expanding access to treatment
- Co-location of medical and mental health services within addiction treatment services
- Enhancing recovery services for patients

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Conclusion

- The US and the State of Maryland are in the midst of an Opioid Epidemic which is a major public health crisis
- There are extremely lethal synthetic opioids that are being abused that are causing soaring overdose death rates
- The over prescribing of opioid pain medications has been a major contributor to the crisis
- Effective life saving treatments do exist but there are significant barriers preventing patients from accessing them

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District Addiction Consultation Service (DACS)

DACS provides support to primary care and specialty prescribers in addressing the needs of their patients with substance use disorders and chronic pain management.

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