Housekeeping Items

- Welcome to L.A. Care Provider Continuing Education (PCE) Program's Live Webinar!
- Webinar participants are muted upon entry and exit of webinar.
- ***Webinar attendance will be noted via log in and call in. There are 2 Requirements: Please log in through a computer (instead of cell phone) to Join Webinar / Join Event and also call in via telephone by choosing the Call In Option with the event call in number, event access code and assigned unique attendee ID number. If your name does not appear on the WebEx Final Attendance and Activity Report (only as Caller User #) and no submission of online survey, no CME or CE certificate will be provided.***
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- Questions will be managed through the Chat feature and will be answered at the end of the presentation. ***Please keep your questions brief and send to All Panelists.*** One of the Learning and Development Team members / Panelist and webinar co-host, will read the questions submitted via Chat when it's time for Q & A session (last 30 minutes of live webinar).
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- Any questions about L.A. Care Health Plan's Provider Continuing Education (PCE) Program and our CME/CE activities, please email Leilanie Mercurio at lmercurio@lacare.org

Presenter's Bio

Larissa Mooney, M.D., is a Professor of Clinical Psychiatry and Director of the Addiction Psychiatry Division in the Department of Psychiatry and Biobehavioral Sciences at UCLA. She directs the UCLA Addiction Psychiatry Clinic and the UCLA-VA Addiction Psychiatry Fellowship Program, where she teaches psychiatrists in training in the clinical management of substance use and mental health disorders.

Dr. Mooney previously served as the Section Chief for Substance Use Disorders at the Greater Los Angeles VA. She is the President of the American Academy of Addiction Psychiatry (AAAP), a Distinguished Fellow of the American Psychiatric Association (APA), and a fellow of the American Society of Addiction Medicine (ASAM).

Dr. Mooney has conducted research at UCLA Integrated Substance Abuse Programs (ISAP) on pharmacological and behavioral treatment interventions for addictive disorders. She is one of two Principal Investigators for the Greater Southern California Node of the National Institute on Drug Abuse (NIDA) Clinical Trials Network. She has current NIDA funding to study functional outcomes in cannabis users and treatment interventions for opioid use disorder and stimulant use disorder.

Medication Treatment for Alcohol and Opioid Use Disorders

Larissa Mooney, M.D.
Professor of Clinical Psychiatry
UCLA Division of Addiction Psychiatry

Directly Provided CME / CE Activity by L.A. Care Health Plan
Live Webinar via Cisco WebEx
October 27, 2022, 12:00 pm – 1:30 pm PST, 1.50 CME/CE Credits

Disclosures

The following CME planners and faculty do not have relevant financial relationships with ineligible companies.

- Leilanie Mercurio, L.A. Care PCE Program Manager, CME Planner
- Alex Li, MD, L.A. Care Deputy Chief Medical Officer, CME Planner
- Larissa Mooney, MD, Medical Director, International Fellowship Program, UCLA Integrated Substance Abuse Programs; Director, UCLA Addiction Psychiatry Clinic, CME Faculty

An ineligible company is any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

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Learning Objectives

1) List three (3) approved medications for the treatment of alcohol use disorder.

2) Identify three (3) approved medications for the treatment of opioid use disorder.

3) Describe the mechanism of action of acamprosate, disulfiram, buprenorphine, methadone, and naltrexone.

4) Identify three (3) opioid overdose risk factors that warrant naloxone education and prescription.

Overview

- Alcohol Use Disorder (AUD) Medications
  - Approved meds: disulfiram, acamprosate, naltrexone
  - Off-label: gabapentin, topiramate
- Opioid Use Disorder (OUD) Medications
  - Buprenorphine
  - Naltrexone
  - Methadone

Introduction

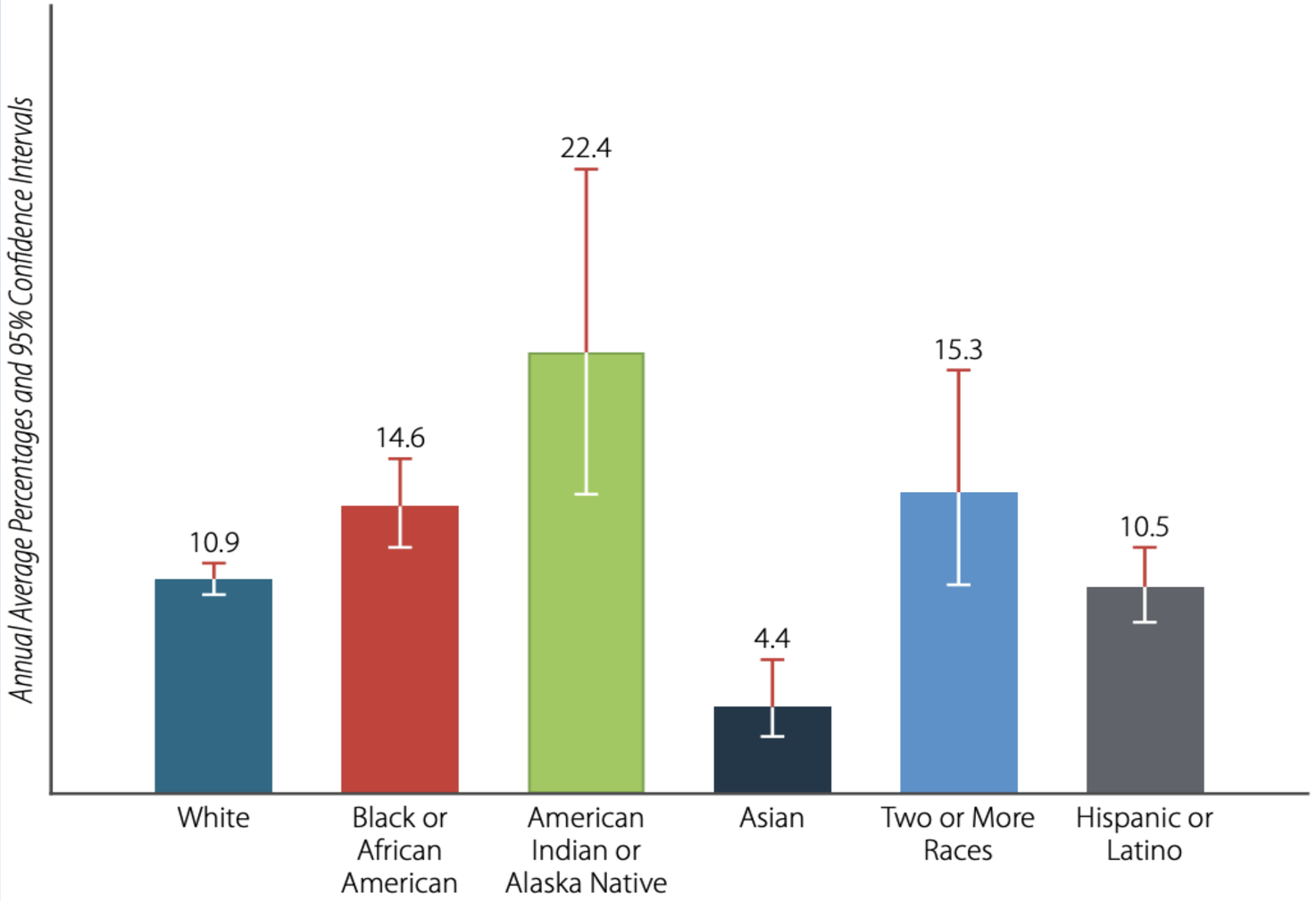
- Addiction is a chronic, relapsing brain disease characterized by compulsive use despite harmful consequences
- Medications may be used as part of *comprehensive* treatment plan
- Treatment approaches incorporate Bio-Psycho-Social Model:
  - Medications (Bio)
  - Therapy, lifestyle changes (Psycho-Social)

Medications for AUD are Underutilized

- Alcohol use disorder (AUD) is one of only 3 substance use disorders with FDA approved medications (tobacco, opioids, alcohol)
- Also non-approved pharmacotherapy options with some efficacy
- 14.5 million US adults had AUD in 2019
- Yet very little use of AUD medications
- Only about 7% individuals with AUD receive formal treatment including medications (NSDUH 2019)

SAMHSA, Center for Behavioral Health Statistics and Quality.
2019 National Survey on Drug Use and Health.

FIGURE 6.1 **Received Alcohol Use Treatment at Any Location in the Past Year among People Aged 12 or Older Who Needed Alcohol Use Treatment in the Past Year, by Race/Ethnicity: 2015–2019, Annual Averages**



Note: Estimate of Native Hawaiian or Other Pacific Islander not reported due to low precision.

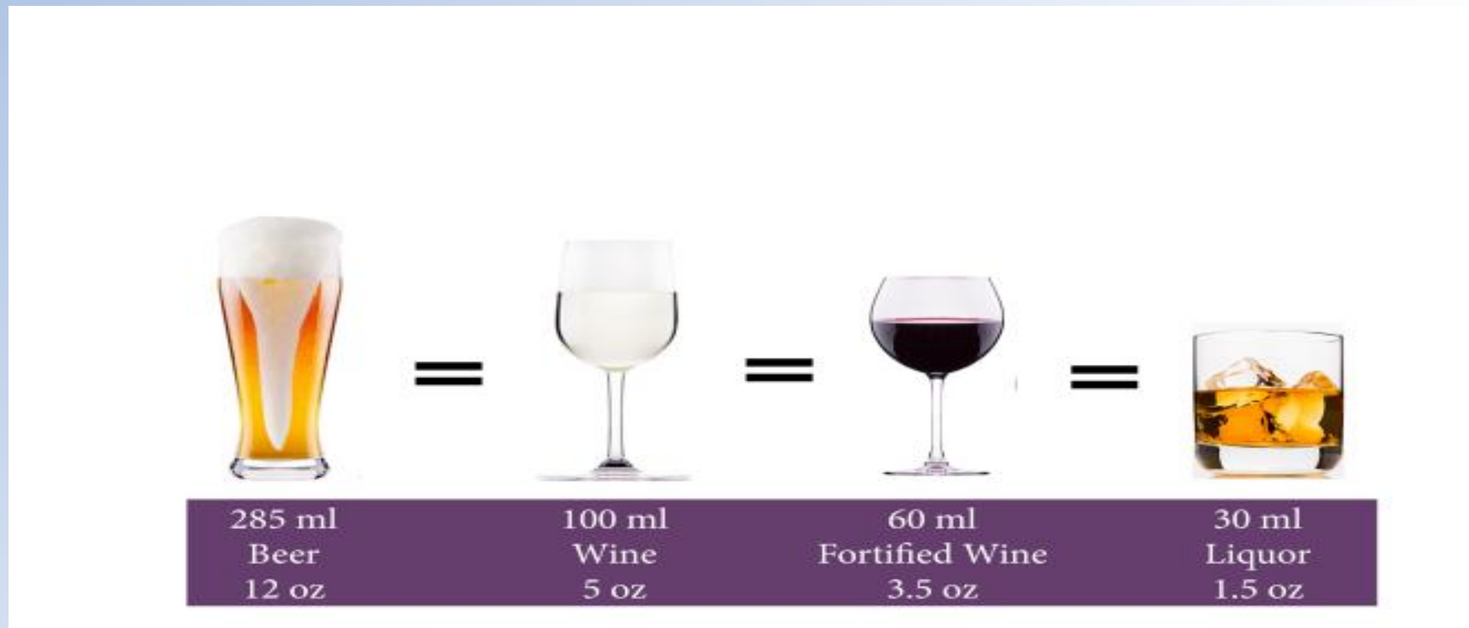
Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2015–2019.

“One Glass” of Alcohol

2020-2025 US Dietary Guidelines

Moderate drinking cutoffs:

- **Men**: No more than **2** drinks/day
- **Women**: No more than **1** drink/day



NIAAA Standard Drink Equivalents

Rethinkingdrinking.NIAAA.gov

Four Main Neurotransmitters Relevant to Alcohol Effects

endogenous opioids
reduce pain and cause euphoria

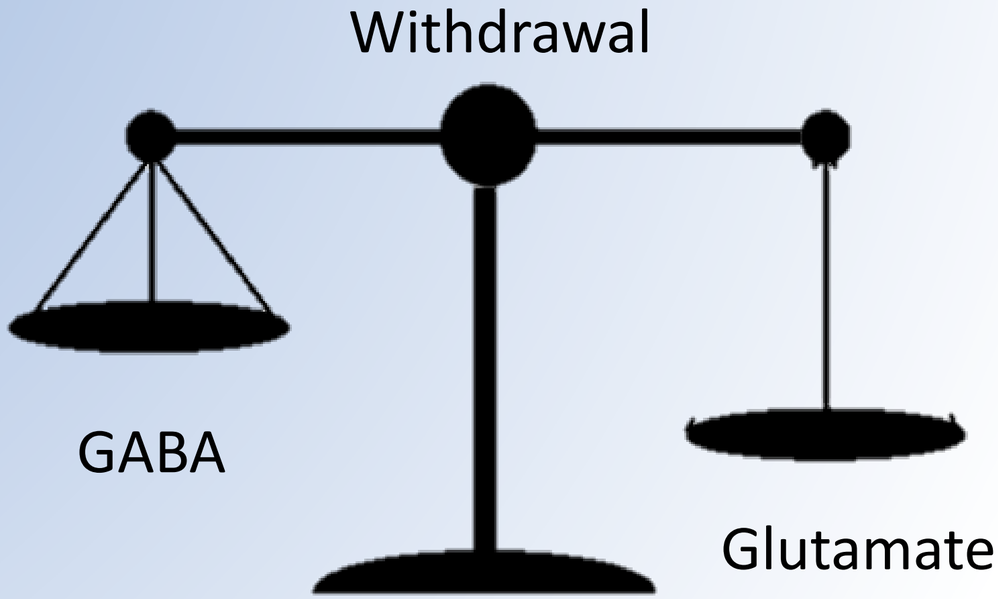
glutamate
excitatory neurotransmitter…
speeds you up

dopamine
causes pleasure and reward

GABA
inhibitory neurotransmitter…
slows you down

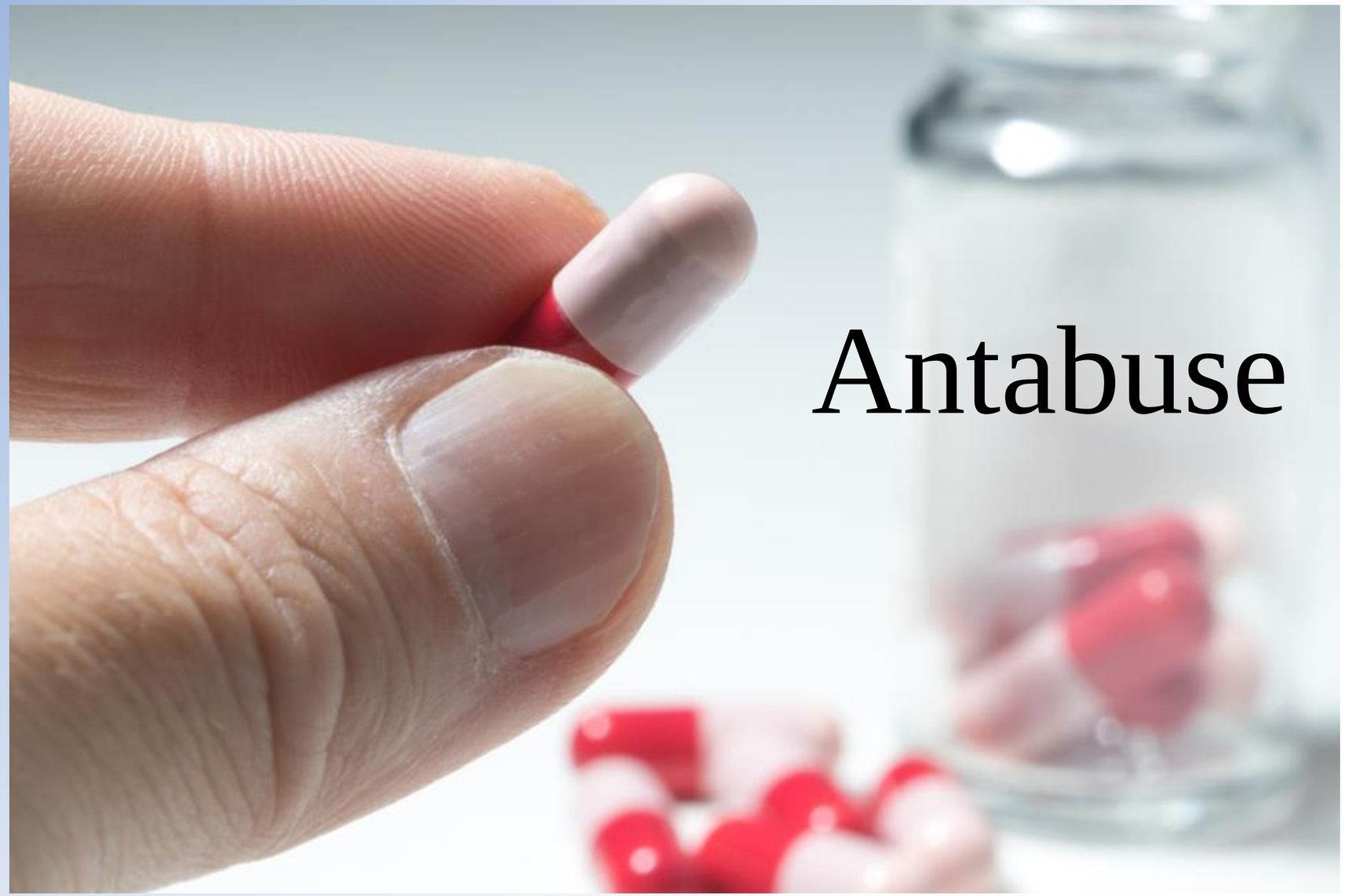
Neuronal Activity During Withdrawal

If alcohol is abruptly discontinued = Withdrawal



Symptoms/Risks: tremulousness, anxiety, elevated vital signs, seizures, delirium tremens (potentially fatal)

Disulfiram



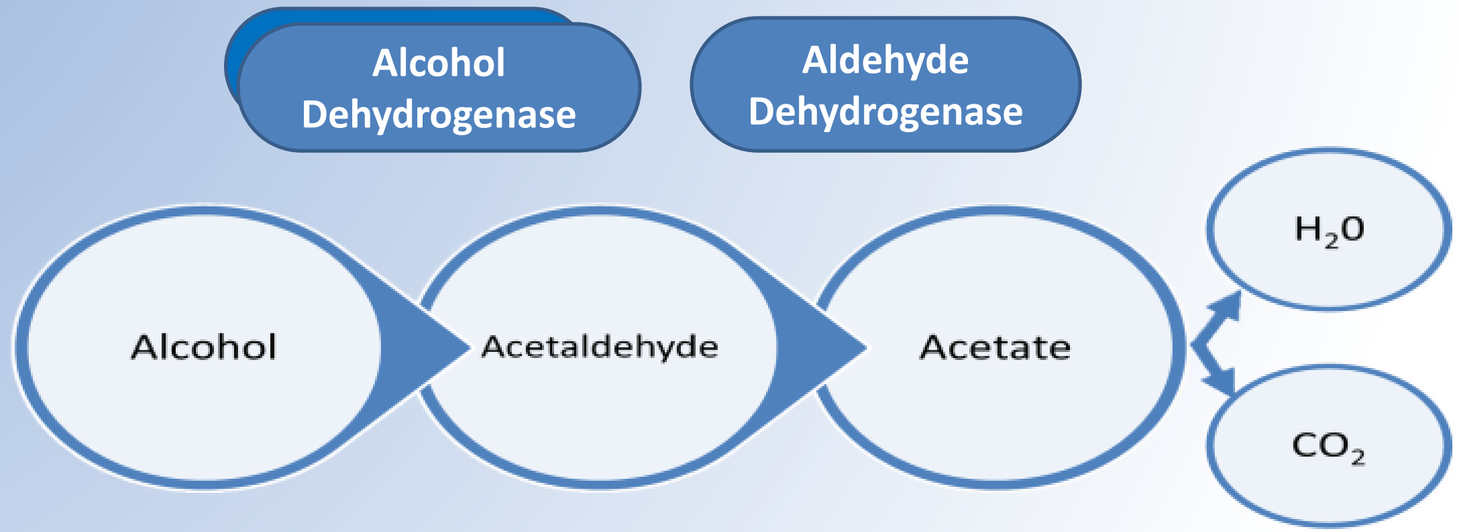
Disulfiram

- Marketed as Antabuse®
- FDA Approved in 1951
- Indication: An aid in the management of selected individuals with AUD who want externally “enforced sobriety” so that supportive and psychotherapeutic treatment may be applied to best advantage.
- Disfulfiram discourages drinking by causing unpleasant physical effects when alcohol is consumed.

Additional Disulfiram Information

- **Third-Party Payer Acceptance:** covered by most major insurance carriers, Medicare, Medicaid, and the VA.
- **Dosing:** 250-500 mg by mouth per day
- **Abstinence Requirements:** must be taken at least 12 hours after last alcohol use
- **Adverse Effects:** metallic taste, hepatotoxicity, optic neuritis, peripheral neuropathy

Disulfiram Mechanism of Action



Disulfiram works by irreversibly blocking the enzyme aldehyde dehydrogenase. This causes acetaldehyde to accumulate in the blood at **5 to 10 times higher amounts** than what would normally occur with alcohol alone.

Disulfiram-Alcohol Reaction

Since acetaldehyde is toxic, a buildup of it produces a highly unpleasant series of symptoms

- throbbing in head/neck
- brief loss of consciousness
- throbbing headache
- lowered blood pressure
- difficulty breathing
- marked uneasiness
- copious vomiting
- nausea
- flushing
- sweating
- thirst
- weakness
- chest pain
- dizziness
- palpitation
- hyperventilation
- rapid heartbeat
- blurred vision
- confusion
- respiratory depression
- cardiovascular collapse
- myocardial infarction
- congestive heart failure
- unconsciousness
- seizures
- death

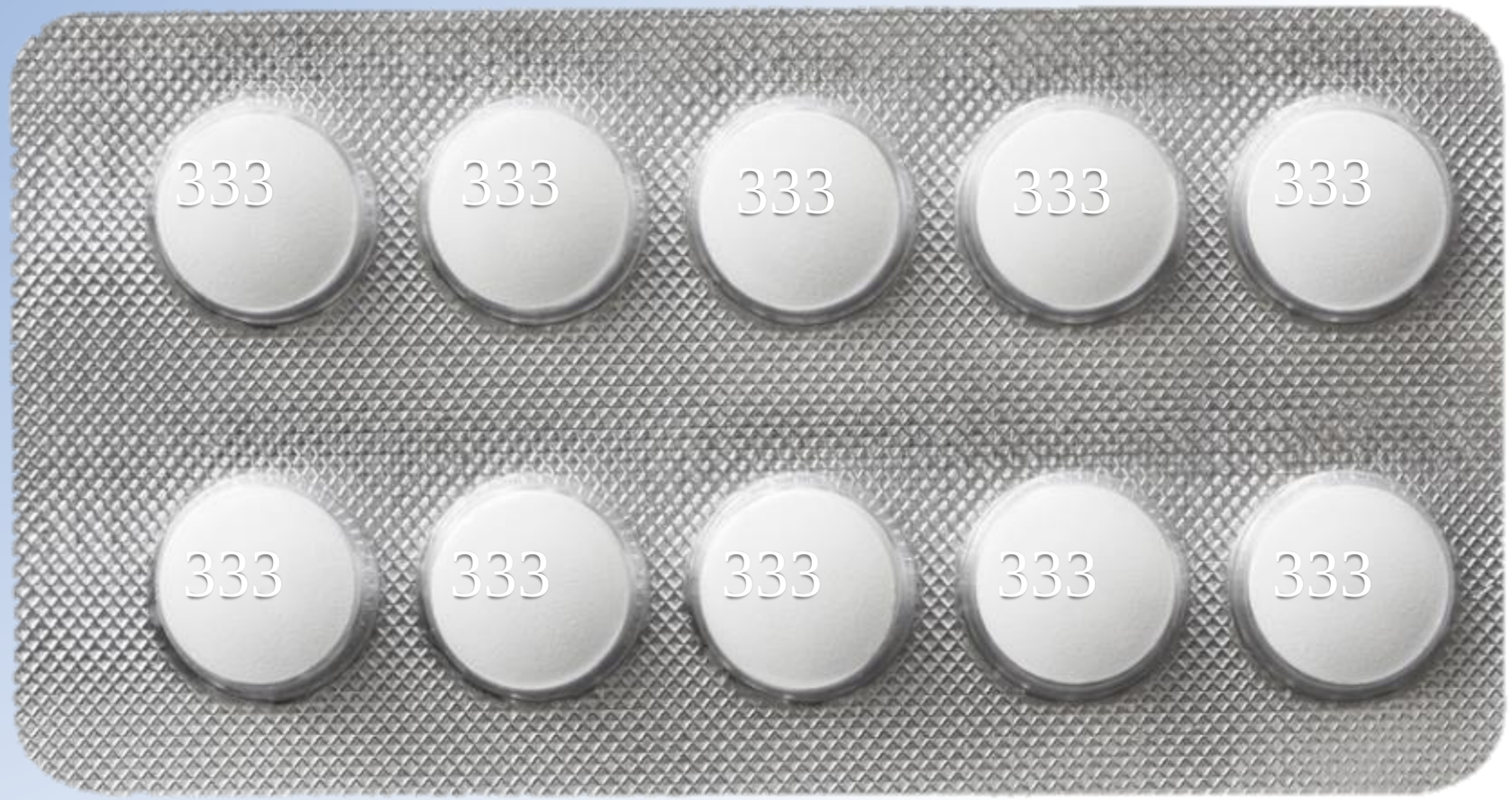
Disulfiram Contraindications

- The disulfiram-alcohol reaction usually lasts for 30 to 60 minutes, but can continue for several hours depending on the amount of alcohol consumed.

- Should never be administered to a patient when he or she has consumed alcohol recently or is currently intoxicated from alcohol.

- Should never be administered to a patient that has consumed alcohol-containing preparations such as cough syrup, tonics, etc.

Acamprosate



Acamprosate

- Marketed as Campral®
- FDA Approved in 2004
- **Dosing**: two 333 mg tablets PO three times a day
- **Indication**: For the maintenance of abstinence from alcohol in patients with alcohol use disorder who are abstinent at treatment initiation by reducing post-acute withdrawal symptoms.
- **Side effects**: diarrhea, GI upset
- Renal clearance; thus dose adjustment required in renal impairment

Acamprosate Mechanism of Action

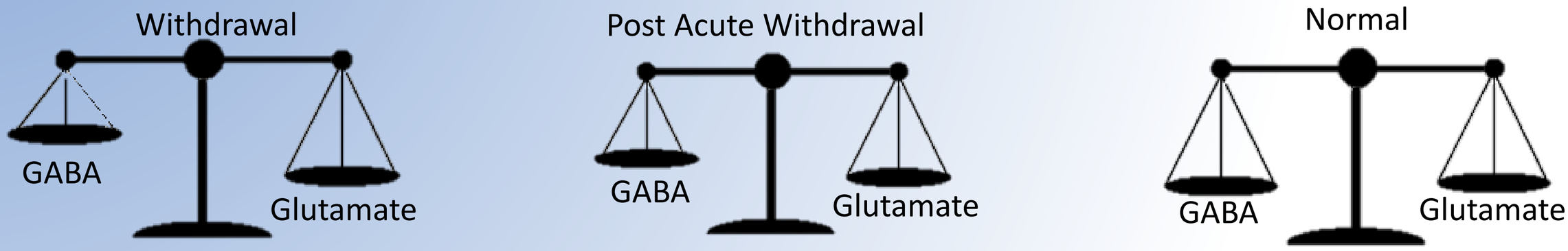
While the exact mechanism of action is not known, Acamprosate is thought to be:

a glutamate receptor modulator

The brain responds to repetitive consumption of alcohol by increasing glutamate receptors, thereby counteracting alcohol's depressive (GABAergic) effects.

Scott et al., 2005

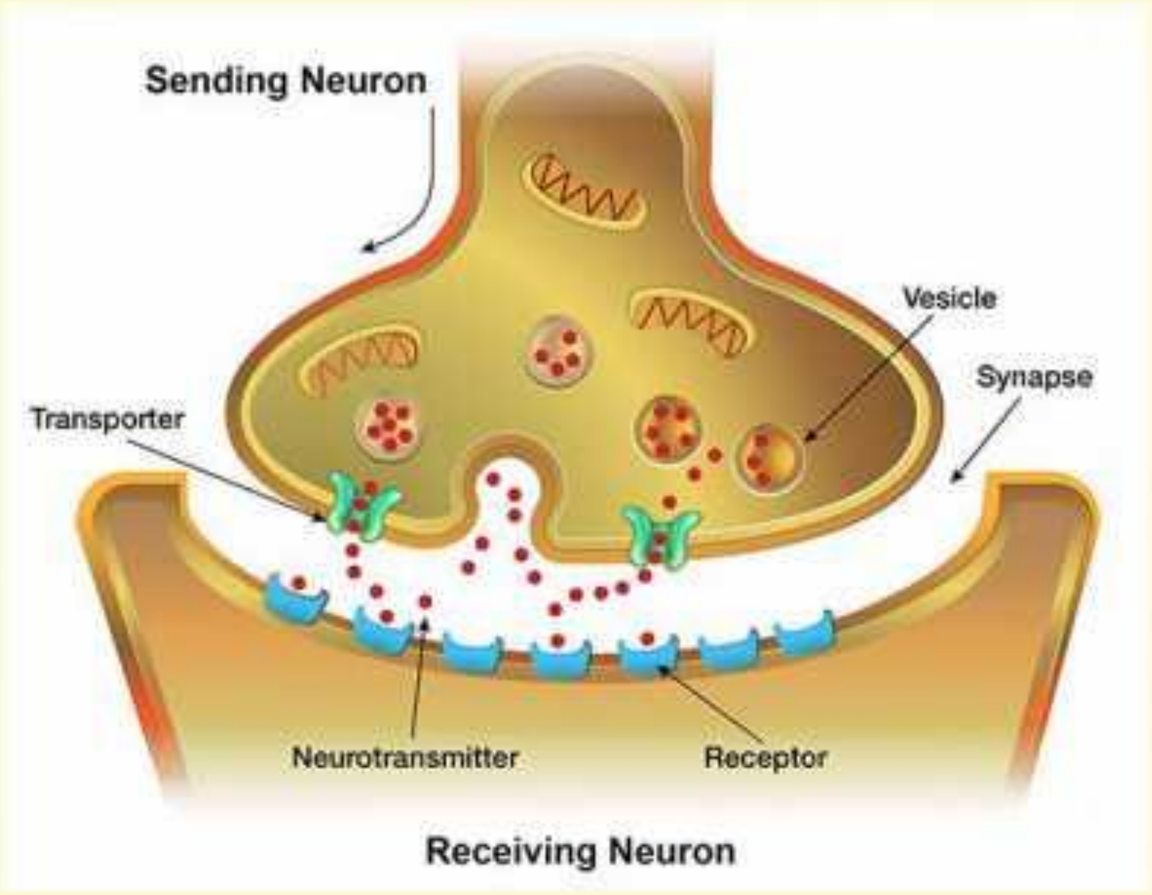
How Does Acamprosate Work?



- Even after acute withdrawal, the glutamate system continues to be overactive as it readjusts by down regulating the glutamate receptors.
- During this time, individuals may continue to feel anxiety, irritability and insomnia that can lead to relapse.

Acamprosate and Glutamate

- Acamprosate is thought to reduce amount of glutamate released, and
- Reduce the activity of the glutamate receptors



Research on Acamprosate for AUD

- In studies leading to FDA approval, participants treated with acamprosate were able to **maintain complete abstinence** more frequently and had **prolonged time to first drink** than those treated with placebo.

- Participants treated with acamprosate had a greater reduction in the number of drinking days during the entire study than those treated with placebo.

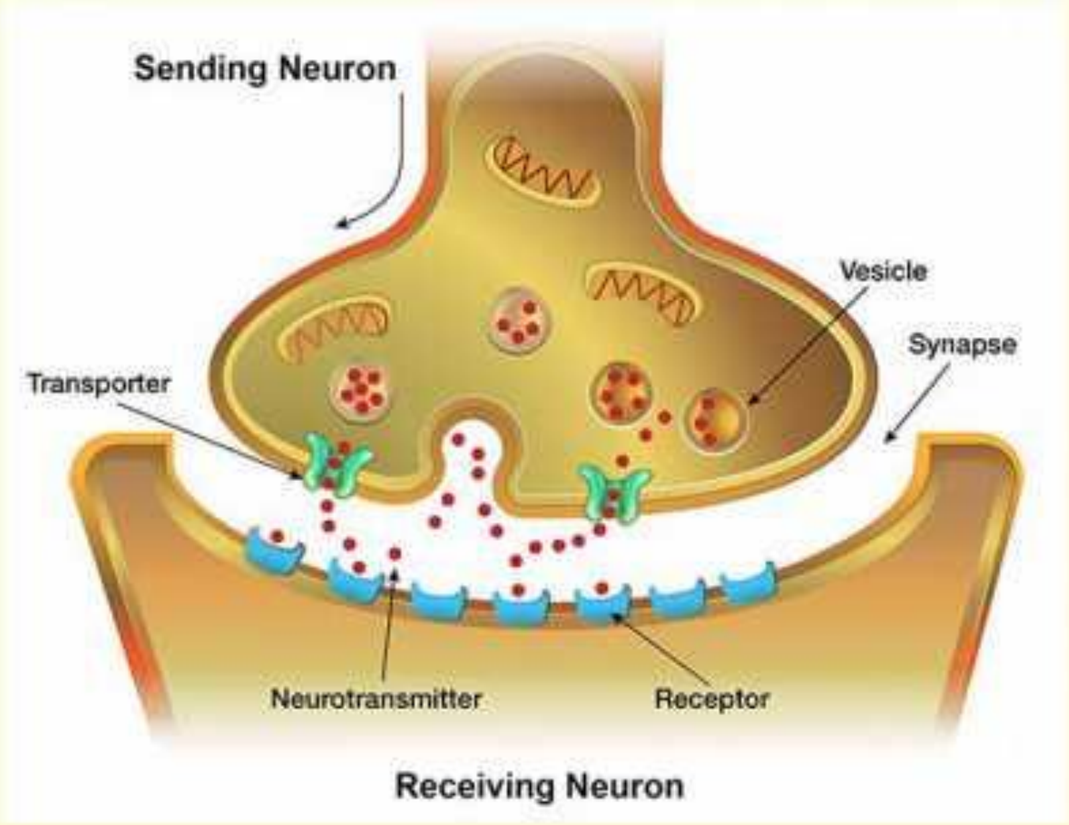
- In all three studies, participants treated with acamprosate were able to **regain complete abstinence** after one relapse more frequently than those treated with placebo.

Pelc et al., 1997; Sass et al., 1996; Paille et al., 1995

Naltrexone

Naltrexone Mechanism of Action

- Naltrexone is an opioid receptor antagonist and blocks opioid receptors.
- This prevents the effects of self-administered opioids.
- Subsequent dopamine release is also diminished after alcohol consumption, reducing the pleasurable effects.



Naltrexone Hydrocholoride

- Marketed As: ReVia® and Depade®
  - **Indication**: Used in the treatment of alcohol or opioid use disorder; used for blockade of the effects of exogenous administered opioids and/or decreasing the upleasurable effects experienced by consuming alcohol.
- **Dosing**: 50 mg PO per day
- Administering naltrexone will cause opioid withdrawal symptoms in patients who are physically dependent on opioids.
  - **Side Effects**: nausea, vomiting, depression, elevated liver function enzymes

Additional Information

- **Third-Party Payer Acceptance**: covered by most major insurance carriers, Medicare, Medicaid, and the VA.

- **Abstinence requirements**: must be taken at least 7-10 days after last consumption of opioids; abstinence from alcohol is not required.

Research on Naltrexone for AUD

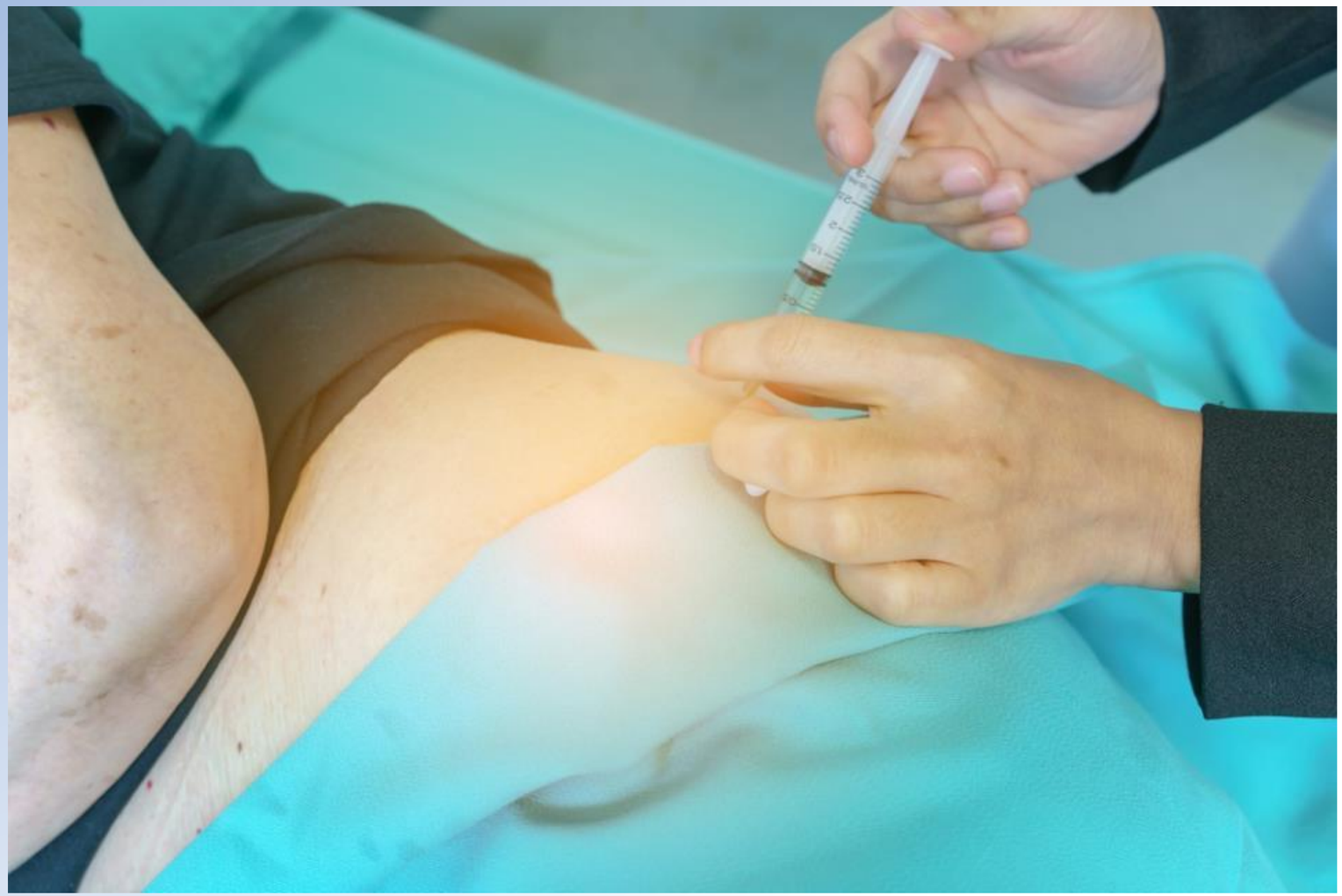
- In some studies, participants treated with naltrexone were not able to maintain complete abstinence more frequently than those treated with placebo.

- More consistently, participants treated with naltrexone had a **greater reduction in relapse** during the study than those treated with placebo and had reduced cravings.

- Participants treated with naltrexone had **fewer heavy drinking days** than those treated with placebo

Volpicelli et al., 1992; Pettinati et al., 2006

Extended-Release Injectable Naltrexone



Extended-Release Naltrexone

- **Dosing:** 380mg injection in deep gluteal muscle every 4 weeks; alternate sides each month.

- Blocks opioid receptors for **one entire month** compared to approximately 28 doses of oral naltrexone.

- **Adverse effects:** injection site reactions, nausea/vomiting, precipitated opioid withdrawal, depression, elevated LFTs

- ***Note:*** *Large doses of opioids may be required to override the blockade in a medically monitored setting*.

Topiramate for AUD

- Approved as anticonvulsant and for migraine prophylaxis
- Off-label for AUD, good evidence from clinical trials in reduction of heavy drinking days, drinking outcomes
- Mechanism of action: facilitates GABA neurotransmission, inhibits AMPA-kainate glutamate transmission
  - May reduce post-withdrawal dysphoria, cravings, impulsivity
- Studies have titrated dose slowly up to 300 mg/day
- Adverse effects: cognitive, paresthesias, dizziness, altered taste, weight loss; (rare: kidney stones, metabolic acidosis, narrow-angle glaucoma)

Johnson et al., 2007; 2008

Gabapentin for AUD

- Off-label but emerging evidence for use in treatment of alcohol use disorder
- Proposed mechanism: reduction of post-acute withdrawal symptoms (anxiety, insomnia, etc.)
- Study results: Improved rates of abstinence and heavy drinking, particularly at 1800 mg/day total dose (titrate from lower dose, e.g. 300 mg PO TID)
- Improved symptoms of insomnia, dysphoria, and craving
- Improved outcomes in 1st 6 weeks when added to naltrexone
- Adverse effects: dizziness, fatigue, GI sx's, headache, impaired coordination, abuse potential

Mason et al., 2014 and Anton et al., 2011

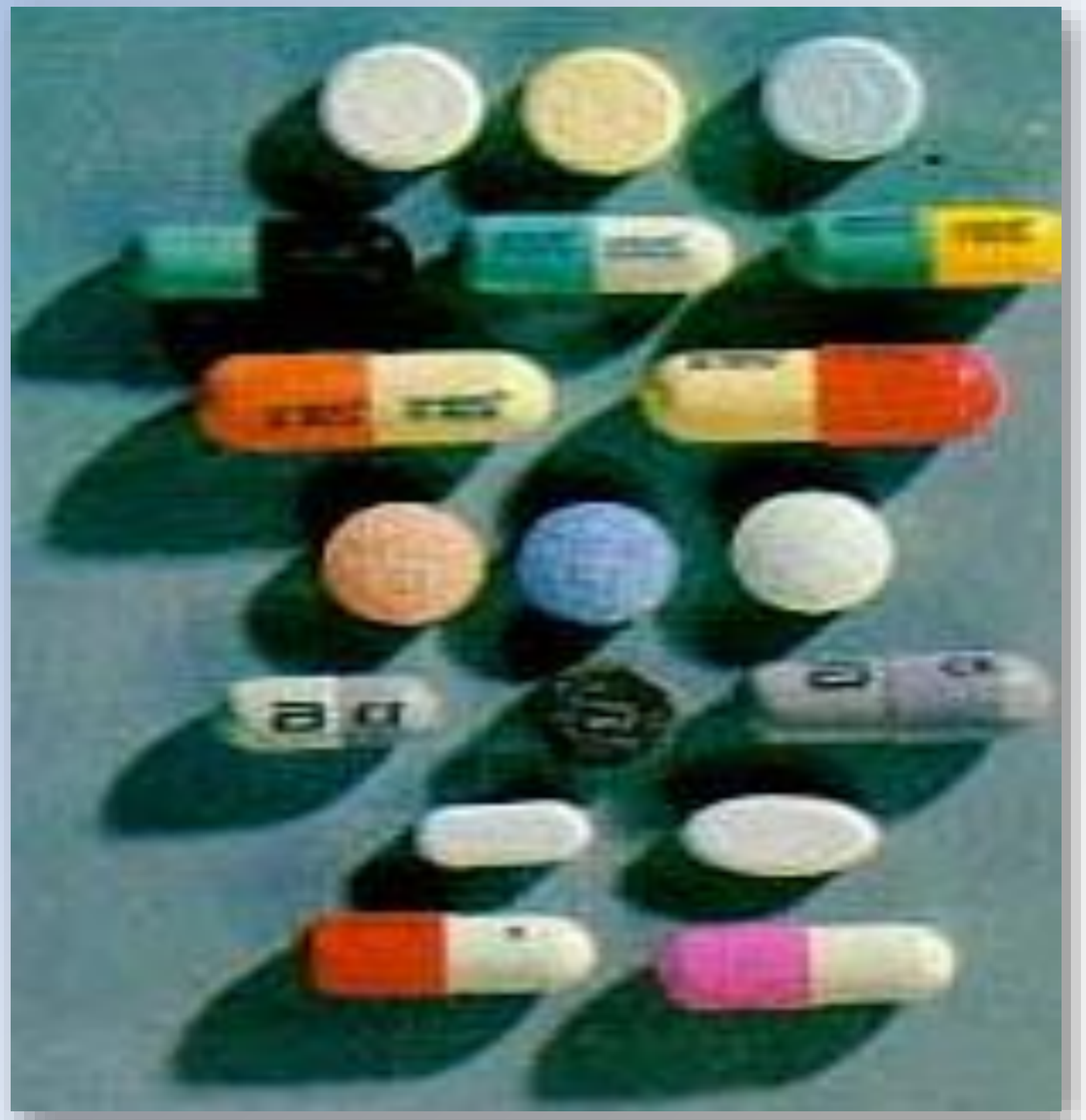
Case Vignette: Primary Care Setting

- 52 y.o. man with long history of heavy drinking, reports daily consumption of 2 bottles wine
- Denies other substance use and endorses symptoms of depression and insomnia
- Meets criteria for alcohol use disorder (AUD), moderate severity, and endorses cravings for alcohol
- Liver function enzymes are elevated 2 Xs upper limit of normal; macrocytosis is only other lab abnormality
- Denies symptoms of alcohol withdrawal or history of complicated withdrawal
- Has never received treatment for AUD or psychiatric disorder
- Has a history of chronic lower back pain for which he takes low-dose oxycodone 1-2 X/s month during flare-ups

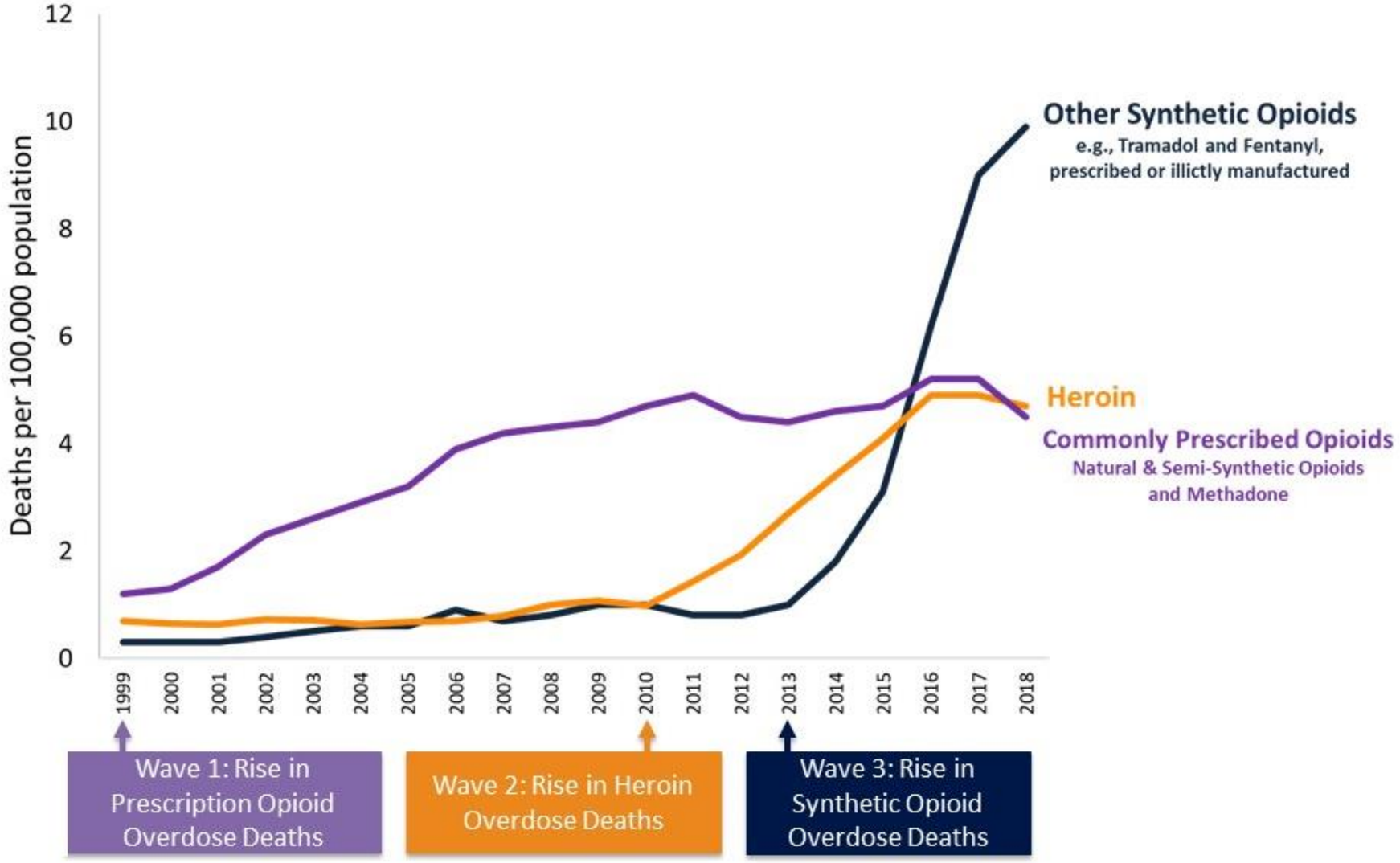
Question 1

Which medication would you consider for treatment of alcohol use disorder in this patient?

1. Acamprosate
2. Disulfiram
3. Naltrexone (PO or IM)
4. Gabapentin
5. Topiramate



3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

CDC: https://www.cdc.gov/drugoverdose/epidemic/index.html

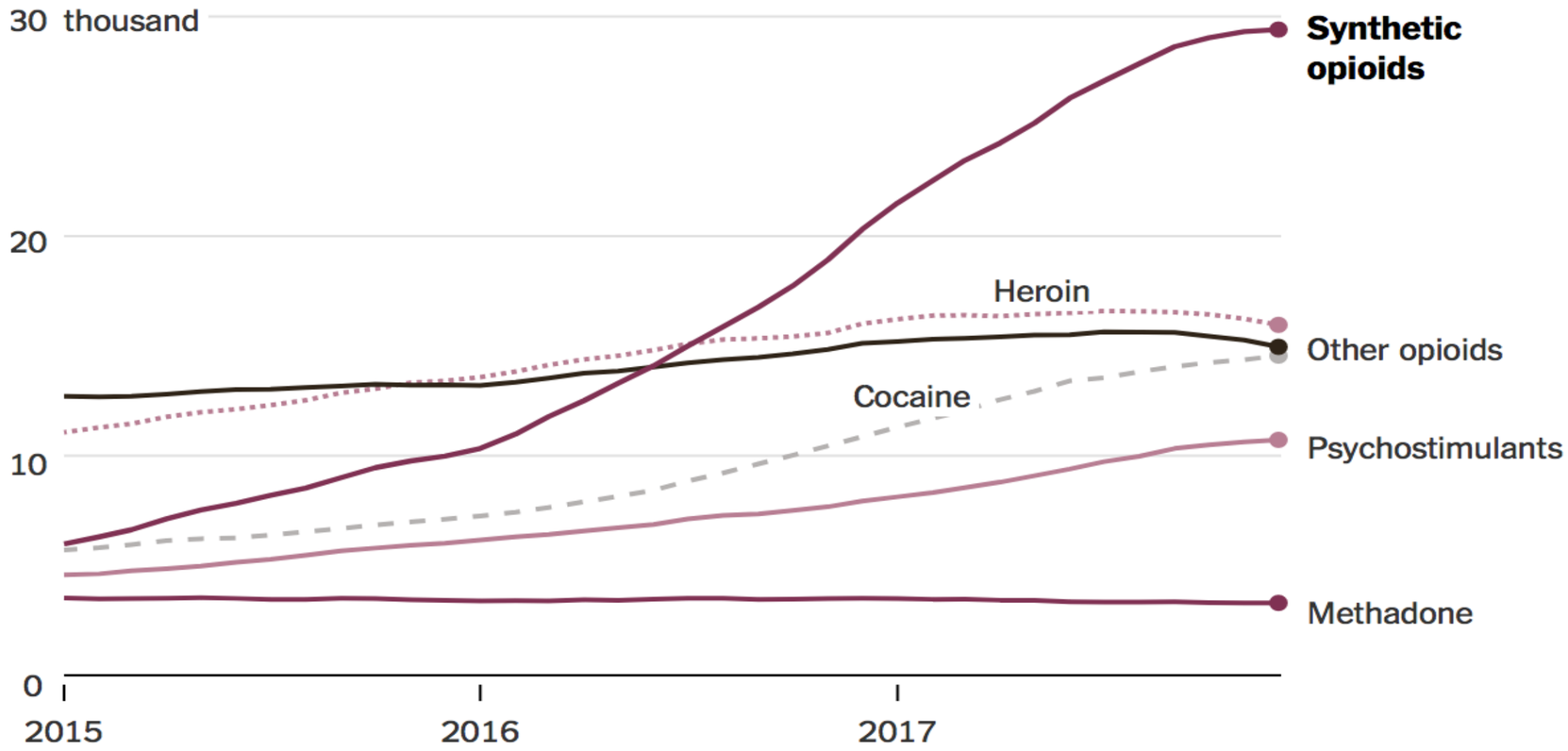
Nonmedical Opioid Use and Overdose: Epidemiology

- 4 in 5 individuals who use heroin started out misusing prescription painkillers. As a consequence, the rate of heroin overdose deaths nearly quadrupled from 2000 to 2013.
- In 2017, the number of opioid-related overdose deaths was 6 times higher than in 1999.
- 2021 overdose rates CDC: 100,306 drug overdose deaths in U.S., with about 75.4% linked to opioids
  - Increase in synthetic opioid-related deaths, and stimulant-related

CDC 2020; 2014 NSDUH, Hedegaard MD et al, 2015

Synthetic Opioids Are Driving Up the Overdose Rate

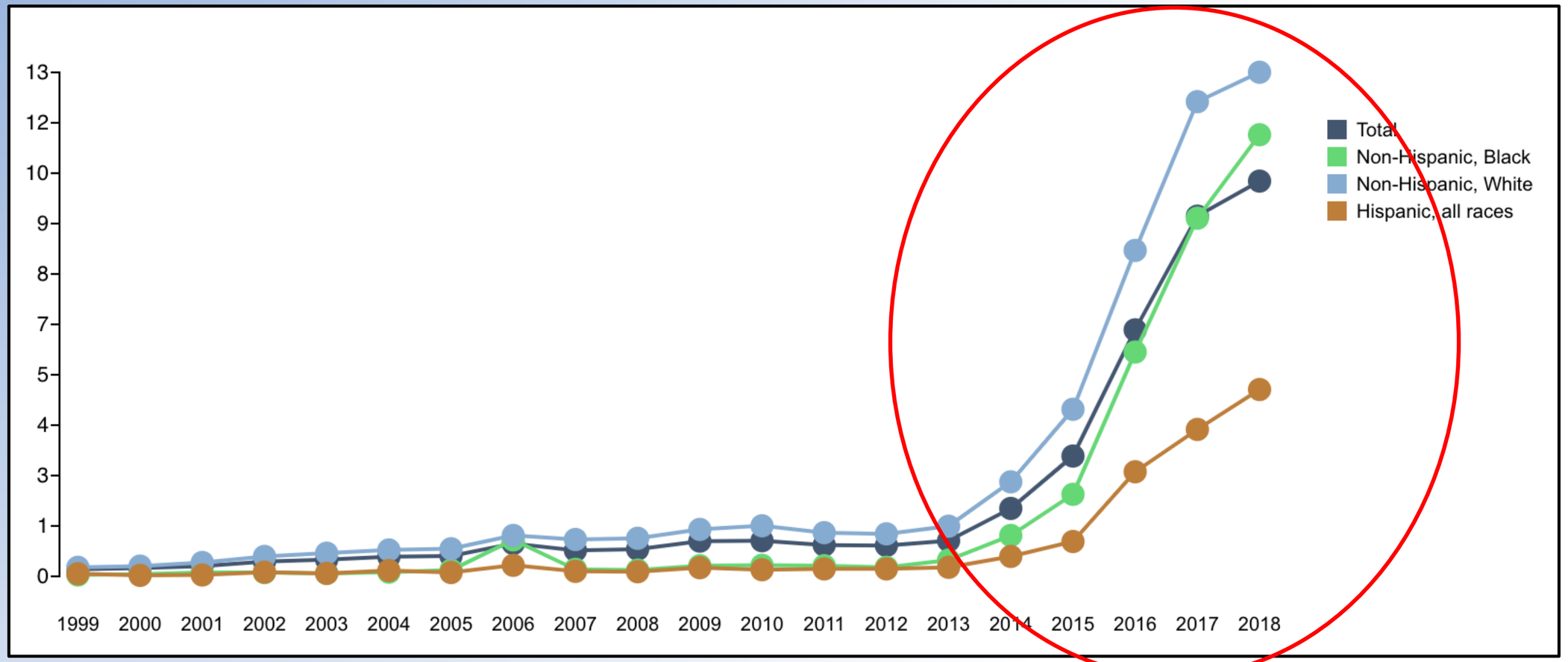
Overdose deaths in thousands in preceding 12 months



Note: These numbers are adjusted to account for some death investigations that are not completed. Some deaths involve more than one drug.

By The New York Times | Source: The Centers for Disease Control and Prevention

Drug Overdose Deaths Involving Synthetic Opioids, Excluding Methadone, Per 100,000 Resident Population Per Year, 1999-2018



Source: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System - Mortality.

Opioid Use Disorder Treatment Approaches

- Medically assisted withdrawal management (detox):
  - Opioid-based (methadone, buprenorphine)
  - Non-opioid based (clonidine, lofexidine, supportive meds)
- Relapse prevention:
  - Agonist maintenance (methadone)
  - Partial agonist maintenance (buprenorphine)
  - Antagonist maintenance (IM naltrexone)
- Psychosocial treatment
  - To promote lifestyle and behavior change

Why Not Detoxification?

POST-DETOXIFICATION RELAPSE RATES APPROACH 100% WITHIN THE FIRST 90 DAYS FOLLOWING COMPLETION OF DETOXIFICATION.

Buprenorphine

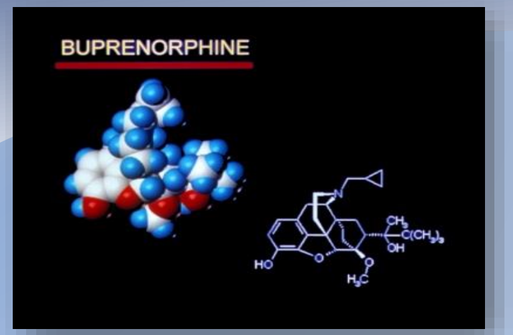
Transmucosal Buprenorphine Formulations

- Sublingual dose: 2mg-24mg/day
- Subutex (buprenorphine) (2mg, 8mg)
- Suboxone (4:1 bup:naloxone)
  - -2mg/0.5 mg , 8mg/2mg
  - -(now also in 4mg/12mg)
- Zubsolv (4:1 bup:naloxone)
  - -(1.4/0.36mg- 11.4/2.9mg)
- Bunavail (6:1 buccal film bup:naloxone)
  - -(2.1/0.3mg, 4.2/0.7mg, 6.3/1mg)
- Belbuca (75-900mcg buccal film for pain)

Buprenorphine for Opioid Use Disorder

- FDA approved 2002, age 16+
- Mandatory certification from DEA (100 pt. limit, or 275 with certifications)
- Mechanism: partial mu agonist
- Office-based, expands availability
- Analgesic properties
- Ceiling effect
- Safer in overdose

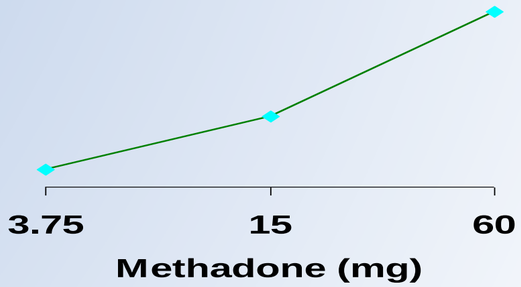
Suboxone Tablets 8mg. and 2mg

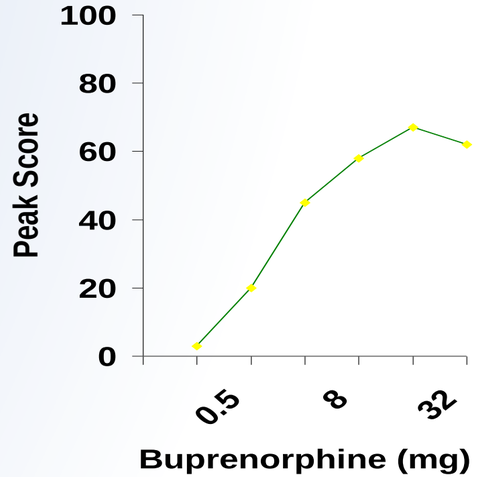


Buprenorphine: Pharmacological Characteristics

Partial Agonist (ceiling effect)

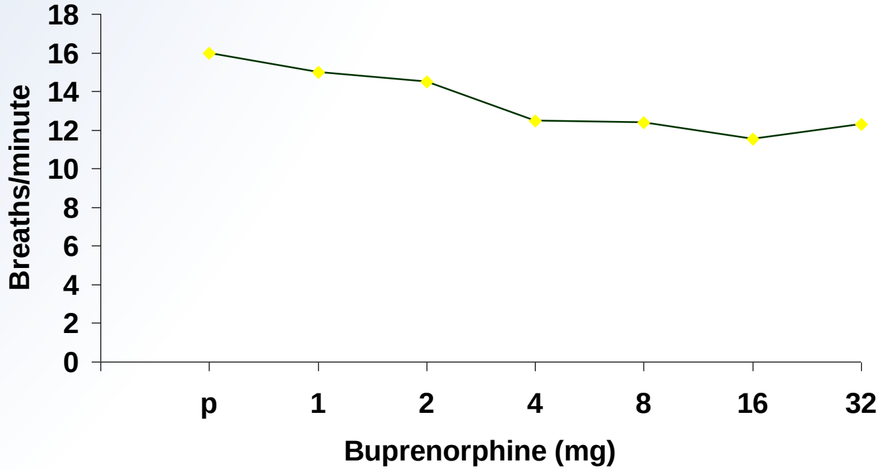
- less euphoria
- safer in overdose





Strong Receptor Binding

- long duration of action
- 1st dose given during withdrawal



Extended-Release Injectable Naltrexone for Opioid Use Disorder (OUD)

Research About Extended-Release Naltrexone for OUD

When compared to placebo, those receiving extended-release naltrexone for 6 months:

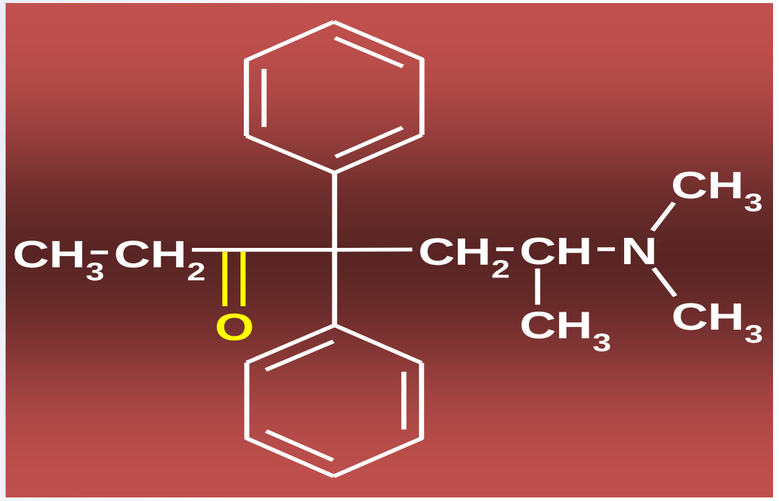
- Had fewer opioid positive urines
- Stayed in treatment longer (improved retention)
- Had fewer cravings
- Showed greater improvement in the mental component of quality of life and overall health status
- Generally tolerated the medication without significant adverse effects

Krupitsky, et al., 2010

Methadone

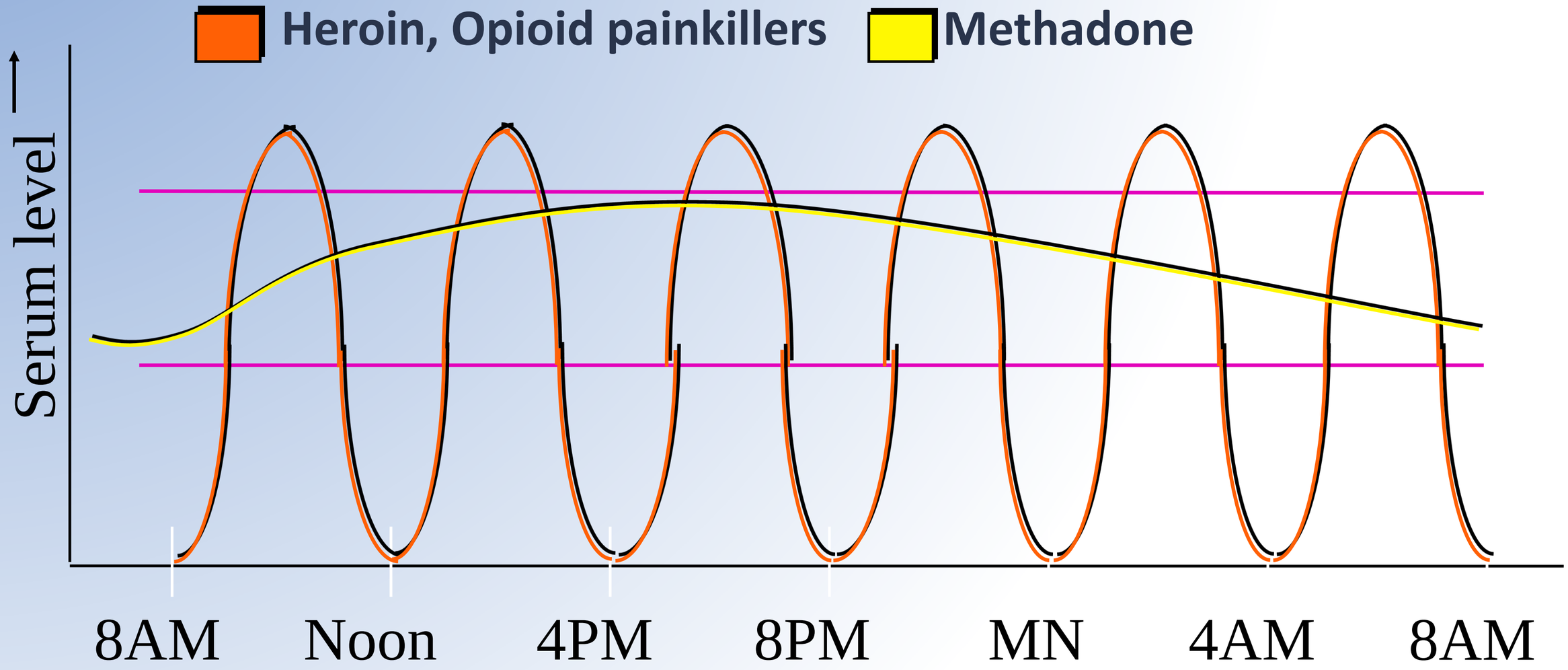
- Alleviates opioid withdrawal and craving (without intoxication)
- Also known under brand names:
  - Methadose®
  - Dolophine®
- FDA approved in 1964

Methadone: Clinical Properties



- Orally active synthetic μ agonist
- Action: CNS depressant/ analgesic
- Long half-life, slow elimination
- Effects last 24 hours
- Once daily dosing maintains constant blood level
- Prevents withdrawal, reduces craving and use
- Facilitates rehabilitation
- Clinic dispensing limits availability

Blood levels: methadone vs. short-acting opioids



Treatment Outcome Data: Methadone

- 8-10 fold reduction in death rate
- Reduction in drug use
- Reduction in criminal activity
- Increased treatment retention
- Engagement in socially productive roles; improved family and social function
- Increased employment
- Improved physical and mental health
- Reduced spread of infectious disease/HIV

Naloxone

Short-acting opioid antagonist

- High affinity for mu opioid receptor
- Displaces opioids from receptor
- Rapidly reverses effects of opioid overdose (minutes)
- Effects last 20-90 mins
- FDA approved for IV, SC, IM, intranasal use

- Opioid overdose-related deaths can be prevented when naloxone is administered in a timely manner.
- **www.PrescribeToPrevent.org**

Clinical Conundrums

- **Fentanyl**: 50-100Xs more potent than morphine
  - lipophilic, higher binding affinity than other opioid agonists (except buprenorphine)
  - Alternate buprenorphine induction strategies sometimes utilized, e.g. “macro-induction”, “micro-induction”
  - May be mixed with other drugs, such as cocaine and methamphetamine
  - Shorter window to administer naloxone, multiple doses?
- **Benzodiazepines**: FDA guidance advises not to withhold MOUD
- **Stimulants**: consider MOUD + contingency management (CM)

https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-urges-caution-about-withholding-opioid-addiction-medications

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Resources

- https://www.rethinkingdrinking.niaaa.nih.gov/
- https://www.niaaa.nih.gov/health-professionals-communities/core-resource-on-alcohol
- https://alcoholtreatment.niaaa.nih.gov/
- https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline?
- https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002

Frequently Asked Questions (FAQs)

1. Which of the following medications are approved for the treatment of alcohol use disorder:

a) Topiramate

b) Naltrexone

c) Disulfiram

d) Acamprosate

e) B, C, & D

Answer: E

2. Which medications are approved for the treatment of opioid use disorder:

a) Buprenoprhine

b) Methadone

c) Naltrexone

d) Naloxone

e) A, B, & C

Answer: E

3. In what order were the three waves of the opioid epidemic? :

a) Synthetic opioids (e.g. fentanyl), heroin, prescription opioids

b) Prescription opioids, heroin, synthetic opioids (e.g. fentanyl)

c) Heroin, prescription opioids, synthetic opioids (e.g. fentanyl)

d) Heroin, synthetic opioids (e.g. fentanyl), prescription opioids

Answer: C

4. Which of the following is true about naloxone:

a) Naloxone can only be administered by emergency medical personnel and clinicians

b) Naloxone can rapidly reverse symptoms of opioid overdose

c) Naloxone is a long-acting opioid antagonist

d) Naloxone cannot be dispensed by a pharmacy without a doctor’s prescription

e) All of the above

Answer: B

Thank you!

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Q & A

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