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Learning objectives

- Describe the facts about the increase of opioid analgesic use in America
- List the resulting risks of overdose and other medical conditions related to opioid analgesic use and misuse.
- Describe some of the proposed uses of medical marijuana
- Identify the ways marijuana effects the body and other medicines
- Review the latest legislative actions surrounding medical marijuana use
- Understand the impact of medical marijuana use on Medical Set Aside allocations

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THE FACTS ABOUT OPIOID ANALGESICS

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Three waves of the rise in opioid overdose deaths

Deaths per 100,000 population

17
16
15
14
13
12
11
10
9
8
7
6
5
4
3
2
1
0

1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019

Any Opioid

Other Synthetic Opioids
(e.g., Tramadol or Fentanyl, prescribed or illicitly manufactured)

Heroin

Commonly Prescribed Opioids
(Natural & Semi-Synthetic Opioids and Methadone)

Wave 1: Rise in Prescription Opioid Overdose Deaths Started in 1999

Wave 2: Rise in Heroin Overdose Deaths Started in 2010

Wave 3: Rise in Synthetic Opioid Overdose Deaths Started in 2013

SOURCE: National Vital Statistics System Mortality File.

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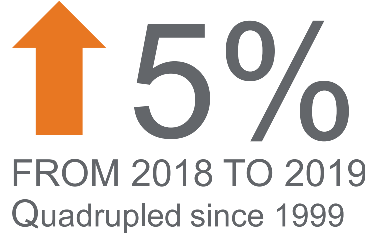
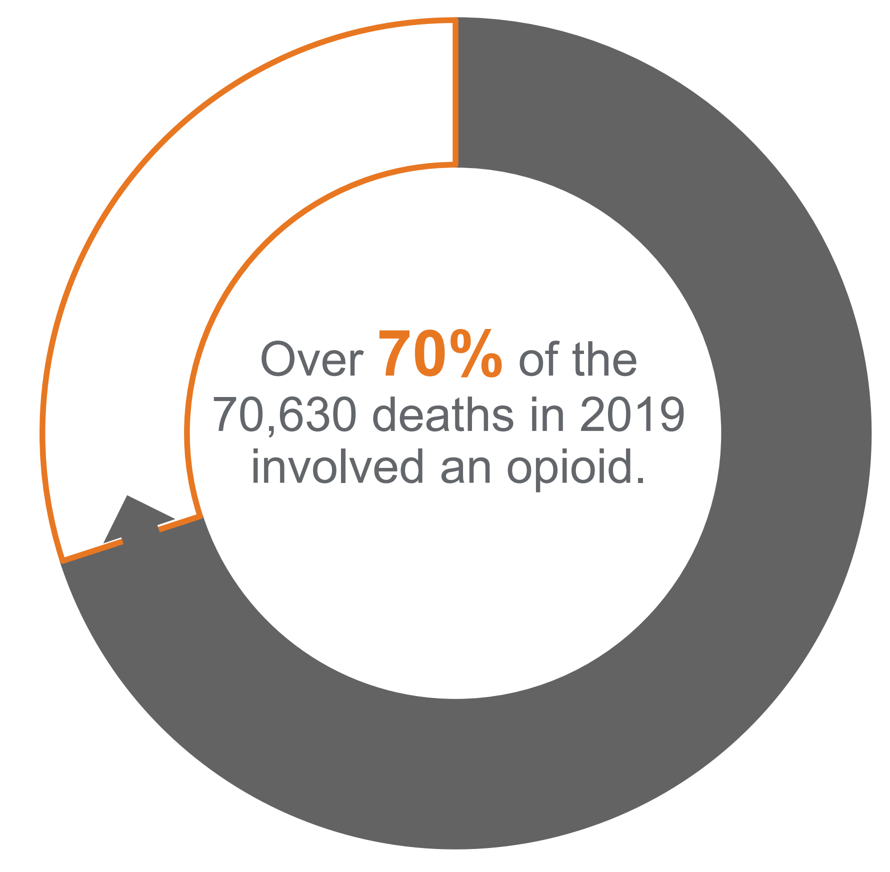
Center for Disease Control stats on opioid deaths 2018-2019

DRUG OVERDOSE DEATHS



FROM 2018 TO 2019
Quadrupled since 1999



Significant changes in opioid-involved death rates:

Opioid-involved death rates	↑ 6%+
Prescription opioid-involved death rates	↓ ~7%
Heroin-involved death rates	↑ 6%+
Synthetic opioid-involved death rates (excluding methadone)	↑ 15%+

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

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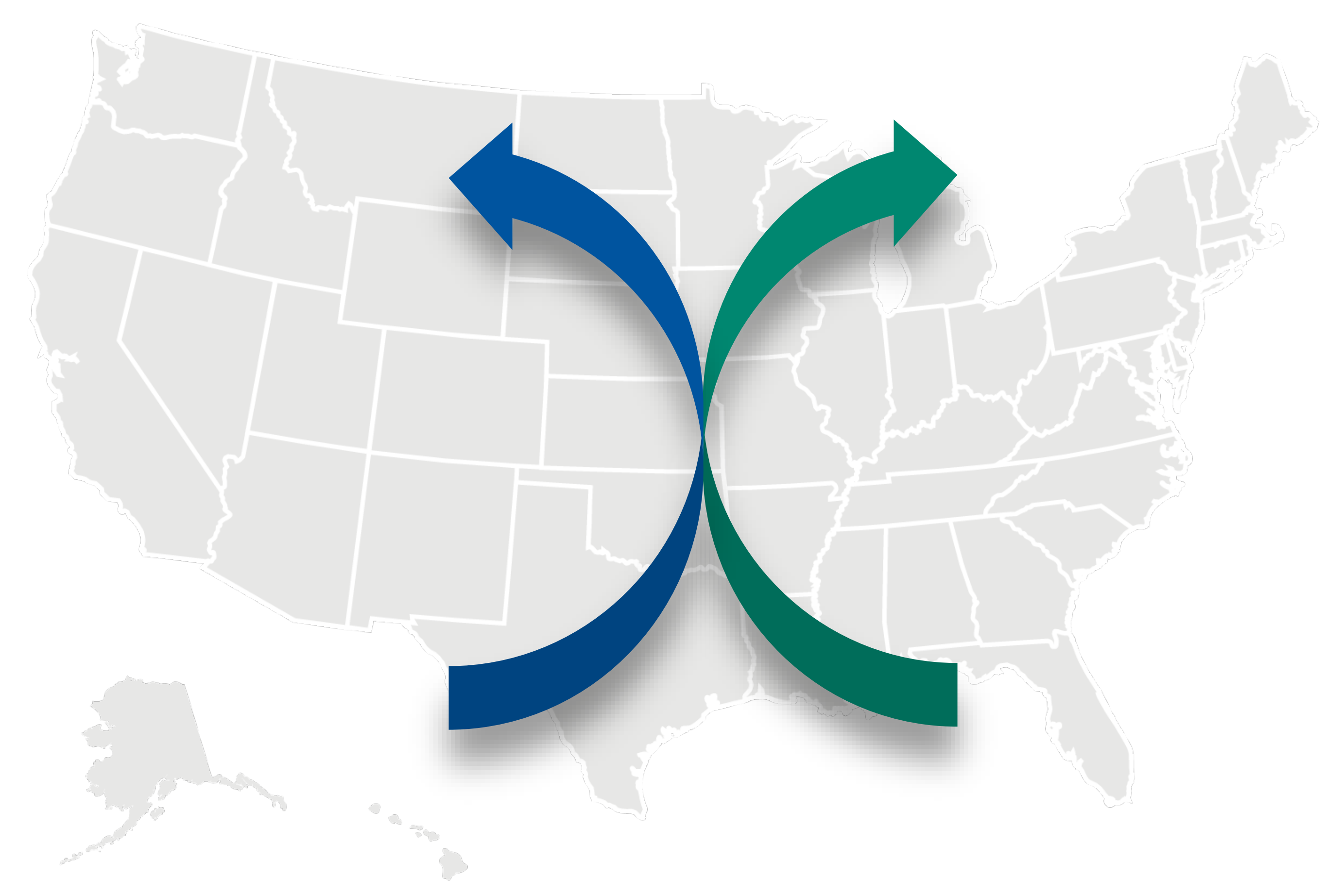
Differing opinions on a controversial topic



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THE FACTS ABOUT MEDICAL MARIJUANA

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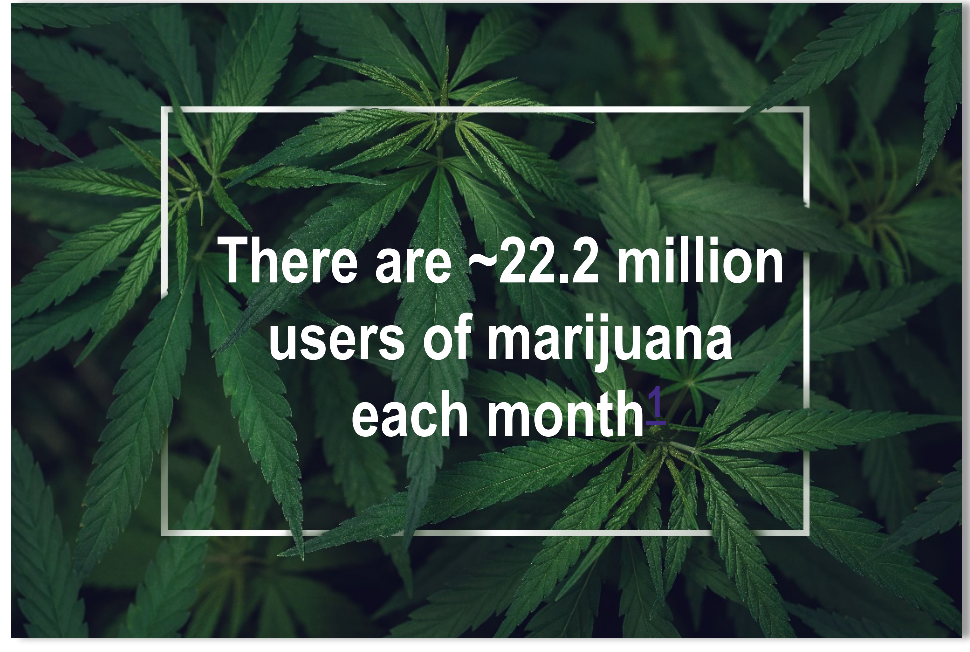
Marijuana is the most commonly used illegal drug in the United States

- **33.8+M legal medical marijuana patients in the U.S. as of July 2020**
- Marijuana refers to dried flowers and leaves of the cannabis plant (there are various species but Indica and Sativa most common for medical marijuana)
- Dried flowers, leaves and stems are smoked, vaporized or cooked for ingestion of the extracts
- Alternative methods of administration avoid combustion and are considered less harmful to the lungs
- Schedule I Federal Controlled Substance: Similar to ecstasy, heroin, cocaine, LSD: no legitimate medical use, lack of accepted safety under medical supervision, and a high potential for abuse



1.Results from the 2015 National Survey on Drug Use and Health: Detailed Tables, SAMHSA, CBHSQ. http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.htmExternal. Accessed October 11, 2016.

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Recreational vs. medical marijuana

RECREATIONAL MARIJUANA

Higher THC levels for the euphoria or “high”

MEDICAL MARIJUANA

- Higher ratio of CBD to THC
- Grown under quality control conditions
- Still difficult to ensure consistent ratios

Sources: Medical Marijuana. Volume 2017, Course No. 231. Pharmacist’s letter/Therapeutic Research Center.

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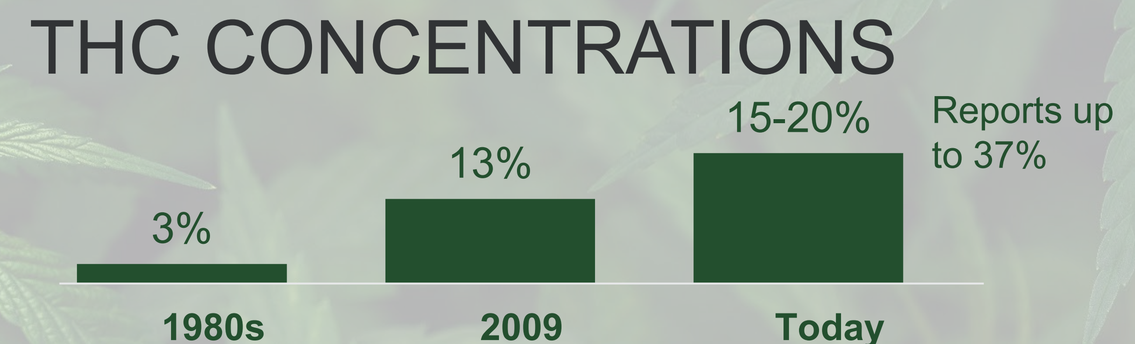
Marijuana in America

537 chemical entities, including 20 cannabinoids

Two main components of cannabinoids: Delta-9-tetrahydrocannabinol (THC) and Cannabidiol (CBD)



CANNABIS SATIVA
Highest THC level

CANNABIS INDICA
More CBD than THC

CANNABIS RUDERALIS
Low THC

Sources: Medical Marijuana. Volume 2017, Course No. 231. Pharmacist's letter/Therapeutic Research Center.

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Marijuana as medicine

- Evidence-based guidelines, such as ODG, do not recommended marijuana for the treatment of pain.
- DEA Schedule I classification
- Lacks essential quality control measures required to ensure safe prescribing
- 5.4 million legal medical marijuana users in 36 states and 4 territories

INJURED PERSONS USING MARIJUANA:

- Concurrent use of opioids is not recommended
- Caution is advised when using medications that can impair cognition

FDA-approved drug product derived from botanical marijuana	Cannabadiol (epidiolex)	Indicated for treatment of Lennox-Gastaut Syndrome and Dravet Syndrome
FDA approved synthetic Delta-9-tetrahydrocannabinol (THC) and research of cannabidiol (CBD)	Dronabinol	Indicated for chemo induced nausea and vomiting and anorexia in HIV patients
	Nabilone	Indicated for refractory chemo induced nausea and vomiting

Source: https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#notapproved
https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx#1

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Is marijuana medicine?

CANNABINOID CHEMICALS	The natural cannabinoid receptor system in the human body was only recently discovered in the past two decades
ANANDAMIDE	• A natural messenger chemical present in the brain at low levels • Endocannabinoid; role in pain, depression, appetite, memory and fertility
DELTA-9-TETRAHYDROCANNABINOL (THC)	• Most psychoactive cannabinoid • Interacts with CB_1 and CB_2 receptors giving the effects of feeling high
CANNABIDIOL (CBD)	Non-psychoactive; interacts differently with CB_1 and CB_2 receptors along with a serotonin receptor giving the effects of feeling relaxed and heavy (stoned)

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Pharmaceutical cannabinoids

SYNTHETIC CANNABINOIDS (FDA-APPROVED)

Made in laboratories; requires prescription by physician

Marinol® (dronabinol): Synthetic Oral THC

- Schedule III controlled substance
- Nausea/vomiting from cancer chemotherapy, refractory
- Anorexia/weight loss in patients with AIDS

Syndros® (dronabinol): Synthetic Oral THC (liquid)

- Schedule II controlled substance
- Nausea/vomiting from cancer chemotherapy, refractory
- Anorexia/weight loss in patients with AIDS

Cesamet®: Synthetic Oral THC analogue

- Schedule II controlled substance
- Nausea/vomiting from cancer chemotherapy, refractory

PHYTOCANNABINOIDS – CANNABIS

Found in the plants, contains hundreds of cannabinoids, most notably THC and CBD

Sativex® (Canada/UK): Herbal cannabis extract (THC/CBD, 1:1)

- Sublingual spray adjunct treatment for central neuropathic pain and spasticity in MS and cancer pain
- Rapid acting, easy to use, transmucosal
- Not approved in the United States

Epidiolex® : Herbal cannabis extract (CBD)

- Approved for severe, orphan, early-onset, treatment-resistant epilepsy syndromes
- Oral solution

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Adverse effects of synthetic cannabinoids dronabinol and nabilone

- Drowsiness/dizziness
- Euphoria
- Dysphoria
- Paranoia
- Impaired cognition
- Hypotension/tachycardia

Additional warning for dronabinol:

- Potential for adverse effects and severity increases at higher doses
- Seizures and seizure-like activity have been reported

Contraindicated with psychotic diseases

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Marijuana as an alternative to opioid analgesics

- Treatment of the underlying condition vs. medication
- Respiratory depression and overdose
- Lack of long-term evidence
- Addiction potential
  - THC is considered an addictive substance
  - Nine percent of marijuana users may develop some degree of marijuana use disorder vs. 26 percent of opioid users
- Drug-drug interactions
- Adverse effects, especially in adolescents
- Increased risk of abuse of other substances
  - Rodent studies have shown an enhanced response to other addictive substances
  - Majority of marijuana users do not go on to abuse other drugs
- Not standardized

Source: https://www.drugabuse.gov/publications/drugfacts/marijuana

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How medical marijuana works

Chemical substances in marijuana are called *cannabinoids;*
483 compounds/chemicals identified

The body contains two major molecular structures known as **receptors** that interact with cannabinoids:

- CB_1 receptors in the nervous system and brain
- CB_2 receptors in the immune system

Similar to a lock and key where the receptor is the lock and the key is the cannabinoid. Once the cannabinoid enters the receptor, various effects occur in the body.

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The effects of CBD

SIDE EFFECTS OF CBD

- Possible immunosuppressive effects
- Sedation – what are comorbidities
- High concentrations of CBD and potential effects on blood sugar
- Feeling heavy
- Overdoses (up to 300 mg/kg IV) in Monkeys – Tremors, convulsions, vomiting, sedation to prostration in 30 minutes, cardiac failure

DRUG INTERACTIONS OF CBD

- BIGGEST CAUTION
- Drugs metabolized by CYP450 3A4, 2C19, and 2B subfamilies can be affected when given at the same time as CBD; may induce or inhibit metabolism, which can lead to increased or reduced amounts of other drugs. Interacts with THC as THC is metabolized by 3A4 and 2C19.
- The potential for drug interactions may be large and includes interactions with HIV medications, antibiotics, and others
- CBD could interact with anticancer drugs (P-glycoprotein)
- CBD unclear if there is an interaction with NSAIDs

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HOW MARIJUANA INTERACTS WITH THE BODY

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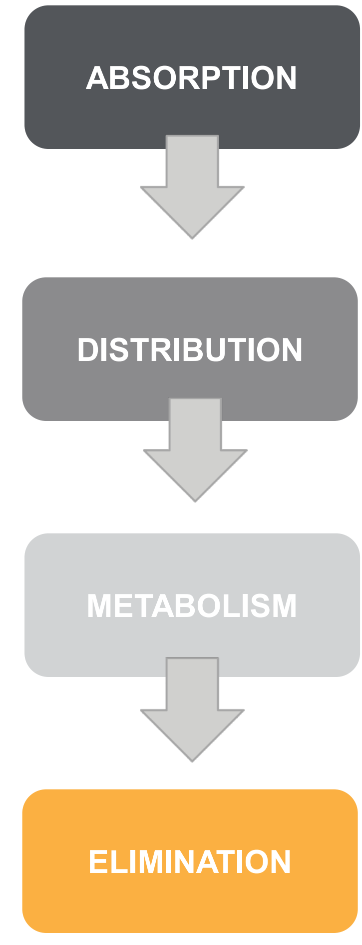
How the body interacts with cannabinoids

- Rate and amount of drug entering the body varies greatly on administration method and formulation
  - Smoking, swallowing, topical, rectal
  - Smoking provides quicker effects than swallowing
- THC and CBD go into the brain and body tissues from the bloodstream giving rapid effects
- The body interacts with THC and CBD making new modified chemicals, some are active with the receptor(s) and others are not
- 80% - 90% excreted within five days
- In heavy cannabis users, THC can accumulate in fatty tissues giving prolonged detection of cannabis use (up to 30 days and longer)



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Medical marijuana's effects on the body

DELTA-9-TETRAHYDROCANNABINOL (THC)	CANNABIDIOL (CBD)
• Psychoactive • Mood changes, such as anxiety or depression • Cognitive effects – Decreased concentration – Short-term memory loss – Decreased attention span – Paranoia – Time distortion • Antispasmodic • Increased appetite • Analgesia • Abuse and dependence potential (psychological and physical) • Immunosuppression	• Anxiolytic • Antipsychotic • Anticonvulsant • Neuroprotective properties • Analgesia • Anti-inflammatory • Antispasmodic • Reduced blood pressure • Immunosuppression

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Adverse effects-perceived safety over opioids?

DELTA-9-TETRAHYDROCANNABINOL (THC)	CANNABIDIOL (CBD)
• Psychosis • Addiction • Impaired judgment • Increased risk of mental disorders • Increased heart rate and blood pressure • Red eyes • Immunosuppression • No respiratory depression • There are no reports of fatal overdoses	• Sedation – What are comorbidities • Dry mouth • Feeling heavy • Slowed reaction time (2-3x increased risk of a driving accident) • Immunosuppression • Overdoses– tremors, convulsions, vomiting, sedation, weakness, cardiac failure • Levels were exponentially higher than those achieved with medicinal or recreational use

DRUG INTERACTIONS

- Drugs metabolized by CYP450 3A4, 2C19, and 2B subfamilies and P-glycoprotein can be affected when given at the same time; may induce or inhibit metabolism, which can lead to increased or reduced amounts of other drugs.
- The potential for drug interactions may be large and includes interactions with HIV medications, antibiotics, chemotherapy and others
- CBD may slow the metabolism of THC (inhibit CYP 450 in some)
- CBD unclear if there is an interaction with NSAIDs

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Safety and marijuana

Study from 1993-2013 by Dr. Wayne Hall, University of Queensland

Major findings based on recreational use of marijuana:

- No respiratory depression (person stops breathing) with Marijuana when used alone
- No reports of fatal overdoses in the epidemiological literature
- Increased risk of driving accident

DUI increased risk for car crash

Marijuana use	Alcohol use
2-3X	6-15X

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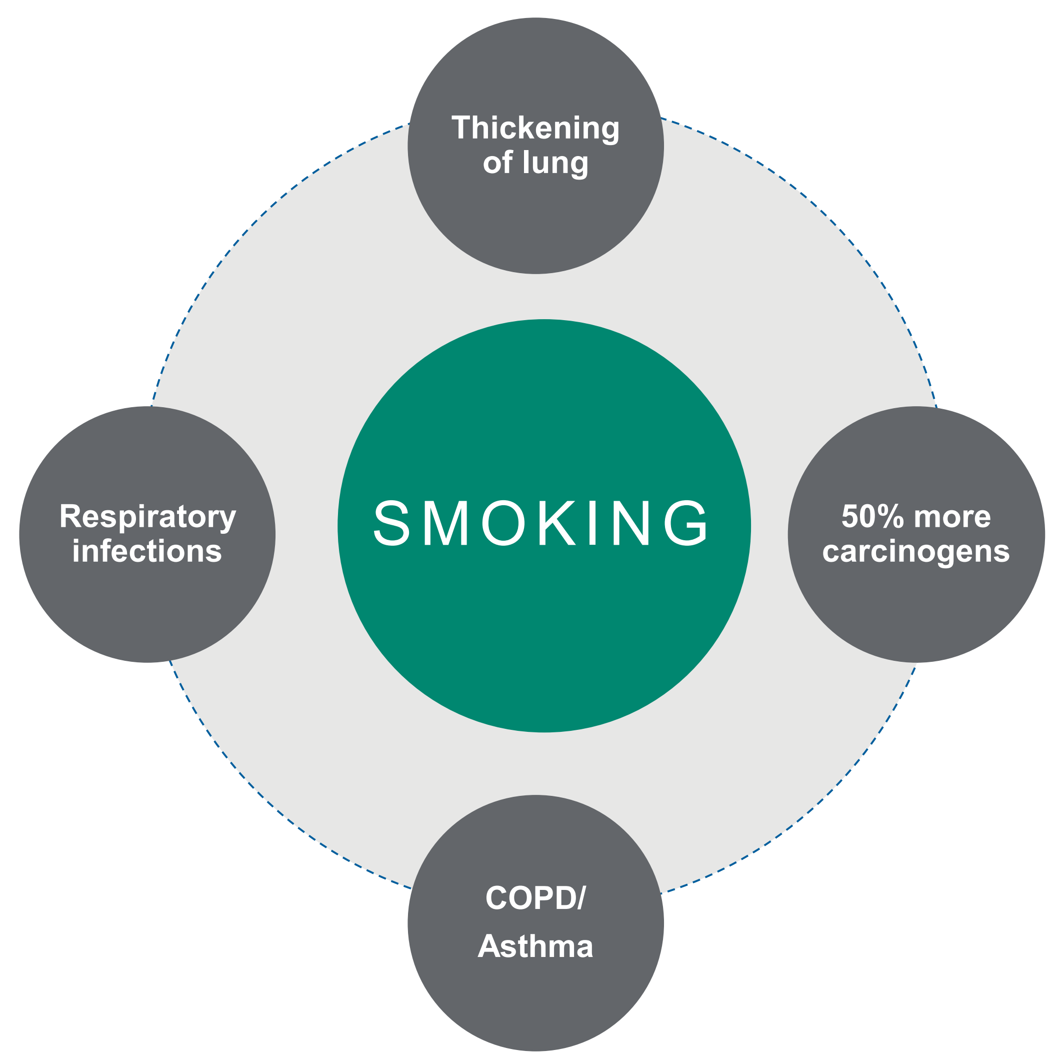
Marijuana use effect on lungs



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Smoked medical marijuana

AMERICAN MEDICAL ASSOCIATION (AMA)	INSTITUTE OF MEDICINE (IOM)
• "Despite the public controversy, less than 20 small randomized controlled trials of short duration involving ~300 patients have been conducted over the last 35 years on smoked cannabis." • Reduce the schedule and conduct more research	• Strong evidence for use in chronic and neuropathic pain with multiple sclerosis, spinal cord injury, cancer, tremors, spasms, spasticity, nausea/vomiting produced by cancer chemotherapy, loss of appetite in AIDS/cancer • Development of non-smoked, reliable delivery systems for cannabis-derived products

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Safety and marijuana

- Dependence can occur
  - Estimates show 1 in 6 adolescents are half of daily cannabis users
  - Tolerance develops to THC and withdrawal symptoms can occur if suddenly stopped
  - Strongly associated with use of other illicit drugs
- Negatively impacts IQ (Only where initiated in adolescence and continued into adulthood)
- Effect on respiratory health is inconclusive
- Smoking marijuana has been associated with an increased risk of cardiovascular side effects – caution in middle age and older

Dependence is a physical and mental reliance on drugs or alcohol. People who struggle with substance dependence are unable to stop using despite the negative consequences, and experience cravings and withdrawal symptoms when they do.

https://pacifichealthsystems.com/blog/what-is-the-difference-between-substance-abuse-and-substance-dependence/

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Marijuana and prescription drug misuse

37% of medical marijuana users misused other drugs

Lab data (22K + UDTs) correlation between marijuana and prescription drug use in national population

Approximately 45% of patients who use recreational marijuana also used other non-prescribed drugs (i.e., sedatives and narcotics)

Marijuana most frequently detected non-prescribed drug in >26% of patients who do not use medications as prescribed

Marijuana most frequently detected drug in the nation’s workforce, March 2013 drug test index report

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California example

The laws in many states define the medical conditions, circumstances and methods of consumption in which an individual can secure and use medical marijuana.

California allows treatment with marijuana when determined by a doctor to be appropriate for the following "serious medical conditions."

- AIDS
- Anorexia
- Arthritis
- Cachexia/wasting away
- Cancer
- Chronic/severe pain
- Migraine

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Proposed medical uses

- Persistent muscle spasms, including, but not limited to spasms associated with multiple sclerosis
  - Seizures, including, but not limited to seizures associated with epilepsy
  - Epilepsy/seizure disorders - *(Charlotte's Web) Hemp Oil – used for children*
  - Severe Nausea
- Any other chronic or persistent medical symptom that either:

  a. Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans and Disabilities Act of 1990 (Public Law 101-336).

  b. If not alleviated, may cause serious harm to the patient's safety or physical or mental health.

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Proposed uses of medical marijuana

EVIDENCE SUPPORTS INDICATION FOR USE	LACKS EVIDENCE FOR USE
• Chronic pain	• Crohn’s disease
• Seizures	• Fibromyalgia
• Inflammation	• Hypertension
• Muscle spasms	• Osteoporosis
• Nausea (chemotherapy)	• Rheumatoid arthritis
• Weight loss (HIV)	• Glaucoma
	• Diabetes
	• Asthma
	• Migraines
	• Alzheimer's
	• Parkinson's

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PUBLIC POLICY UPDATE

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Medical marijuana is illegal at the Federal level

- The use of marijuana for medicinal purposes at the federal level has been illegal since 1970, when Congress passed and President Nixon signed into law the Controlled Substances Act (CSA).
- CSA classified marijuana as a Schedule I substance. Schedule I substances are considered to have high abuse potential, no accepted medical use and a lack of accepted safety data.
- Since 1970, there have been numerous efforts to reclassify marijuana as a Schedule II substance in an attempt to decriminalize the use of marijuana for medical purposes at the federal level. None of these efforts have been successful to date.

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Medical marijuana is illegal at the Federal level

- The Schedule I status of marijuana continues to prohibit assignment of a National Drug Code (NDC), thus pharmacy benefit managers (PBMs) are unable to process claims for this treatment option.
- Today, while marijuana and/or CBD oils are legal for medicinal purposes in 37 states and Washington, DC, it's still illegal at the federal level.

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Policy actions

- Gaining ground in workers' compensation agencies as acceptable treatment for workers' compensation injury-related pain
- Chronic pain and PTSD expansion by legislature as qualifying conditions under state medical marijuana programs
- Touted as an opioid replacement for pain therapy – basis for several favorable state workers' compensation legal challenges
- Lack of comprehensive clinical studies/data

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Medical and Recreational Marijuana

WA OR CA AK ID MT NV UT WY CO AZ NM HI ND SD NE KS OK TX MN IA MO AR LA WI IL MI IN OH KY TN MS AL GA FL SC NC VA WV PA NY VT ME NH MA RI CT NJ DE MD DC

- Medical use of marijuana currently prohibited with legalized usage of cannabidiol (CBD) for limited purposes
- Legalized medical marijuana
- Legalized recreational and medical marijuana
- Medical use of marijuana currently prohibited

Source: ProCon.org *Includes workers' comp fee schedule reimbursement for medical marijuana. Current as of **January 2021.**

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Legislative Action

State/Action	Description	Status
Federal	• House passes Secure and Fair Enforcement Banking Act (SAFE) – Provides safe-haven for banks and states which engage in sanctioned business of medical or recreational marijuana – Legitimate cannabis-related business would not be subject to money laundering or racketeering laws • U.S. Senate President Schumer renews push for change on existing marijuana controlled substance status: Cannabis Administration and Opportunity Act	Currently in development
Kansas SB 287	• Permits the usage and sale of MM in the state • Modifies existing regulations to permit usage by an injured worker as part of the state MM program	Currently in Senate
Maryland HB 683 SB 461	Would have added medical cannabis into the definition of medicine for treatment of workers compensation claims	Died at end of session

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Legislative Action

State/Action	Description	Status
New Jersey AB 21	• Permits possession, cultivation and utilization of recreational marijuana for people over the age of 21 • Permits the state sale of recreational marijuana after rule-making developments	Effective February 22, 2021
New Jersey SB 3406	Requires benefits plans – such as workers' compensation – to provide coverage for medical marijuana	Currently in Senate
New Mexico HB 2a	• Permits possession, cultivation and utilization of recreational marijuana for people over the age of 21 • Permits the state sale of recreational marijuana after rule-making developments	Currently With Governor
New York SB 854	• Permits the possession, cultivation and utilization of up to a certain amount of recreational marijuana • Permits the state sale of recreational marijuana after rule-making developments	Effective March 31, 2021
Virginia HB 2312	• Permits possession, cultivation and utilization of recreational marijuana for people over the age of 21 • Permits the state sale of recreational marijuana after rule-making developments	Currently with Governor

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Legal and Regulatory Action

State/Action	Description	Status
Massachusetts Legal	State Supreme Court held that a workers' compensation insure cannot be required to pay for an injured workers' medical marijuana expenses	Effective November 2020
Mississippi	State Supreme Court strikes down voter approved referendum allowing policy development for a state-wide medical marijuana program	NA
New Hampshire Legal	• Injured claimant under workers' compensation seeks reimbursement for use of MM under the state MM program • State Supreme Court ruled that the Controlled Substances Act does not criminalize reimbursement by the insurer	Effective March 2, 2021
New York Legal	State Appellate upheld WCB decision that granted a variance for MM treatment provided to an injured worker and ordered the insurer to reimburse for the care	Effective February 25, 2021
New York Regulatory	WCB proposes modify drug formulary rule – proposal contains outline of PAR requirements for MM under the existing formulary requirements	Currently in rule-making

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Employer challenges

- Heightened level of concern when claimant returns to a safety-sensitive occupation, such as driving or construction, while subject to potential adverse cognitive and psychological effects of marijuana
- Quantification of the amount of marijuana consumed by claimant is not available through urine medication testing, thereby limiting ability to determine if he or she has consumed prescribed dose, or is in fact acutely intoxicated
- Understanding the potential impact to medication Free Workplace policies as well as other safety and risk management protocols and programs

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Employer viewpoint

- Safety-sensitive occupations (driving and construction)
- Quantification of the amount of marijuana consumed
- Prescribed dose or intoxicated
- Drug-free workplace policies
- Pre-hire drug testing
- Employee assistance programs
- To pay or not to pay in a workers' compensation case
  - Guidelines
  - Federal opinion
  - Lack of NDC

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Medical Marijuana and Medicare Set Asides

- As the Medicare Secondary Payer Act (MSP) requires, and the Centers for Medicare and Medicaid Services (CMS) has provided, parties settling workers compensation claims in which the injured worker is a current or potential Medicare beneficiary must take Medicare's future interests into account.
- One of the acceptable methods of taking such interests into account is by producing a Medicare set aside, allocating a specific amount for future medical needs associated with the work related injury that Medicare would otherwise allow and pay for.
- Since marijuana remains a Schedule I substance, CMS will not provide payment for expenses related to the use of medical marijuana. Consequently, even if an authorized medical provider has appropriately and legally prescribed medical marijuana pursuant to that state's law, because Medicare will not allow for and pay for such care, CMS will not allow for marijuana in a Medicare set aside.
- Instead, Medicare may require either previously prescribed or other similar medication, which could be significantly more costly to fund.

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Appendix: Links to guidelines

- **American College of Occupational and Environmental Medicine (ACOEM)** ***Guidelines for the Chronic Use of Opioids.*** Available by subscription
- **American Pain Society and the American Academy of Pain Medicine.** Chou R, Fanciullo G, Fine P, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. 2009:10(2) p 113-130 available at: download.journals.elsevierhealth.com/pdfs/journals/1526-5900/PIIS1526590008008316.pdf
- **Center for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain-United States, 2016.** http://www.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf
- **Chronic Pain Medical Treatment Guidelines (MTUS).** www.dir.ca.gov/dwc/DWCPropRegs/MTUS_Regulations/MTUS_ChronicPainMedicalTreatmentGuidelines.pdf
- **New York Workers' Compensation Board Medical Treatment Guidelines.** http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/MTGOverview.jsp
- **Official Disability Guidelines (ODG).** Available by subscription
- **The Department of Veterans Affairs (VA) and Department of Defense** ***Management of Opioid Therapy for Chronic Pain*** **revised 2017.** **https://www.healthquality.va.gov/guidelines/Pain/cot/**
- **Washington State Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain 3rd Edition released 2015.** www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf

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