

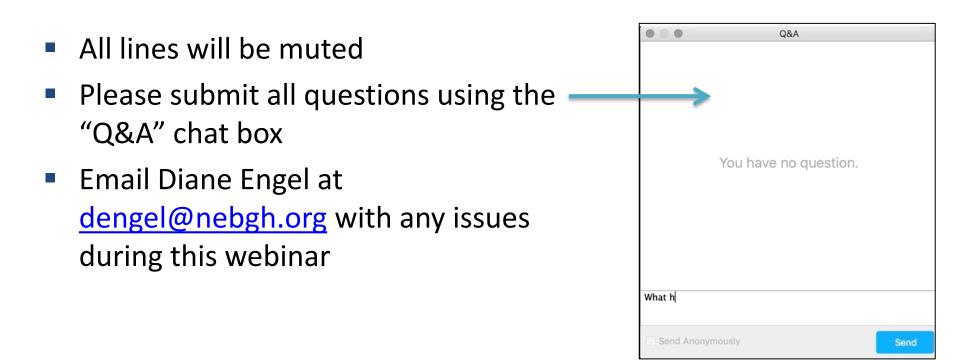


Tuesday, February 26, 2019 12:00 – 1:00 PM

Nathaniel Glasser, JD

Member of the Firm; Employment, Labor & Workforce Management Practice *Epstein Becker Green* Julia Arnsten, MD Chief of the Division of General Internal Medicine; Director of Medical Marijuana Program *Montefiore* Dr. Mark Cunningham-Hill (Moderator) Medical Director Northeast Business Group on Health

Webinar Procedures







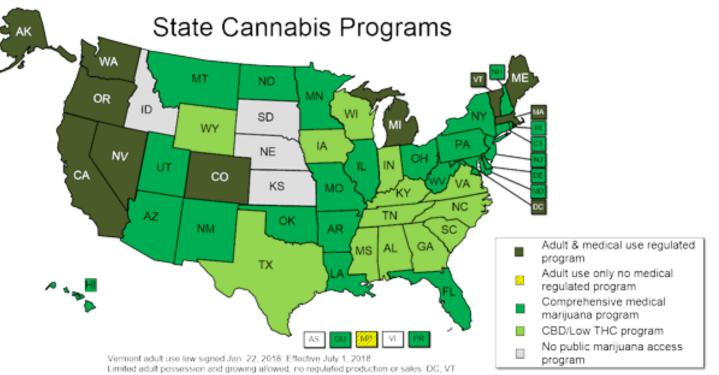


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Medical Cannabis

Julia H. Arnsten, MD, MPH

Medical cannabis available since 1996, now in 33 states and Washington, D.C.



November 2018





U.S. cannabis laws

- Federal law lists cannabis as a schedule 1 drug: use prohibited for any purpose
- Different states have issued their own laws
 - Most states (33) have some form of legal medical cannabis
- All states limit conditions for which cannabis can be prescribed
- Most states require physicians to obtain a state registration prior to prescribing cannabis, and physicians must have a "bona fide" relationship with the patient
- Cannabis is supplied to patients through specified dispensaries in every state
 - Dispensaries can provide herbal cannabis, cannabis-derived products, and consumption devices
 - Smoking cannabis is prohibited in many states



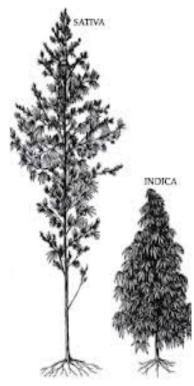


Cannabis plants and products

- Two major plant subspecies (many hybrids)
 - Cannabis sativa
 - Higher THC, higher potency, stimulating
 - Cannabis indica
 - Higher CBD, sedating
- Whole plant contains >60 phytocannabinoids
 - THC (delta-9-tetrahydrocannabinol)
 - CBD (cannabidiol)
 - Ratio of THC:CBD plus other cannabinoids and terpenes engineered for effect (thousands of strains)
 - > THC side effects: fatigue, dizziness, dry mouth, anxiety, cognitive
 - Tolerance to THC psychoactive effects develops over time
- > Two FDA-approved cannabinoids (pills) in U.S. not herbally derived
- Dronabinol (trade name: Marinol®)
 - > Synthetic chemical form of THC (not naturally occurring)
 - Nabilone (trade name: Cesamet® or Canemes®)
 - Synthetic cannabinoid agonist, similar to (but not) THC
- Non-U.S. approved herbal-derived cannabis medication (approved in 29 countries)
 - Nabiximols (trade name: Sativex®)
 - Oromucosal spray 1:1 THC:CBD
 - Many studies conducted in Europe with this preparation
 - Most common indication for use is multiple sclerosis/MS-associated neuropathic pain
- > Epidiolex herbal-derived form of CBD, approved 2018 for severe forms of childhood epilepsy







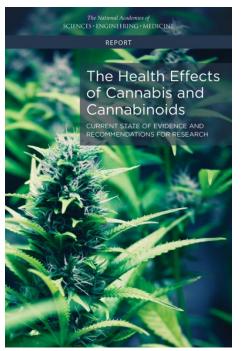
Herbal cannabis routes of administration

Smoking	Vaporization	Oral	Other
Most common but not recommended	Increasingly common	Oils, capsules, "edibles"	Topicals, suppositories, concentrates
Combustion at high heat produces toxic byproducts (e.g. aromatic hydrocarbons, carbon monoxide)	Moderate heat, still some release of toxic byproducts	No byproducts	No byproducts
Chronic use associated w/pulmonary symptoms (cough, bronchitis); patients may mix with tobacco and elevate risk of COPD, cancer	Fewer pulmonary symptoms	No pulmonary symptoms	?
Rapid onset (5-10 min), short duration (2-4 hr)	Rapid onset (5-10 min), short duration (2-4 hr)	Oromucosal: short onset (15-30 min) Capsules: Longer onset (1-3 hr), longer duration (6-8 hr)	?
Up to 50% of cannabis lost to "side-stream" smoke	?	Standardized ratio and quantity of THC and CBD	?
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What are the health effects of medical cannabis?



The National Academies of SCIENCES • ENGINEERING • MEDICINE

- 2017 committee-generated report summarizing health impacts of cannabis and cannabis-derived products
- Lead sponsor: CDC
- Stakeholders: FDA, NIDA, NCI, NHTSA, state governments
- Report focuses on key health endpoints, including therapeutic effects, cancer, CV risk, respiratory disease, immune function, injury/death, pregnancy-related outcomes, psychosocial outcomes, mental health, CUD, other substance use
- Systematic review process, >24,000 articles
- Conclusive/substantial evidence in 3 therapeutic areas:
 - chronic pain
 - chemotherapy-induced nausea/vomiting
 - spasticity associated with multiple sclerosis
 - Patients treated with cannabis or cannabinoids more likely to have significant reduction in pain symptoms
- "Conclusive" suggests strong RCT evidence; "Substantial" suggests strong evidence from good quality studies (with no credible opposing findings)





Do cannabis and cannabinoids affect pain? Summary of six meta-analyses of RCTs

Author	Year	# of Studies	Type of pain	Medication	Results
Iskedjian	2007	7	MS-related neuropathic pain	Cannabinoid medications (dronabinol, CBD)	Significant decrease in pain intensity
Martin- Sanchez	2009	18	Multiple non- malignant and malignant pain etiologies	Cannabinoid and plant- based medications	Significant pain reduction
Whiting	2015	28	Multiple non- malignant and malignant pain etiologies	Cannabinoid and plant- based medications, inhaled cannabis	Higher incidence of pain reduction
Andreae	2015	5	Chronic neuropathic pain	Inhaled cannabis	Short term pain intensity reduction
Aviram	2017	43	Multiple pain etiologies	Cannabinoid and plant- based medications, inhaled cannabis	More pain reduction in chronic pain, especially by inhalation, compared to placebo
Nugent	2017	27	Multiple pain etiologies	Plant-based cannabis preparations or whole plant extracts	Clinically significant pain relief among patients with neuropathic pain





Improvement in cancer pain (observational)

- 3000 cancer patients treated with medical cannabis in Israel 2015-17
- Mean age 60, multiple cancer types (breast, lung, pancreatic, colorectal), over half with stage 4 disease.
- In 6 months before cannabis, 54% hospitalized (median 10 d)
- After 6 months of cannabis, 61% of survivors responded
- Improvements in pain, quality of life, nausea/vomiting, sleep, anxiety/depression, restlessness, headaches (all >85%)
- More than half stopped or decreased use of opioids
- Most common side effects: dizziness (8%), dry mouth (7%), sleepiness (3%), psychoactive effect (3%)

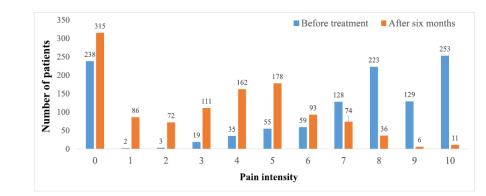


Fig. 2. Assessment of pain intensity. Pain intensity was assessed on 0–10 scale, before and after six months of cannabis therapy. p < 0.001.



Prospective analysis of safety and efficacy of medical cannabis in large unselected population of patients with cancer

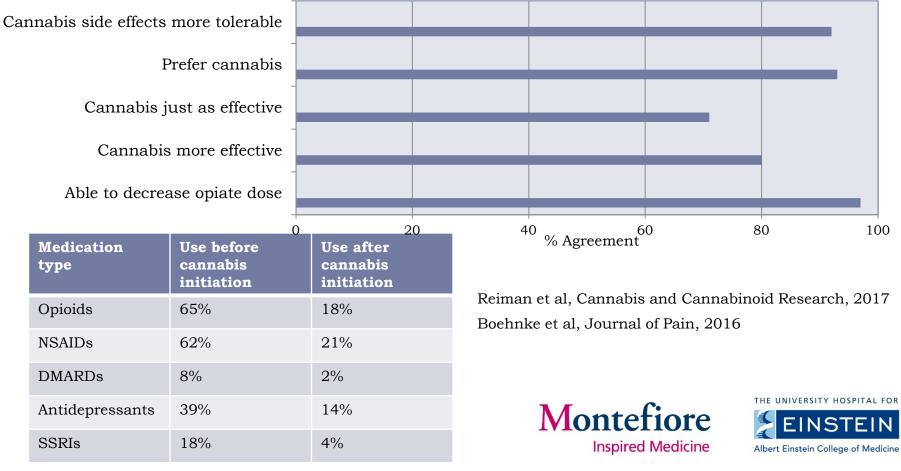
Lihi Bar-Lev Schleider^{a,b}, Raphael Mechoulam^c, Violeta Lederman^b, Mario Hilou^b, Ori Lencovsky^a, Oded Betzalel^b, Liat Shbiro^a, Victor Novack^{a,*}

^a Clinical Cannabis Research Institute, Soroka University Medical Center and Faculty of Health Sciences, Ben-Gurion University of the Negev, Béler-Sheva, Israel
^b Research Department, Tikun Olam LTD, Israel

^c Institute for Drug Research, School of Pharmacy, the Hebrew University of Jerusalem, Israel

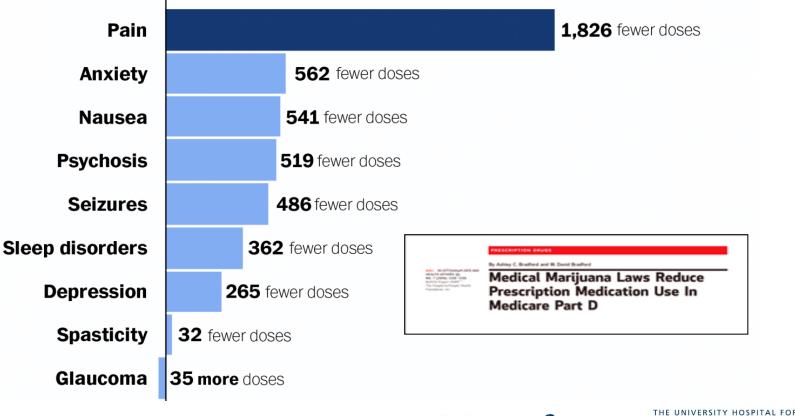
How does cannabis use affect use of opioids and other medications for chronic pain?

- > 2897 medical cannabis users (841 opioid users) in California
- > 244 medical cannabis users in Michigan



Fewer pills prescribed in states with medical cannabis laws

Difference between annual drug doses prescribed per physician in medical marijuana states, and in states without medical marijuana laws, by drug category





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Different states, different laws

State	Year	Possession limit	Home cultivation ?	Chronic pain indication?
California	1996	8 oz usable; 6 mature or 12 immature plants	Yes	Yes
Colorado	2000	2 oz usable, 3 mature and 3 immature plants	Yes	Yes
Hawaii	2000	4 oz usable, 7 plants	Yes	Yes
Maine	1999	2.5 oz usable, 7 plants	Yes	Yes
Massachusetts	2012	60 day supply (10 oz) for personal use	Selected	Yes
Connecticut	2012	2.5 oz usable/month	No	Selected
New Jersey	2010	2 oz usable/month	No	No
New York	2014	30-day supply non- smokable marijuana	No	Yes



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Medical cannabis in New York State

- Operational as of January, 2016
 - Much more restrictive than other states
- Providers
 - Certify patients who then register with NYS state
 - 4-hour online course

Patients

- Must be diagnosed with a severe, debilitating or life threatening conditions
- AND have an associated or complicating condition
- Patients obtain products from dispensaries, home cultivation is NOT allowed, 30 day supply
- Products and product testing
 - 3 formulations
 - Liquid/oil for oromucosal/sublingual administration
 - Metered liquid/oil for vaporization
 - Capsules for oral administration
 - Registered organizations manufacture up to 5 "brands" including (1) equal ratio THC:CBD and (2) low-THC to high-CBD ratio
 - Testing is conducted for contaminants and cannabinoid profile by independent lab certified by NYS Environmental Laboratory Approval Program (NYSDOH Wadsworth Center).
- Contraindications
 - Pregnancy/lactation
 - Psychosis
 - Unstable cardiac disease

Conditions

- Cancer
- HIV/AIDS
- Amyotrophic lateral sclerosis
- Parkinson's disease
- Multiple sclerosis
- Spinal cord injury with spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathy
- Huntington's disease
- Chronic pain
- PTSD

Associated or complicating conditions

- Cachexia/wasting
- Severe/chronic pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms









Marijuana in the Workplace



Federal Law

Controlled Substances Act

- Marijuana classified as a Schedule I drug
- Drug-Free Workplace Act (DFWA)
 - Requires federal contractors to, among other things, maintain a drug-free workplace, but does not require testing





State Legalization





Marijuana: Does Federal Law Preempt State Law?

No clear answer yet...

DFWA does not preempt state law

- Carlson v. Charter Communication, LLC (9th Cir. 2018)
- Noffsinger v. SSC Niantic Operating Company (D. CT. 2018)

CSA does not preempt state law

- Chance v. Kraft Heinz Foods Company (DE. 2018)
- Noffsinger v. SSC Niantic Operating Co. (D. Conn. 2017) [earlier decision]
- Callaghan v. Darlington Fabrics Corp. (R.I. Super. Ct. 2017)

CSA DOES preempt state law

- Garcia v. Tractor Supply Co. (D. N.M. 2016)
- Emerald Steel Fabricators, Inc. v. Bureau of Labor & Indus. (OR. 2010)





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Medical Marijuana: If Not Preempted by Federal Law...

Differences in State Laws May Result in Different Outcomes for Employer

What protections, if any, does state law afford certified medical marijuana users?

- Carlson v. Charter Communication, LLC (9th Cir. 2018): Federal contractor could fire employee who failed drug test since there is no duty to accommodate under Montana Medical Marijuana Act
- Wild v. Carriage Services (D.N.J. 2017): No duty to accommodate under New Jersey law
- Whitmire v. Wal-Mart Stores Inc. (D. Az. 2019): Employee fired after failing drug test could sue under state's marijuana law prohibiting discrimination, where test did not establish impairment on work time
- Noffsinger v. SSC Niantic Operating Company (D. Conn. 2018): Applicant who failed drug test could sue employer for refusal to hire under CT's Palliative Use of Marijuana Act's anti-discrimination provision
- Chance v. Kraft Heinz Foods Company (Del. 2018): Employee who was fired after failing drug test could sue employer under anti-discrimination provision of state's marijuana law

Bottom Line: If state marijuana statute contains anti-discrimination provision, applicant/employee may be protected from adverse action based <u>solely</u> on positive drug test result



Medical Marijuana and Disability Accommodation

Example: New York Medical Marijuana Law

- Employers may prohibit employees from performing employment duties while impaired by a controlled substance
- An employer is not required to do any act that would put it in violation of federal law or cause it to lose a federal contract or funding



- But: Being a certified patient qualifies as having a "disability" under state human rights and civil rights laws
 - It is an unlawful discriminatory practice for an employer to refuse to provide reasonable accommodations to the known disabilities of an applicant or employee in connection with a job or occupation sought or held





Medical Marijuana

Guidelines

Before taking adverse action, consider possible legal obligations:

- 1. Does state law prohibit discrimination against certified medical marijuana user? (E.g., AZ, AR, CT, DE, IL, ME, MN, OK, PA, RI, WV)
 - If so, ensure policies are applied consistently (e.g., drug testing)
- 2. Is there a duty to reasonably accommodate employee based on underlying health condition justifying the use of medical marijuana? (E.g., NY) If so:
 - Engage in a **fact-based inquiry** to determine whether the individual is a permitted medical marijuana user and whether the job can accommodate marijuana usage
 - Engage in the interactive process to determine whether medical marijuana use can be accommodated in the workplace
 - Note: Some jurisdictions have stricter requirements, e.g., New York City ("Cooperative Dialogue" Law)
- 3. BUT: Employers still may prohibit drug use on their premises and take adverse action if employee's use of the drug "impairs" ability to perform job functions or employee is "under the influence" (as defined by state law)



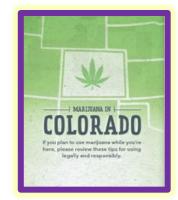


Recreational Marijuana

- Recreational marijuana is legal in: AK, CA, CO, DC, ME, MA, MI, NV, OR, VT, WA
- Pre-employment testing
 - Employer's discretion as to how to treat positive test
 - Consider talent pool implications

• Employer may:

- Ban use on premises
- Take adverse action if employee is "impaired" or "under the influence"
- Can probably take adverse action for off-duty/off-premises use, e.g., *Coats v. Dish Network, LLC* (Colo. 2015)









Pending Legislation

Legalization

industrial hemp

- CT recreational
- IA expanded medical
- IL recreational
- IN medical
- KY medical
- KS medical
- MS medical
- NE medical
- NJ recreational
- SC medical
- SD Growth of

.

- VA recreational
- TX expanded medical
- VT– production and sale of recreational
- WV recreational

Anti-discrimination protections for certified medical marijuana users

 MA (including banning workplace drug testing for marijuana), MD, MT, NV, NJ, OK, NY, RI

Expungement of criminal convictions

 AK (restricted access to conviction records), IL, WA

Federal

- Sensible Enforcement of Cannabis Act
- Legitimate Use of Medicinal Marihuana
 Act
- Compassionate Access, Research Expansion, and Respect States Act
- VA Medicinal Cannabis Research Act



General Pre-Employment Drug Testing Guidelines

No comprehensive federal law regulates drug testing in the private sector

• **States:** Testing permissible but many have restrictions, e.g.:

- May be conducted only AFTER conditional offer of employment, e.g., AL, ME, OH, OK, VT, WA
- Prior notice to applicant of testing requirement, e.g., AL, AZ, CT, HI, IA, MN, OK, RI, VT, WA

Maintenance of written policy – e.g., MN

 $_{\odot}$ All applicants must be tested $\,$ -- e.g., MN

Best practices:

- $_{\odot}$ Provide notice and obtain consent from applicant
- Conduct only AFTER conditional job offer
- Apply policy CONSISTENTLY
- If applicant fails test, consider possible obligations under disability discrimination laws and medical marijuana laws



