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CANNABIS & HEMP CONFERENCE

OCTOBER 24-25, 2019 | MARRIOTT MARQUIS | NEW YORK CITY

Medical Professional Liability Implications of Medicinal Cannabis

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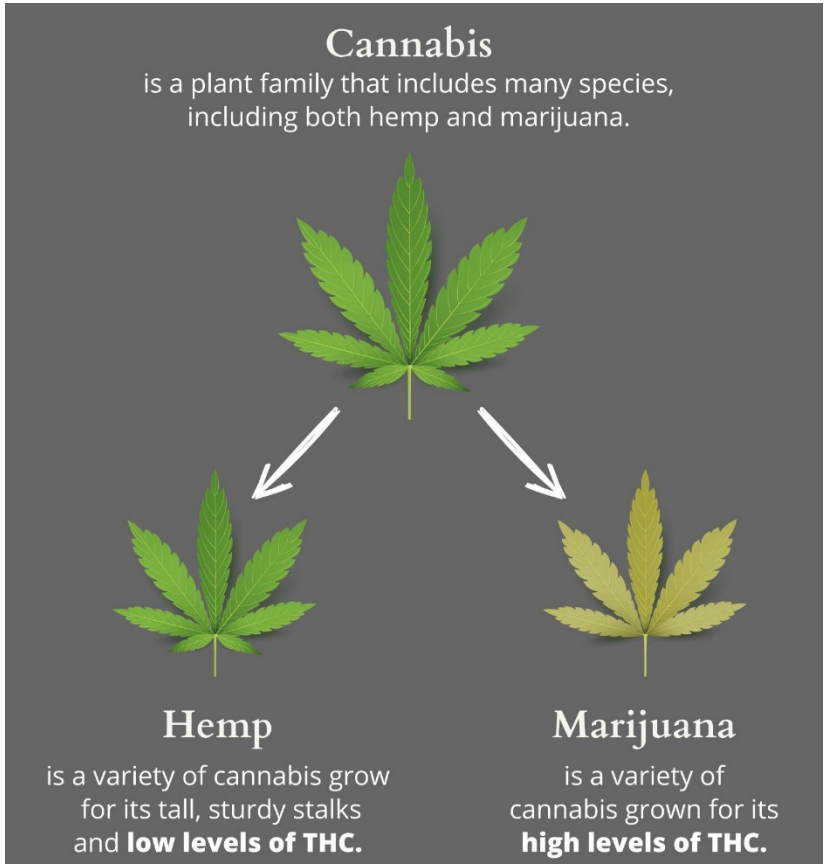
CBD (Cannabidiol) vs. THC (Tetrahydrocannabinol)

- Scientifically, hemp & marijuana are similar plants
- Different genetic profiles (genus & species)
- THC & CBD: phytocannabinoids (natural compounds)
- Marijuana: commonly greater THC concentration
  - THC can induce a mind-altering “high” (euphoria) or hunger
- Hemp: naturally greater CBD concentration
  - CBD does not cause euphoria: can reduce anxiety, inflammation, pain, etc.
- Hemp is used for food, fuel, fabric, fiber, etc.

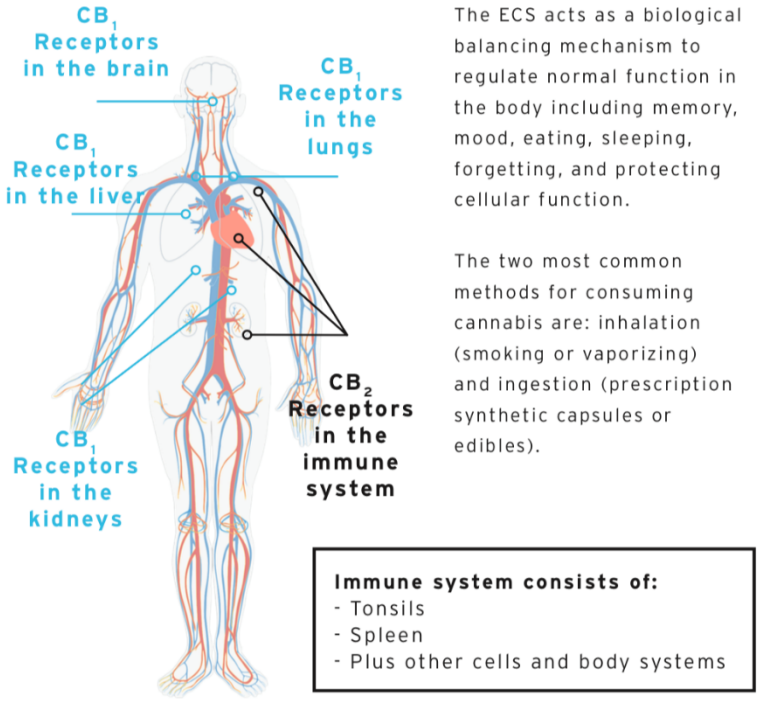


The Endocannabinoid System

Mammals evolved to have a unique ECS

- Function of the ECS:
  - ***Homeostasis***

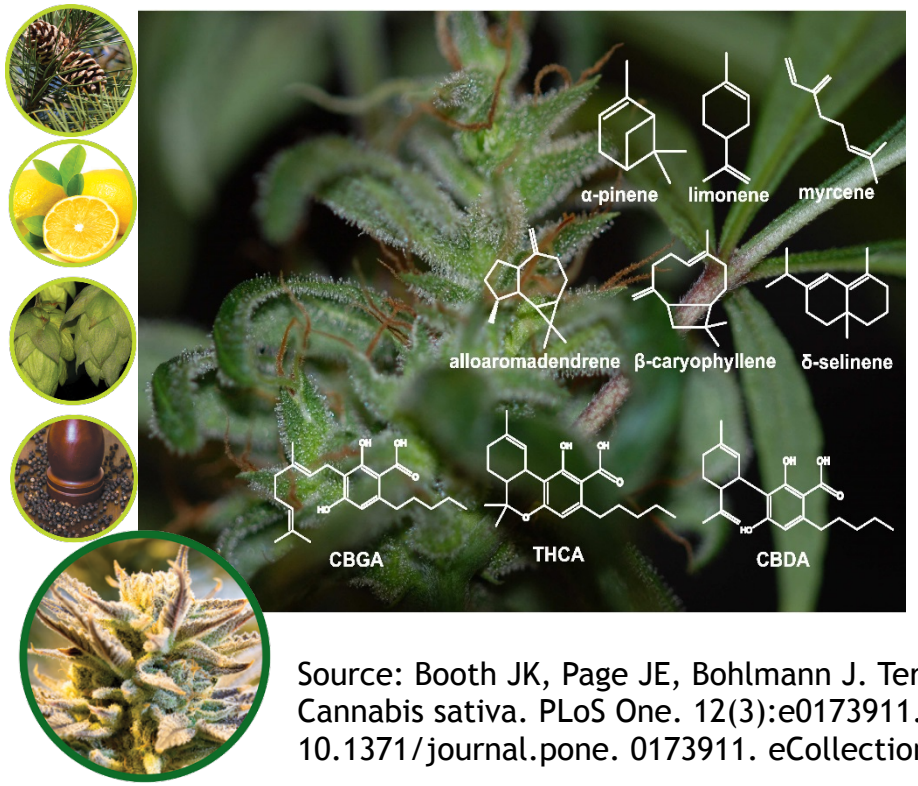
- Components of the ECS:
  - Receptors
  - Ligands
  - Enzymes



Source: Americans For Safe Access (2018). Medical Marijuana Access In the United States. A Patient-Focused Analysis of the Patchwork of State Laws. Washington, DC: Americans for Safe Access.

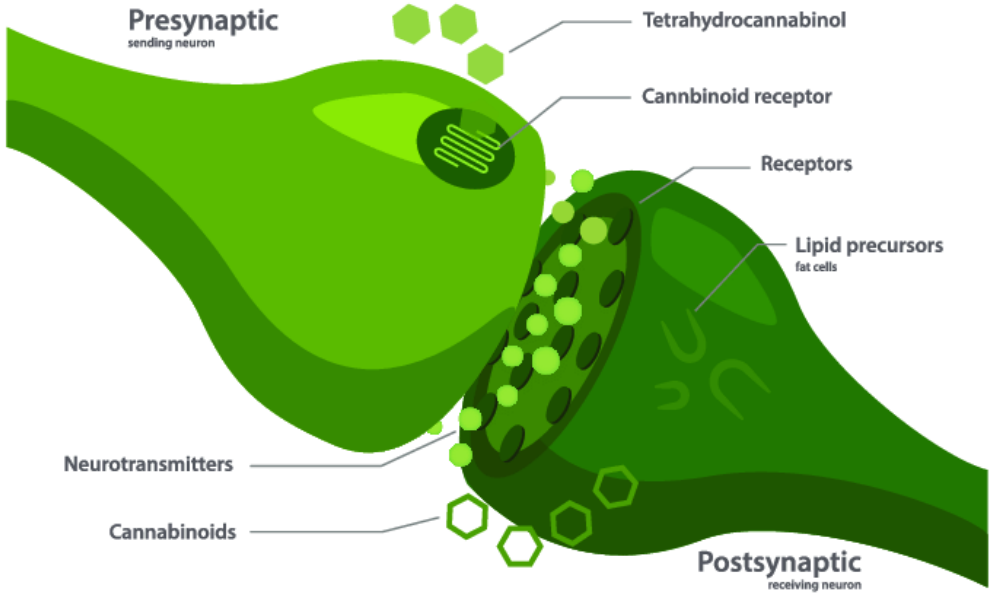
Cannabis Pharmacology

- Mechanism of action in the ECS



Source: Booth JK, Page JE, Bohlmann J. Terpene synthases from Cannabis sativa. PLoS One. 12(3):e0173911. doi: 10.1371/journal.pone. 0173911. eCollection 2017. PubMed PMID

- Cannabis contains phytochemicals
  - ***Cannabinoids***
  - ***Terpenes***
  - ***Flavonoids***

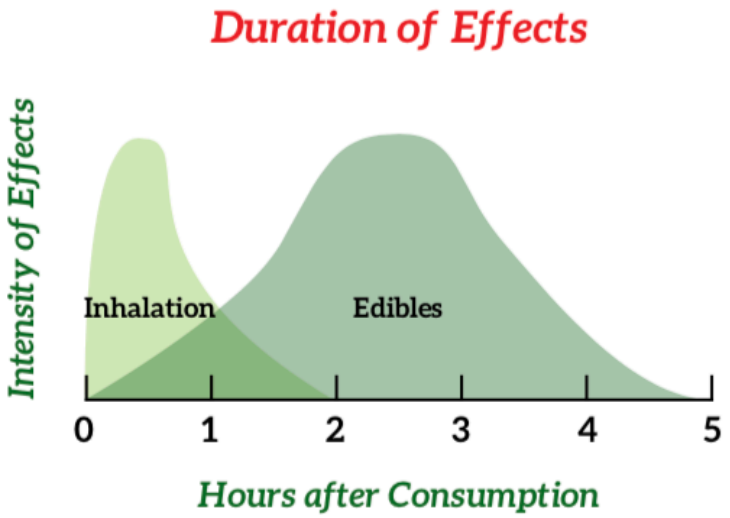


Source: Colucci, Dennis. (2019). Cannabis and Hearing Care: History, Legalization, and Biochemistry. The Hearing Journal. 72. 44. 10.1097/01.HJ.0000575388.97345.12.

Potency & Product Formulations

DELIVERY METHODS

PATIENTS USE MANY METHODS TO TAKE CANNABIS. THE METHOD USED CAN DEPEND ON PERSONAL CHOICE, THE MEDICAL CONDITION BEING TREATED, THE AGE OF THE PATIENT, THE PATIENT'S TOLERANCE FOR THE METHODS, ETC.



TOPICAL

Product types: lotions, salves, oils
Expected onset: a few minutes
Duration: 1-4 hours

BUCCAL

Product types: alcohol-based tinctures, lozenges
Expected onset: 0-60 minutes
Duration: 1-8 hours

Remember...
start low, go slow!

INHALATION

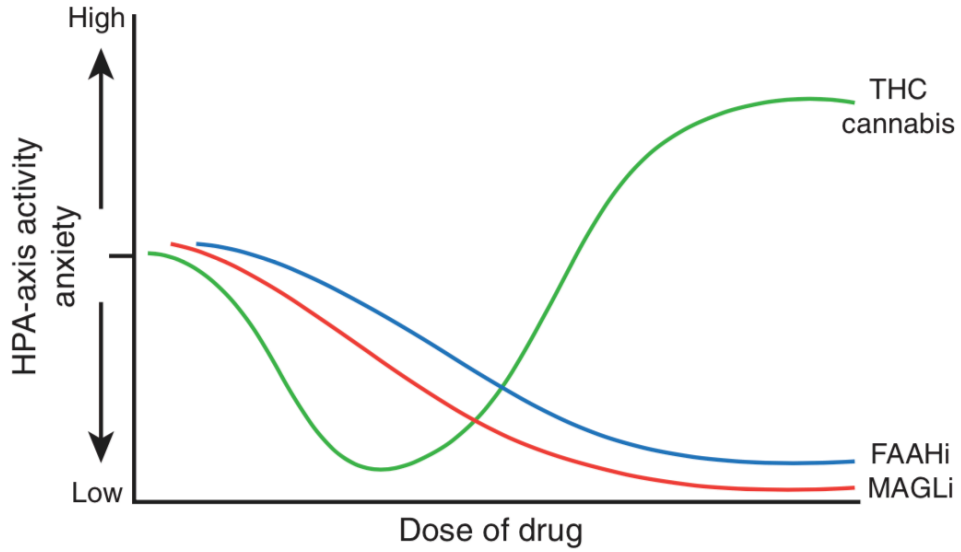
Types of products: whole plant, oils, waxes, and concentrates
Expected onset: 0-10 minutes
Duration: 1-4 hours

INGESTION

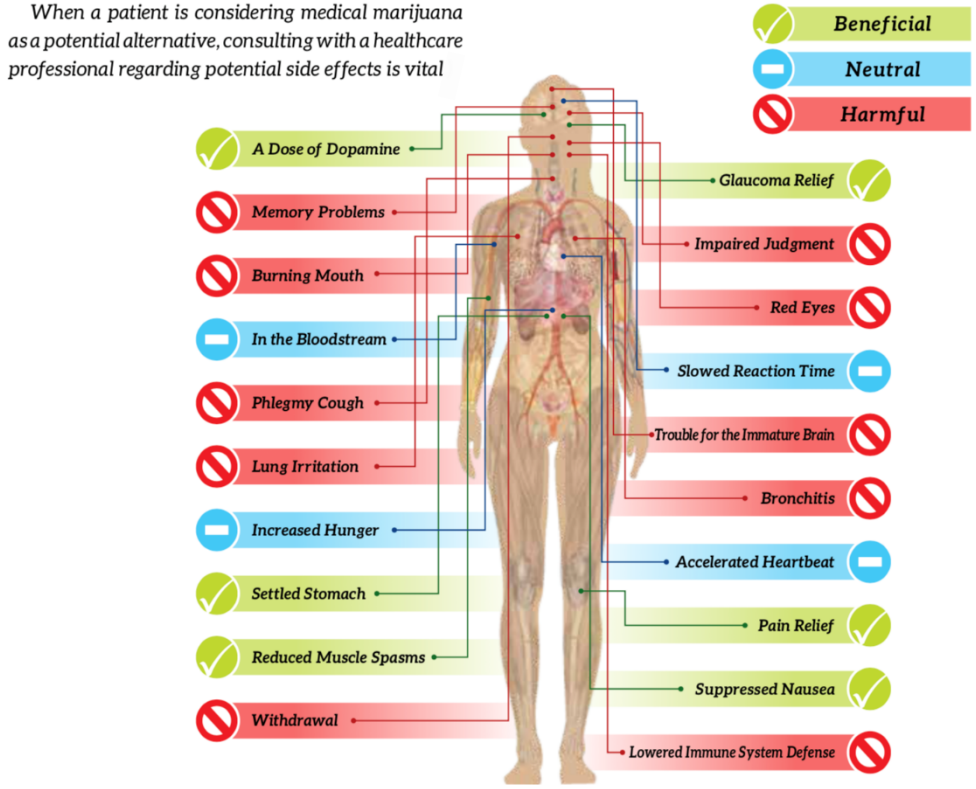
Product types: edible products, beverages, teas, capsules
Expected onset: 30 to 90 minutes
Duration: Up to 8 hours

Source: Americans For Safe Access (2018). Medical Marijuana Access In the United States. A Patient-Focused Analysis of the Patchwork of State Laws. Washington, DC: Americans for Safe Access.

Dose-Dependent Short-Term & Long-Term Effects



Source: Hill MN, et al. Integrating Endocannabinoid Signaling and Cannabinoids into the Biology and Treatment of Posttraumatic Stress Disorder.Neuropsychopharmacology. 2018 Jan;43(1):80-102. doi: 10.1038/npp.2017.162. Epub 2017 Jul 26. Review. PubMed PMID: 28745306; PubMed Central PMCID: PMC5719095.



Source: National Academies of Sciences, Engineering, and Medicine. (2017). The Health Effects of Cannabis and Cannabinoids: The current state of evidence and recommendations for research. Washington, DC: The National Academies Press

STANDARD OF CARE?

- Provider –Patient relationship
- History and Physical
- Formulating a diagnosis
- Treatment plan—with informed consent discussion
- Monitoring efficacy of treatment

- AND OF COURSE…..DOCUMENTATION!

Medical Use of Cannabis

- As cannabis in its various forms becomes legal in many of our States it is important for the medical community to react to the availability of these drugs
- It is important for physicians in States where marijuana is only legal for medical uses, that there continue to be restrictions on how and when cannabis can be certified and/or obtained – and each State's rules are different
- Considerations for physicians – will they practice in multiple States where the laws may be different as to the legality of cannabis?
- More considerations for physicians – are they treating patients who have medical cards in more than one State OR in a State where it is legal but living in a State where it is not?
- How readily available is cannabis to the patients in your State?
- Challenge is that our patients are accessing the drugs before the medical community truly understands it

Considerations: Medical Use of CBD

- Part of the concern with CBD use by patients is that it is being sold as a supplement and not a medication. As such, patients may not feel that they need to disclose their use of CBD to their physician.

- Research suggests any side effects that do occur with CBD use are likely the result of drug-to-drug interactions between CBD and other medications you may be taking.
  - So – for physicians, it will be critical to understand how CBD could interact with other medications.

- New research is also beginning to look at the effect of CBD on the liver in those patients taking it for prolonger periods.

Use of CBD – Malpractice Risk

- While the vast majority of the science indicates CBD oil is safe for use and consumption, it does pose a few risks that, if not properly understood, could lead to malpractice claims.
- CBD Oil is an inhibitor. What this means is that it can act to keep other medications from being processed by the body as quickly as intended so the drug remains in the patient's system longer than anticipated causing unwanted side effects or potential for overdose. Here are some examples:

Steroids	Anesthetics
HMG CoA reductase inhibitors	Antipsychotics
Calcium channel blockers	Antidepressants
Antihistamines	Anti-epileptics
Prokinetics	Beta blockers
HIV antivirals	PPIs
Immune modulators	NSAIDs
Benzodiazepines	Angiotension II blockers
Antiarrythmics	Oral hypoglycemic agents
Antibiotics	Sulfonylureas

Considerations: Medical Use of Marijuana (THC)

- Heart disease: Marijuana might cause rapid heartbeat, short-term high blood pressure. It might also increase the risk of a having heart attack.

- A weakened immune system: Cannabinoids in marijuana can weaken the immune system, which might make it more difficult for the body to fight infections.

- Lung diseases: Long-term use of marijuana can make lung problems worse. Regular, long-term marijuana use has been associated with lung cancer and also with several cases of an unusual type of emphysema, a lung disease.

- Seizure disorders: Marijuana might make seizure disorders worse in some people; in other people it might help to control seizures.

Malpractice Risks - THC

- Physicians are suddenly faced with having to know how cannabis can interact with other medications – EVEN IF THEY DO NOT CERTIFY FOR ITS MEDICAL USE
    - Example – Oncologist is working with a cancer patient who discloses use of cannabis for control of pain. Oncologist did not certify the patient for its use, but now needs to know how it could affect all of the other medications the patient takes for their cancer.
    - What if he/she prescribes a medication that is contraindicated with cannabis?
    - How will they educate themselves on those medications?
    - What is the effect of long term use of Marijuana?

Diverse Delivery Methods

- NY & NJ Medical Marijuana Program (MMP) approve different formulations:
- NY – non-smokable formulations
  - Oils/Pens
  - Tincture/drops
  - Gels, creams, lotions, or ointments
  - Capsules
  - Vaping (vaporizing)
- NJ – permits smokable formulations
  - Cannabis flower (bud) for vaping (preferred) or smoking (typically not recommended)
  - Oils/Pens
  - Tincture/drops
  - Gels, creams, lotions, or ointments
  - Capsules

NOT ALL PRODUCTS ARE THE SAME

- Oral ingestion peaks in 1-6 hours and then has a 20-30 minute half life
- Inhalation peaks at 2 to 10 minutes and decline begins within 30 minutes
- Potency levels vary
- Ration of THC to CBD varies

Use of Marijuana Where Legal for Recreational – Malpractice Risk

- Physicians are suddenly faced with patients asking them what they think about using cannabis

  - Example – General primary care physician is treating a patient with a diagnosis of severe rheumatoid arthritis. The patient is in constant pain and asks the doctor what she thinks about her using cannabis recreationally to ease the pain. The doctors says that it might be a good option for the patient to deal with her pain.

  - Patient obtains and uses cannabis as it is legal for recreational use

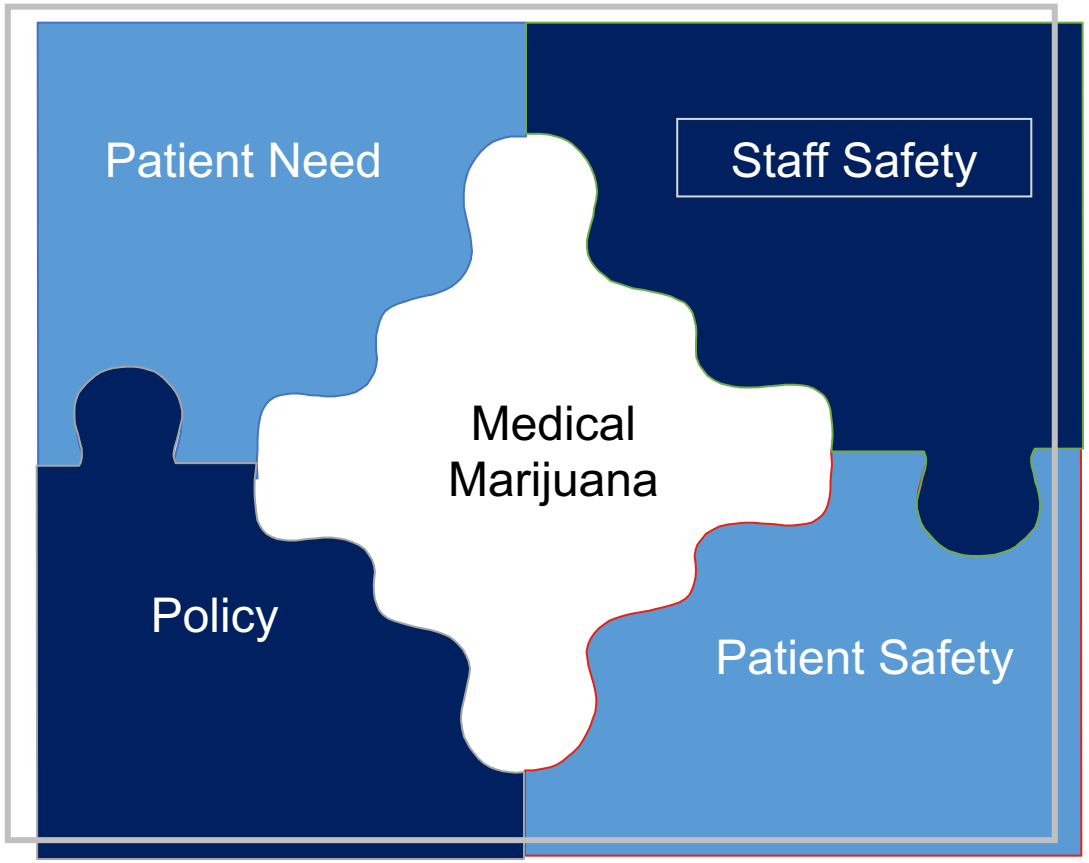
  - Patient has an adverse reaction to the cannabis and blames the physician saying that he/she said it was a good idea to use it.

LACK OF INFORMED CONSENT

RISKS:

Drug interaction
Increased risk of falls
Short term memory impairment
Increased confusion
Pregnancy/breast feeding, fertility
Impaired brain development
Increased risk of suicidal thoughts
Increase of symptoms of bipolar disorder
Smoking increases risk of respiratory illnesses
Increased risk of lung cancer in tobacco user who inhale
Dependence/addiction

Considerations for use in Hospital Setting



Balancing Act

Marijuana & Federal Law

Remains illegal

1. Schedule I controlled substance (21 U.S.C. §812[c][10]);

2. This means, pursuant to 21 U.S.C. §812(b)(1)(emph. supp.):
   A. The drug or other substance has a **high potential for abuse**.
   B. The drug or other substance has **no currently accepted medical use** in treatment in the United States.
   C. There is a **lack of accepted safety for use** of the drug or other substance under medical supervision.

Problem: In theory, any program designed to enable inpatients to use medical marijuana (and any program that gives a facility "possession" of medical marijuana) jeopardizes Medicare participation and could invite sanctions…

Marijuana & Joint Commission

Joint Commission

The Joint Commission Standard MM.03.01.05 policy that states: “The hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners.”[1]

This standard includes the following elements of performance:

- The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.
- Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.
- The hospital informs the prescriber and patient if the medication brought into the hospital by patients, their families, or licensed independent practitioners is not permitted.

1. The Joint Commission. Revisions to the medication management standards regarding sample medications. December 18, 2013. http://www.jointcommission.org/assets/1/6/Sample-Medications_HAP.pdf.

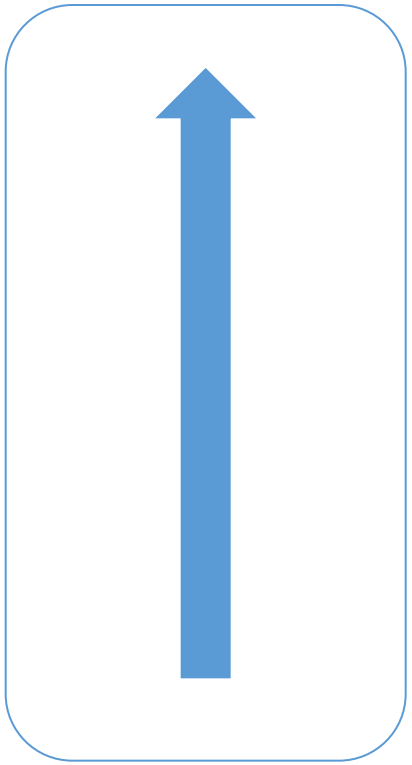
Patient Need & Safety

- Any patient who reports the use of medical marijuana at home and requests to use their medical marijuana while in the hospital will be asked for their New York State Department of Health Medical Marijuana Program ID card. A copy of the card will be scanned into the medical record.
- The patient or registered caregiver is responsible for the medication at all times.
- Only medical marijuana obtained from a NYS dispensary will be permitted in its original packaging.
- If at any time, the patient's clinical status suggests that the potential risk of using medical marijuana outweighs the potential therapeutic benefits of its use, the attending physician may state that the patient is not allowed to use medical marijuana during the hospital stay.

Patient comes through the door with medical marijuana – now what?

Turn a blind eye?

Patient Care & Safety



Claims and Lawsuits

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Sanctions & Fines

Can we get a policy?

Who's at the table?

So Many Questions

How do we document?

Some Ways to Lock it up…

- "The hospital is not responsible for storing or handling marijuana products. The medication will be secured in the patient's room."
- *Seems like a simple idea…Putting it into practice is not as easy as it seems.*

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OCTOBER 24-25, 2019 | MARRIOTT MARQUIS | NEW YORK CITY

Medical Cannabis in the Nursing Home

Zachary J. Palace MD CMD FACP
Medical Director, Hebrew Home at Riverdale

History of Cannabis

- 2700 BC – China
- 1400 BC – India
- 1000 BC - Tibet
- 70 AD – Greece

- 1842 – United Kingdom
- 1850 – United States

Approved indications - NYS

- Multiple Sclerosis
- Parkinson’s Disease
- Huntington’s Disease
- ALS
- Seizures
- Spinal cord injury
- Chronic or acute pain
- Neuropathy
- Cancer
- Inflammatory bowel dis
- AIDS
- HIV
- PTSD
- Opioid use disorder

Challenges In the Nursing Home

- Federal law – skilled nursing facility.
  Restrictions on possession, administration

- State law – patient.
  Rights of the individual NYS resident

How can we find a safe (and legal) balance?

Medical Marijuana
NYT, February 2017

The New York Times

"the News That's Fit to Print"

MONDAY, FEBRUARY 20, 2017

Reprinted With Permissio

New York

When Older Age Comes With Daily Doses of Medical Marijuana

The president and chief executive of RiverSpring Health, Daniel Reingold. He said he administered marijuana to his father as a painkiller shortly before his death.

PHOTOGRAPHS BY SANA PASKOVA FOR THE NEW YORK TIMES

Ruth Brunn, 98, pointing to her marijuana pill at her nursing home in the Bronx. "I don't feel high or stoned," she said.

By WINNIE HU

Ruth Brunn finally said yes to marijuana. She is 98.

She pops a green pill filled with cannabis oil into her mouth with a sip of vitamin water. Then Ms. Brunn, who has neuropathy, settles back in her wheelchair and waits for the jabbing pain in her shoulders, arms and hands to ebb.

"I don't feel high or stoned," she said. "All I know is I feel better when I take this."

Ms. Brunn will soon have company. The nursing home in New York City where she lives, the Hebrew Home at Riverdale, is taking the unusual step of helping its residents use medical marijuana under a new program to treat various illnesses with an alternative to prescription drugs. While the staff will not store or administer pot, residents are allowed to buy it from a dispensary, keep it in locked boxes in their rooms and take it on their own.

From retirement communities to nursing homes, older Americans are increasingly turning to marijuana for relief from aches and pains. Many have embraced it as an alternative to powerful drugs like morphine, saying that marijuana is less addictive, with fewer side effects.

For some people, it is a last resort when nothing else helps. Marijuana, which is banned by federal law, has been approved for medical use in 29 states, including New York, and the District of Columbia. Accumulating scientific evidence has shown its effectiveness in treating certain medical conditions. Among them: neuropathic pain, severe muscle spasms associated with multiple sclerosis, unintentional weight loss, and vomiting and nausea from chemotherapy. There have also been reports that pot has helped people with Alzheimer's disease and other types of dementia as well as Parkinson's disease.

Across the nation, the number of marijuana users who are in their later years is still relatively limited, but the increase has been significant, especially among those 65 and older, according to recent studies.

"It's a bigger issue than we thought," said Brian Kaskie, a professor of health policy at the University of Iowa who co-

Ruth Brunn taking her medical marijuana with vitamin water this month. She said it eased the pain of her neuropathy.

"People are using it, and we need know how to respond," she said.

But as older people come to represent an emerging frontier in the use of marijuana for medical purposes, questions are being raised about safety and accessibility. Even in states where medical marijuana is legal, older people who stand to benefit often cannot get it. Most nursing homes do not openly sanction its use, and many doctors are reluctant to endorse pot use, saying not enough is known about the risks in the oldest age groups.

"This is a target demographic that may have their access limited, if not cut off altogether, simply because they reside in a facility," said Paul Armentano, deputy director of NORML, a group that advocates the legalization of marijuana. "It is a problem that may infringe on their quality of life."

A drug that nursing home residents must buy and administer themselves.

often resorting to a "don't ask, don't tell" approach.

"If residents are taking it, they are taking it undercover without the staff knowing so it's not part of their care plan," said Dr. Cheryl Phillips, senior vice president for public policy and health services for LeadingAge, an industry group representing more than 2,000 nursing homes. "I think that creates a safety problem."

Fred Miles, a Colorado lawyer who represents nursing home operators, said nursing homes — unlike assisted living facilities — were regulated by the federal government, and were fearful of jeopardizing their Medicare and Medicaid funding. Staff members who administer marijuana could also theoretically face criminal prosecution under federal law, he said, though he has never heard of that happening.

The federal Centers for Medicare and Medicaid Services said no nursing home had specifically lost financing or been penalized for permitting the use of marijuana. In New York State, which started a medical marijuana program in 2016, its use is restricted to people with designated medical conditions, including neuropathy, epilepsy, multiple sclerosis, Parkinson's, H.I.V. AIDS and cancer.

At the Hebrew Home in the Bronx, the medical marijuana program was years in the making. Daniel Reingold, the president and chief executive of RiverSpring Health, which operates the home, said he saw its powers firsthand when his own father, Jacob, was dying from cancer in 1998. To ease his father's pain, Mr. Reingold boiled marijuana into a murky brown tea. His father loved it, and was soon laughing and eating again.

"The only relief he got in those last two weeks was the tea," Mr. Reingold said.

When Mr. Reingold requested approval from the nursing home's board members, there were no objections or concerns, he said. Instead, they joked that they would have to increase the food budget.

Then Dr. Zachary Palace, the medical director, developed a program that seeks to offer marijuana as an option but also comply with federal regulations. Though the nursing

LE TEMPS MARDI 14 MARS 2017

20 Société

Du cannabis pour le troisième âge

ÉTATS-UNIS A New York, dans le Bronx, un home pour personnes âgées permet à ses résidents de recourir au cannabis pour soulager certains maux. Rencontre avec le Dr Zachary Palace, responsable du projet pilote

«Nous avons toujours cherché à agir contre la surmédication. Le cannabis peut être une solution»

ZACHARY PALACE

LÉGISLATION

Et en Suisse?

The Nursing Home With A Medical Cannabis Program The Feds Can Live With

https://www.forbes.com/sites/abbierosner/2019/02/19/the-nursing-home-with-a-medical-cannabis-program-the-feds-can-

Forbes | Billionaires | Innovation | Leadership | Money | Consumer | Industry

The Nursing Home With A Medical Cannabis Program The Feds Can Live With

Abbie Rosner Contributor

Vices

I cover how older adults are discovering and re-discovering cannabis.

https://oglobo.globo.com/sociedade/lar-de-idosos-usa-maconha-para-melhorar-qualidade-de-vida-21626524

O GLOBO | SOCIEDADE | COMPARTILHAR

Lar de idosos usa maconha para melhorar qualidade de vida

Centro em Nova York incentiva adoção de cannabis para tratar doenças que acompanham o envelhecimento

POR JULITA LEMGRUBER

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January 2019

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Medical Cannabis in the Skilled Nursing Facility: A Novel Approach to Improving Symptom Management and Quality of Life

Zachary J. Palace MD, CMD *, Daniel A. Reingold MSW, JD

Hebrew Home at Riverdale, Bronx, NY

ABSTRACT

Throughout the millennia, the cannabis plant has been utilized as a recognized therapy for pain relief and symptom management. Following the Prohibition-era stigmatization and criminalization of all forms of cannabis of the early 20th century, there has been a recent nationwide and worldwide resurgence in interest and use of the cannabinoid compounds extracted from the cannabis plant, that is, medical cannabis. Although at the Federal level, cannabis remains a Schedule I substance, 31 states have already decriminalized possession and use of medical cannabis for specific diagnoses. It is noteworthy that many of these indicated diagnoses are prevalent in the skilled nursing facility (SNF). This creates regulatory concerns as SNFs and other healthcare facilities must maintain compliance with Federal laws, while balancing the individual resident's rights to utilize medical cannabis where indicated. The authors developed an innovative program that affords their residents the ability to participate in a state-approved medical cannabis program while remaining compliant with Federal law. As medical cannabis use becomes more widespread and accepted, clinicians providing medical care in healthcare facilities will encounter residents who may benefit from and request this alternative therapy. Studies examining older adults that are utilizing medical cannabis legally have demonstrated significant decreases in prescription medication use, most notably a reduction in opioid analgesic usage. As such, medical cannabis should be viewed as an additional option in the clinician's toolbox of therapeutic interventions for symptom relief.

Keywords: Medical cannabis, medical marijuana, alternative medicine, skilled nursing facility, symptom management

Problem/Significance

An essential principle in the practice of geriatric medicine in the skilled nursing facility (SNF) is the need for ongoing drug regimen review, with a keen focus of attention on simplifying medication regimens, avoiding polypharmacy, and eliminating medications with potentially harmful side effect profiles. As in general outpatient practice, clinicians practicing in the SNF have traditionally considered options for symptom management based on currently available Food and Drug Administration (FDA)–approved over-the-counter and prescription medications. In recent years, however, there has been a significant nationwide resurgence in the use of cannabis as a medical therapy. In fact, to date, 31 states in the US have now approved the use of medical cannabis for a variety of chronic conditions. Given the fact that cannabis remains a Schedule I controlled substance, what role, if any, does medical cannabis play in the SNF?

To begin to answer this question, historical records dating back to China (2700 BC), India (1400 BC), and ancient Greece (77 CE) describe the widespread therapeutic use of the cannabis plant for pain, inflammation, and spasticity.[1] In 1850, cannabis extract was added to the United States Pharmacopeia. During the second half of the 19th century, medical use of cannabis became a commonly prescribed remedy, well documented in the medical literature for the treatment of rheumatic pain, spasm, seizure, emesis, and neuralgia. In 1915, Sir William Osler, the father of modern medicine, describes cannabis as the "most satisfactory remedy" for migraine.[2]

Despite the role that medical cannabis held as a botanical therapy with a documented history supporting its use for symptom management, therapeutic use of cannabis ceased during the early 20th century. Prohibition-era social and political factors in the United States led to a significant national stigma associated with cannabis use for both medicinal and recreational purposes. The passage of the Marihuana Tax Act of 1937 as well as subsequent legislation resulted in the criminalization of possession and/or use of cannabis for any purpose. The Controlled Substances Act of 1970 categorized cannabis as a Schedule I drug, labeling it as a substance with no currently accepted medical use and with high potential for abuse.

During the 1990s, the discovery of the primary endogenous cannabinoids arachidonoylethanolamine and 2-arachidonoylglycerol and their corresponding CB1 and CB2 receptor sites both in the central nervous system and peripherally led to a major resurgence of interest in the therapeutic benefits of cannabis. Since the legalization of medical cannabis in the state of California in 1996, 30 additional states and the District of Columbia have passed similar legislation legalizing medical cannabis use. Nevertheless, cannabis possession and administration continue to remain illegal at the Federal level, given its continued status as a Schedule I controlled substance. As a recipient of Medicare and Medicaid funding, SNFs are required to remain in compliance with Federal law. As such, neither can the SNF purchase and store medical cannabis nor can facility nursing staff administer it to residents, as is common practice for all other medications and treatments.

The authors declare no conflicts of interest.

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https://doi.org/10.1016/j.jamda.2018.11.013
1525-8610/

European Journal of Internal Medicine, March 2018 Volume 49:44-50.

•**Epidemiological characteristics, safety and efficacy of medical cannabis in the elderly.**

-2736 patients above 65 years of age began cannabis treatment and responded to the questionnaire. Mean age was 74.5 ± 7.5 years. The most common indications for cannabis treatment were pain (66.6%) and cancer (60.8%).

-**Results:**

-After six months of treatment, 93.7% of the respondents reported improvement in their condition and the reported pain level was reduced from a median of 8 on a scale of 0-10 to a median of 4.

-35% reported decrease in total number of meds or dosage.

-18.1% stopped using opioid analgesics or reduced their dose.

•**Adverse effects:**

•Falls (21.9%), Dizziness (9.7%), dry mouth (7.1%)

•**Conclusion:**

•Therapeutic use of cannabis may decrease the use of other prescription medicines, including opioids.

Health Affairs, July 6, 2016

- Question: Is there data that medical cannabis is effective as a medication?

- Data source: Medicare Part D enrollees from 2010 to 2013, in District of Colombia and 17 states where medical cannabis laws were enacted.

- Data collected: Total number of prescriptions filled during the study period was measured.

Health Affairs, July 6, 2016

- Findings: Use of prescription drugs for pain, depression, seizures, anxiety, nausea, psychoses, and sleep disorders decreased significantly, once a medical marijuana law was implemented.

- National reductions in Medicare program and enrollee spending when states implemented medical marijuana laws were estimated to be $165.2 million/year in 2013.

- Conclusions: The availability of medical marijuana has a significant effect on prescribing patterns and spending in Medicare Part D.

Conclusions

- Wealth of historical clinical experience.
- Limited high quality scientific clinical trials.
- Symptom management – spasticity, pain, emesis, seizure.
- Clinical decision-making should always be individualized.
- Residing in a NH should not be a contraindication to use.