Supporter

• Cosponsored by the American Society for Pharmacy Law.

Disclosures

• Dr. Borgelt has served as a member of six working groups in Colorado:
  • Colorado Department of Public Health and Environment (CDPHE):
    Amendment 64 (Marijuana Legalization) Task Force Working Group:
    Consumer Safety and Social Issues
  • State Licensing Authority Labeling, Packaging, Product Safety and Marketing
  • State Licensing Authority Medical and Retail Marijuana Mandatory Testing
    and Random Sampling
  • State Licensing Authority Serving Size and Product Potency
  • CDPHE Retail Marijuana Public Health Advisory Committee
  • CDPHE Pregnancy and Breastfeeding Guidelines Committee

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Abbreviations

• ATF (Bureau of) Alcohol, Tobacco, and Firearms
• CBD Cannabidiol
• CSA Controlled Substances Act
• DOJ Department of Justice
• MMJ Medical MariJuana
• SCOTUS The United States Supreme Court
Learning Objectives

• At the completion of this knowledge-based activity, participants will be able to:

  1. Describe the legal issues that arise when patients of a hospital or retail pharmacy are using marijuana lawfully under state laws.
  2. Describe the laws and regulations governing clinical research that uses marijuana.
  3. Discuss the impact state and federal marijuana laws have on pharmacists who intend to be involved in marijuana business that is lawful under state laws.
  4. Summarize the holdings of recent court decisions interpreting state marijuana laws.
  5. Describe the conflicts between state and federal marijuana laws.
  6. Explain how to find reliable sources to know the laws governing marijuana in states where the attendee practices pharmacy.

Outline

• Introduction to marijuana and rationale for potential medical uses
• Pharmacology
• Federal laws
• State laws
• Pharmacokinetics Smoked vs. Eaten
• Therapeutic Effectiveness of MMJ
• Discussion of clinical and research conflicts

1. Which of the following forms of marijuana has the slowest onset of action?
   A. Intravenous
   B. Inhaled
   C. Oral
   D. Buccal

2. Which of the following is the most common reason for MMJ use in Colorado?
   A. Cancer
   B. Epilepsy
   C. Glaucoma
   D. Muscle spasms
   E. Nausea
   F. Pain

3. Which is true about a recent federal court case addressing the DOJ's (and DEA's) ability to enforce federal controlled substances laws?
   A. The court ruled the DEA cannot impose penalties or shut down dispensaries acting lawfully under state law.
   B. The court ruled the Supremacy Clause of the U.S. Constitution allows the DEA to arrest marijuana dispensers because marijuana is a schedule I substance.
   C. The court ruled pharmacists were permitted to be involved in marijuana dispensaries because they were acting lawfully under state law.
   D. The court ruled owners of dispensaries could be arrested because of the quantity of marijuana they possessed, but patients could not be arrested.

4. Which of the following is NOT true about federal cannabis law?
   A. Marinol (Dronabinol) capsules are available for commercial use.
   B. Smoked cannabis is a C-1 controlled substance.
   C. Pharmacies may not dispense C-1 controlled substances.
   D. The DEA may not enforce its laws to prevent states from implementing their own state laws.
   E. A series of memoranda from the DOJ prohibit the DEA from enforcing federal marijuana laws in states where marijuana is legal for medical use.
5. Which of the following is true?

A. Pharmacists should never ask patients if they are using marijuana or taking illicit drugs
B. Pharmacists should never put information about patient's marijuana use in the patient profile
C. Pharmacists should counsel patients never to use marijuana
D. Pharmacists should counsel patients about known drug-drug interactions with marijuana

6. Poll Question

I know someone who consumes marijuana for medical or recreational purposes.

A. Yes, medical purposes only
B. No, recreational purposes only
C. Yes, both
D. No

7. Poll Question

I believe the most common reason people seek out marijuana is to...

A. Relieve pain
B. Improve symptoms of nausea and vomiting
C. Relieve muscle spasms associated with multiple sclerosis
D. Get high

INTRODUCTION TO MARIJUANA AND RATIONALE FOR POTENTIAL MEDICAL USES

Patient Case in Colorado

- 47 y.o. male with PMH of hypertension, diabetes, peripheral neuropathy, and chronic pain
  - Pain Treatment Regimen
    - Oxycontin 30mg po BID and oxycodone 5 mg po prn
    - His pain medications have not changed in over one year
    - Today, he admits that he has also been smoking medical marijuana twice daily for the past two years to help his pain (decreased from 8/10 to 4/10)
    - He has been afraid to tell the healthcare team about this because he believes they will not “approve” of this treatment. He states he saw a different physician to get his card and recommendation for MMJ

A Few Questions to Consider

- Are there other ways for him to consume MMJ to avoid the risks of smoking?
- Is MMJ effective for the treatment of pain?
- What adverse effects might this patient experience with chronic use of inhaled MMJ?
- Are there any drug interactions with MMJ?
- How might MMJ impact his opioid use?
- What other issues might this patient need to consider?
- How can I create an environment where patients feel safe to talk with me about all treatments they use?
- What federal and state laws impact my ability to appropriately care for this patient?
Marijuana

- FDA approved products
  - Single molecule pharmaceuticals
    - Dronabinol (Schedule III)
    - Nabilone (Schedule II)
  - Liquid extract: nabiximols (Sativex®)
    - Approved in 27 countries; U.S. - Phase III trials
  - Liquid extract: cannabidiol (Epidiolex®)
    - FDA: orphan drug status for Dravet and Lennox-Gastaut syndromes
    - Expanded access INDs to several independent investigators

Phytocannabinoid-dense botanicals
- Cannabis sativa – medicinal plant (Schedule I)

Key Opinion

Considerations for medical use of marijuana are different than considerations for recreational use of marijuana.

Medical use: benefit - risk
Recreational use: risk - risk

Cannabis

- Plant-derived cannabinoids
  - ∆9-tetrahydrocannabinol - THC
  - ∆8-tetrahydrocannabinol - THC
  - Cannabidiol – CBD
  - Cannabinol - CBN
  - Cannabigerol - CBG
  - Cannabichromene - CBC
  - Cannabicyclol - CBL
  - Cannabielsoin - CBE
  - Cannabidiol - CBG
  - Miscellaneous
    - Cannabidiol (air-oxidation)

Endogenous Cannabinoid System

- Endocannabinoids and their receptors found throughout body:
  - Brain, organs, connective tissues, glands, and immune cells.
  - In each tissue, the cannabinoid system performs different tasks; goal is always homeostasis
  - When cannabinoid receptors are stimulated, a variety of physiologic processes occur
    - CB1 receptors: nervous system, connective tissues, organs, glands
    - CB2 receptors: immune system and associated structures
  - Endocannabinoids are substances our bodies make naturally to stimulate CB1 and CB2
    - Anandamide
    - 2-arachidonoylglycerol (2-AG)
Endogenous Cannabinoid System

• Endocannabinoids and their receptors found throughout body:
  – Brain
  – Organs
  – Connective tissues
  – Glands
  – Immune cells

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– CB1 receptors: nervous system, connective tissues, organs, glands
– CB2 receptors: immune system and associated structures

• Endocannabinoids are substances our bodies make naturally to stimulate CB1 and CB2
  – Anandamide
  – 2-arachidonoylglycerol (2-AG)

What happens when there is potential endocannabinoid deficiency, dysregulation, destabilization, or decreased binding?

Endocannabinoid System

Cannabis Pharmacology

Targets of Marijuana

CB1 Receptors
- Basal ganglia
- Motor activity
- Cerebellum
- Motor coordination
- Hippocampus
- Short-term memory
- Neocortex
- Thinking
- Hypothalamus & limbic
  - Appetite, sedation
  - Periaqueductal gray dorsal horn
- Pain
- Immune cells

CB2 Receptors
- Immunologic cells
- B lymphocytes
- Natural killer cells
- Brain
- Role not established

Endocannabinoid System

Non-Cannabinoid Targets Linked to Cannabis
- Other G-protein receptors: GPR55, GPR55940, etc.
- G-protein-coupled receptors: noncompetitive inhibitor at μ- and δ-opioid receptors, NE, DA, 5-HT
- Ligand-gated ion channels: allosteric antagonism at 5-HT3, nicotinic, and enhance activation of glycine receptors
- Transient receptor potential channels (TRPVs): bind and activate TRPV1 similar to capsaicin, also CB1 receptors are located near TRPV1
- Ion channels: inhibition of Ca, K, Na channels by non-competitive antagonism
- Peroxisome Proliferator-Activated Receptors: PPARα and PPARγ are activated

Another Kid on the Block…
Other cannabinoids found in the plant are also providing effects. The cannabinoid that has sparked the most interest is a non-psychoactive component called cannabidiol (CBD).

Little binding affinity to CB1 / CB2
Suppresses enzyme fatty acid amide hydrolase ("FAAH") – the enzyme that breaks down anandamide
Opposes THC at CB1 receptor
Stimulates release of 2-AG
TRPV-1 receptor agonist
5-HT1A receptor activation
GPR55 antagonist
Potential Physiologic Responses to Cannabis

- Improves sleep
- Anti-convulsant effects and neuroprotection
- Reduces anxiety and psychotic symptoms (PTSD)
- Prevents nausea and stimulates appetite
- Reduces intraocular pressure
- Bronchodilator
- Anti-inflammatory
- Anti-proliferative
- Anti-viral
- Relaxes muscles and reduces muscle spasms
- Relieves pain (especially neuropathic)

Adverse Effects of Marijuana

Effects of Short-term Use
- Impaired short-term memory
- Impaired motor coordination
- Altered judgment
- Motor vehicle accidents (2x)
- Paranoid and psychotic (high doses)

Effects of Long-term/Heavy Use
- Addiction (9% overall)
- Altered brain development*
- Cognitive impairment (with lower IQ)*
- Diminished life satisfaction and achievement*
- Poor educational outcome
- Symptoms of chronic bronchitis
- Increased risk of chronic psychosis disorders
*Effect is strongly associated with initial marijuana use early in adolescence

Drug Interactions

<table>
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<tr>
<th>Cannabinoid</th>
<th>CYP-450 2C9</th>
<th>CYP-450 2C19</th>
<th>CYP-450 3A4</th>
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<tbody>
<tr>
<td>Δ9-THC</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Δ8-THC</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>CBD</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>CBN</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

Application of Information

- 2C9, 2C19, and 3A4 INHIBITORS may increase the pharmacological effect and duration of THC
  - Macrolides (except azithromycin), oral contraceptives, cannabinoid (CBD), paroxetine, fluoxetine, and some PPI’s, HIV antiretrovirals, calcium channel blockers, and antifungals
- 2C9, 2C19, and 3A4 INDUCERS may decrease the pharmacological effect and duration of THC
- **NOTE**: Carbamazepine, rifampin, phenytoin, ritonavir, St. John’s Wort, phenobarbital

- Tachycardia
- Palpitations
- Hypertension
- Coughing
- Wheezing
- Sputum production
- Lethargy, Sedation, Skewed Reaction Time
- Psychological dysfunction
- Impaired coordination, memory formation, recollection, focus
- Visual Disturbances

- Macrolides (except azithromycin), oral contraceptives, cannabinoid (CBD), paroxetine, fluoxetine, and some PPI’s, HIV antiretrovirals, calcium channel blockers, and antifungals

- **NOTE**: CBD is a powerful inhibitor of CYP3A4 and CYP2D6
  - May increase the bioavailability and pharmacological effect of macrolide antibiotics, calcium channel blockers, antihistamines, haloperidol, sildenafil

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Impact of MMJ on Opioid Use

- When used in conjunction with opioids, cannabinoids can lead to greater cumulative relief of pain and potential reduction of opiate use.
- Comparisons in analgesia:
  - 10 mg THC less effective than 60 mg codeine
  - 20 mg THC more effective than 120 mg codeine
- Prevent development of tolerance to and withdrawal from opiates and potentially rekindle opiate analgesia after a prior dosage has become ineffective.
- Potentially less dangerous than opiates (no direct death).

J. Psychactive Drugs 2012;44:125-33

Key Point

Marijuana consists of 60+ cannabinoids. The effects of marijuana are dependent on many factors and very complex. Benefits and risks should be weighed carefully for individual patients.

Federal Laws

Treaty—Single Convention on Narcotic Drugs 1961

- Signed by U.S. and 183 other countries
- Cannabis deemed a banned substance
- Article 28 provides:
  1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply to it the system of controls as provided in article 23 respecting the control of the opium poppy.
  2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
  3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

See, Fink, J.L., Marijuana Producers and Distributors: The Evolving Federal Enforcement Philosophy, Rx Ipsa Loquitur, 42:2; March/April 2015.

Treaty—Single Convention on Narcotic Drugs 1961

- Cannabis is defined as:
  - The flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.
- Schedule I includes:
  - Tetrahydrocannabinol, and five other related substances including isomers and stereochemical variants.
- Legal implications: Treaties take precedence over federal and state laws.

Federal Law—Controlled Substances Act

“Marijuana” means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. 21 USC § 802(16).
Federal Law—Penalties

<table>
<thead>
<tr>
<th>Possession</th>
<th>Amount</th>
<th>Fine</th>
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<tbody>
<tr>
<td>First</td>
<td>$1,000</td>
<td>Up to 1 year</td>
<td></td>
</tr>
<tr>
<td>Second</td>
<td>$2,500</td>
<td>Mandatory minimum 15 days</td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td>$5,000</td>
<td>Mandatory minimum 90 days (up to 3 years)</td>
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</tr>
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21 USC § 844

The Supreme Court Speaks

• Gonzales v. Raich, 545 U.S. 1 (2005)
  – Marijuana users and growers in California sought declaratory relief declaring the Federal Controlled Substances Act unconstitutional as applied to their activities permitted by the California Compassionate Use Act.
  – SCOTUS ruled that Congress’s power under the Commerce Clause includes the power to prohibit local cultivation and use of marijuana because such local activity can substantially affect interstate commerce.

Federal Law—Evolving Views

Law by Memoranda (2009—Ogden)

• “Ogden Memo” October 19, 2009
  – Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana
    • David W. Ogden, Deputy Attorney General
    • Guide to the exercise of investigative and prosecutorial discretion
    • Generally will not pursue “individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.”

Federal Law—Evolving Views

Law by Memoranda (2011—Cole)

• “2011 Cole Memorandum”—June 29, 2011
  – Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use
    • James M. Cole, Deputy Attorney General
    • Response to state and local government inquiries
    • Reiterated Ogden Memo guidance
    • Recognized increased scope of commercial sale, cultivation, distribution and use of marijuana for “purported medical purposes.”
    • Ogden Memo was not a shield from federal prosecution of such activities.
    • Persons in such businesses and those who “knowingly facilitate” such activities are in violation of the Controlled Substances Act.
    • Those engaged in transactions involving proceeds from such activities may be in violation of federal money laundering laws.

Federal Law—Evolving Views

Law by Memoranda (2013—Cole)

• “2013 Cole Memorandum”—August 29, 2013
  – Guidance Regarding Marijuana Enforcement
    • James M. Cole
    • Updated Ogden Memo in light of state ballot initiatives that legalize possession of small amounts of marijuana

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Federal Law—Evolving Views
Law by Memoranda (2013—Cole)

DOJ Marijuana Enforcement Priorities

- Preventing the distribution of marijuana to minors
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and terrorists
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity
- Preventing marijuana possession or use on federal property

Federal Law—Evolving Views
Law by Memoranda (2013—Cole)

- DOJ’s guidance rests on its expectation that states and local governments will implement strong and effective regulatory and enforcement systems that will address the threat those laws could pose to public safety, public health, and other law enforcement interests.
- A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice.
- States must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

GAO Report—December 2015

- **STATE MARIJUANA LEGALIZATION: DOJ Should Document Its Approach to Monitoring the Effects of Legalization**
  - “GAO was asked to review issues related to Colorado’s and Washington’s actions to regulate recreational marijuana and DOJ’s mechanisms to monitor the effects of state legalization.”
  - “GAO recommends that DOJ document a plan specifying its process for monitoring the effects of state marijuana legalization, and share the plan with DOJ components.”

Restricting Federal Enforcement

- In 2014, Congress passed the 2015 Appropriations Act.
- Section 538 reads:
  
  > None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

Medical Marijuana

DEA Authority to Enforce Controlled Substances Act

  
  > RELIEF SOUGHT: Medical marijuana dispensary asked the court to dissolve a permanent injunction that prohibited it from dispensing medical marijuana under California’s Compassionate Use Act because Congress prohibited the Department of Justice ("DOJ") from using any resources to interfere with a state’s ability to implement its own medical marijuana laws.
  > ISSUE: Does Congress’s ban on DOJ’s interference with implementation of state medical marijuana laws warrant lifting the permanent injunction against MAMM?

Medical Marijuana

DEA Authority to Enforce Controlled Substances Act

- **U.S. v. MAMM**
  
  > REASONING: The court explained:

  
  > The plain reading of the text of Section 538 forbids the [DOJ] from enforcing this injunction against MAMM to the extent that MAMM operates in compliance with California law.

  > The Government’s contrary reading so tortures the plain meaning of the statute that it must be quoted to ensure credible articulation. (emphasis added)

  > Where to start? An initial matter, perhaps, is the contradiction inherent in the Government’s assertion that enjoining any one medical marijuana dispensary—here, MAMM—does not impede California’s implementation of its medical marijuana laws.
Medical Marijuana
DEA Authority to Enforce Controlled Substances Act
• U.S. v. MAMM
  – The court explained that the government’s “drop-in-the-bucket is at odds with fundamental notions of the rule of law.”
  – Section 538 does not allow a little bit of enforcement.
  – Congress chose to ban enforcement of federal laws by prohibiting the use of funds for such efforts.
  It defies language and logic for the Government to argue that it does not “prevent” California from “implementing” its medical marijuana laws by shutting down these same heavily-regulated medical marijuana dispensaries; whether it shuts down one, some, or all, the difference is of degree, not of kind.

In April 2015, the drafters of § 538 responded to the DOJ’s “recent statements indicating that the [DOJ] does not believe a spending restriction designed to protect [the medical marijuana laws of 35 states] applies to specific ongoing cases against individuals and businesses engaged in medical marijuana activity:"

As the authors of the provision in question, we write to inform you that this interpretation of our amendment is emphatically wrong. Rest assured, the purpose of our amendment was to prevent the Department from wasting its limited law enforcement resources on prosecutions and asset forfeiture actions against medical marijuana patients and providers, including businesses that operate legally under state law....

Ending Federal Marijuana Prohibition Act of 2013
• Introduced in House on February 5, 2013
• Directs the Attorney General to issue a final order that removes marijuana in any form from all schedules of controlled substances under the Controlled Substances Act.
• Subjects marijuana to the provisions that apply to intoxicating liquors.
• Grants the FDA the same authority for marijuana as it has for alcohol.
• Transfers functions of DEA relating to marijuana enforcement to ATF.
  – Renames: (1) ATF as the Bureau of Alcohol, Tobacco, Marijuana, Firearms and Explosives; and (2) the Alcohol and Tobacco Tax and Trade Bureau as the Alcohol, Tobacco, and Marijuana Tax and Trade Bureau.

Medical Marijuana
DEA Authority to Enforce Controlled Substances Act
• U.S. v. MAMM
  – The comments of lawmakers during the passage of § 538 further undermine the DOJ’s position.
  – Lead Sponsor, Dana Rohrabacher, explained: The harassment from the [DEA] is something that should not be tolerated in the land of the free. Businesspeople who are licensed and certified to provide doctor recommended medicine within their own States have seen their businesses locked down, their assets seized, their customers driven away, and their financial lives ruined by very, very aggressive and energetic Federal law enforcers enforcing a law.

Medical Marijuana
DEA Authority to Enforce Controlled Substances Act
• U.S. v. MAMM
  – HOLDING: As long as § 538 is in place, the DOJ can only enforce federal controlled substances laws against MAMM and other dispensaries if they are not in compliance with California laws.

Compassionate Access, Research Expansion, and Respect States Act of 2015 (S. 683)
• Introduced in Senate March 10, 2015
• Provides that the Controlled Substances Act sections relating to marijuana shall not apply to any person acting in compliance with State law relating to the production, possession, distribution, dispensation, administration, laboratory testing, or delivery of medical marijuana.”
• Removes sanctions against banks for providing services to "services to a marijuana-related legitimate business."
• Last action: Read twice and referred to the Committee on the Judiciary on March 10, 2015.
Respect State Marijuana Laws Act of 2015 (H. R. 1940)

A BILL

To amend the Controlled Substances Act to provide for a new rule regarding the application of the Act to marihuana, and for other purposes.

1. Short title
This Act may be cited as the Respect State Marijuana Laws Act of 2015.

2. Rule regarding application to marihuana
Part G of the Controlled Substances Act (21 U.S.C. 801 et seq.) is amended by adding at the end the following:

Sec. 710. Rule regarding application to marihuana
Notwithstanding any other provision of law, the provisions of this subchapter related to marihuana shall not apply to any person acting in compliance with State laws relating to the production, possession, distribution, dispensation, administration, or delivery of marihuana.

Current Status of State Marijuana Laws

- 24 states and the District of Columbia have passed legislation or voter initiatives legalizing the possession and distribution of marijuana for medical purposes under state or territorial law.
- Five states have legalized recreational use
  - Alaska
  - Colorado
  - Oregon
  - Washington

Medical Marijuana Chronology

- May 1985: Marinol Approved by FDA
- For further details of chronology, see, ProCon.com—Historical Timeline

State Marijuana Laws

Timeline Showing the Years States and the District of Columbia Passed Measures Legalizing Medical and Recreational Marijuana under State Law and the Years DOJ Issued Marijuana Enforcement Policy Guidance

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Sources of Information and Laws

<table>
<thead>
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<td>Marijuana Policy Project</td>
<td><a href="https://www.mppl.org/states/">https://www.mppl.org/states/</a></td>
</tr>
<tr>
<td>DEA Website</td>
<td><a href="http://www.deadiversion.usdoj.gov/Resources.html">http://www.deadiversion.usdoj.gov/Resources.html</a></td>
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Insight into Arguments Pro and Con

• Utah Health and Human Services Interim Committee meetings provide materials presented by both sides
  - May 20, 2015
      - 3J-The Impact of State Medical Marijuana Legislation on Adolescent Marijuana Use (DOPL recommended by Sen. Madsen)
      - 3K-Medical marijuana opponents’ most powerful argument is at odds with a mountain of research (WAPO Wonkblog, recommended by Sen. Madsen)
      - 3L-Medical Marijuana—Potential Objectives and Issues for Study
      - 3M-Medical Marijuana—Legalization Status
      - 3N-Medical Marijuana—Selected List of Stakeholders, Interested Parties, and Other Potential Sources of Information

• Resources from Utah Health and Human Services Interim Committee Meeting August 9, 2015
  - 2A-The Endocannabinoid System and Quality Control of Cannabis Medicines (Marcu)
  - 2B-Patient Focused Certification—Regulators Program Guide for Medical Cannabis (Americans for Safe Access)
  - 2C-Marijuana (Fleckenstein)
  - 2D-Safety and Toxicology of Cannabinoids (Yurgelun-Todd)
  - 2E-Marijuana for Medical Use in Colorado (Gerhardt)
  - 2F-Statement on Proposed Medical Marijuana Legislation (Webster)

2016 Legislative Action

• Utah—Two Competing Bills
  - HB 0086
    - Qualifying illnesses:
      - epilepsy;
      - nausea and vomiting during chemotherapy;
      - appetite stimulation caused by an HIV or AIDS infection;
      - muscle spasticity or a movement disorder; and
      - neuropathic pain conditions as follows:
        - complex regional pain syndrome;
        - peripheral neuropathy caused by diabetes;
        - post herpetic neuralgia;
        - pain related to HIV;
        - pain related to cancer;
        - pain occurring after and related to a stroke; and
        - phantom limb pain.

  - HB 0089
    - Broadens medical use of cannabidiol
    - Allows an individual with a qualifying illness to register and possess and use cannabidiol
    - Directs the Department of Health to issue a medical cannabidiol card to a qualified patient or a designated caregiver of a qualified patient
    - Allows cannabidiol facilities

2016 Legislative Action

• Utah HB0086
  - Qualifying illnesses:
    - epilepsy;
    - nausea and vomiting during chemotherapy;
    - appetite stimulation caused by an HIV or AIDS infection;
    - muscle spasticity or a movement disorder; and
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      - peripheral neuropathy caused by diabetes;
      - post herpetic neuralgia;
      - pain related to HIV;
      - pain related to cancer;
      - pain occurring after and related to a stroke; and
      - phantom limb pain.
2016 Legislative Action

- **Utah SB0073**
  - Allows use of whole cannabis, defined as marijuana
  - Allows licensing of cannabis facilities
  - Qualifying illnesses:
    - acquired immune deficiency syndrome or an autoimmune disorder;
    - Alzheimer's disease;
    - amyotrophic lateral sclerosis;
    - cancer, cachexia, or a similar condition with symptoms that include physical wasting, nausea, or malnutrition associated with chronic disease;
    - Crohn's disease or a similar gastrointestinal disorder;

2016 Legislative Action

- **Utah SB0076**
  - Qualifying Illnesses:
    - epilepsy or a similar condition that causes debilitating seizures;
    - multiple sclerosis or a similar condition that causes persistent and debilitating muscle spasms;
    - post-traumatic stress disorder related to military service; and
    - chronic pain in an individual, if a physician determines that the individual is at risk of becoming chemically dependent on, or overdosing on, opiate-based pain medication.
  - And other conditions approved by a Compassionate Use Committee on a case-by-case basis

State Marijuana Laws

- **Examples of Decriminalization**
  - **Colorado:**
    - November 6, 2012 ballot initiative approved by 55% of voters
    - Amendment 64 ("Use and Regulation of Marijuana") amended Article XVIII of the Colorado Constitution by adding Section 16: In the interest of the efficient use of law enforcement resources, enhancing revenue for public purposes, and individual freedom, the people of the state of Colorado find and declare that the use of marijuana should be legal for persons twenty-one years of age or older and taxed in a manner similar to alcohol. (emphasis added).

State Marijuana Laws (Colorado)

- **Colorado:** Legalization
  - November 6, 2012 ballot initiative approved by 55% of voters
  - Amendment 64 ("Use and Regulation of Marijuana") amended Article XVIII of the Colorado Constitution by adding Section 16: In the interest of the efficient use of law enforcement resources, enhancing revenue for public purposes, and individual freedom, the people of the state of Colorado find and declare that the use of marijuana should be legal for persons twenty-one years of age or older and taxed in a manner similar to alcohol. (emphasis added).
State Marijuana Laws (Colorado)
• Colorado: Legalization
  – Non-Medical—Residents 21 years old or older can:
    • Possess up to 1 ounce of cannabis while traveling
    • Gift up to 1 ounce to another adult
    • Grow up to 3 immature and 3 mature cannabis plants
    • Non-Residents can Purchase up to ¼ oz. in a single transaction
    • Cannot consume “openly or publicly”
    • Cannot travel across state lines while in possession of marijuana

State Marijuana Laws (Connecticut)
• Medical use (11 qualifying chronic uses)
  – 18 years old
  – Must obtain Registration Certificate
  – Marijuana must be grown in Connecticut
• Must be provided by a “dispensary”
• “Licensed dispensary” or “dispensary” means:
  – a pharmacist licensed . . . who the Department of Consumer Protection determines to be qualified to acquire, possess, distribute and dispense marijuana . . . , and who is licensed as a dispensary by the Department of Consumer Protection . . . .

State Marijuana Laws—Medical Use Legal (Hawaii)
• Confidential registry and identification cards
• No criminal penalties for possession by patients who:
  – Possess a signed statement from their physician affirming that he or she suffers from a debilitating condition and that the “potential benefits of medical use of marijuana would likely outweigh the health risks.”
• Possession Limits:
  – An “adequate supply” jointly between patient and the primary caregiver—cannot exceed 3 mature marijuana plants, 4 immature marijuana plants, and 1 ounce of usable marijuana per mature plant.

State Marijuana Laws—Medical Use Legal (Hawaii)
• Approved conditions:
  • Cancer
  • Glaucoma
  • HIV/AIDS positive
  • Chronic or debilitating disease or medical condition or its treatment that produces:
    • cachexia or wasting syndrome
    • severe pain
    • severe nausea
    • seizures, including those characteristic of epilepsy, or severe and persistent muscle spasms, including those characteristic of multiple sclerosis or Crohn’s disease.

States in which Marijuana Legislation has Been Introduced 2016

<table>
<thead>
<tr>
<th>State</th>
<th>Legislation Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>H.B. 2006 and 2007 Would remove criminal liability for small amounts</td>
</tr>
<tr>
<td>Georgia</td>
<td>HB 722 Would allow medical use</td>
</tr>
<tr>
<td>Hawaii SB 873, SB 383, HB 717</td>
<td>Would legalize personal use 18 y.o.</td>
</tr>
<tr>
<td>Massachusetts (Ballot initiative)</td>
<td>Would legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Illinois HB4276</td>
<td>Would legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Kentucky SB16</td>
<td>Cannabis Freedom Act would legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Michigan (HB 4877)</td>
<td>Would legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Missouri HJR 57</td>
<td>Proposes a constitutional amendment legalizing marijuana</td>
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<tr>
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</tr>
<tr>
<td>New Mexico</td>
<td>Proposes ballot initiative for legalizing marijuana</td>
</tr>
<tr>
<td>New York</td>
<td>Would legalize personal use 18 y.o.</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Vermont</td>
<td>Legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Legalize personal use 21 y.o.</td>
</tr>
<tr>
<td>Washington D.C.</td>
<td>Legalize personal use 21 y.o.</td>
</tr>
</tbody>
</table>

Effects on Adjacent States

- Between a Rock and a High Place: How Neighboring States Struggle when Pot Becomes Legal

The Marijuana Civil War—Nebraska & Oklahoma v. Colorado

- “In our constitutional system, the federal government has preeminent authority to regulate interstate and foreign commerce, including commerce involving legal and illegal trafficking in drugs such as marijuana. This authority derives from the United States Constitution, acts of Congress, including the Controlled Substances Act . . . and international treaties, conventions, and protocols to which the United States is signatory.”
- Nebraska and Oklahoma claim Colorado has “created a dangerous gap” in the federal drug-control system and “[m]arijuana flows from this gap into neighboring states,” . . . “draining their treasuries, and placing stress on their criminal justice systems.”

The Marijuana Civil War—Oklahoma v. Oklahoma

- Seven Oklahoma legislators publicly criticized that state’s attorney general for filing suit to strike down Colorado’s marijuana law.
- “[M]any of our Constituents want us to consider filing an amicus brief on behalf of Colorado.”
- “Our primary concerns surround the implications of this lawsuit for states’ rights, the Tenth Amendment, and the ability of states and citizens to govern themselves as they see fit.”
- “We believe this lawsuit against our sister state has the potential, if it were to be successful at the Supreme Court, to undermine all of those efforts to protect our own state’s right to govern itself under the Tenth Amendment to the U.S. Constitution. While it may be open to interpretation, we also do not believe the commerce clause grants the federal government any power to regulate intrastate trade or marijuana.” (emphasis added)
- “If the commerce clause could be interpreted so broadly, there is virtually nothing the federal government could not regulate or control under the guise of ‘commerce.’”
The Marijuana Civil War—Oklahoma v. Oklahoma

- Deep concerns in the lawsuit are "implications for the national sovereignty of our entire country. The suit against Colorado contains multiple references to a series of three United Nations drug conventions. It even argues flatly that these international agreements are the equivalent of constitutional federal laws."
- "The lawsuit also appears to endorse federal commandeering of state and local resources to enforce federal statutes and international treaties."
- "[A]ttempting to undermine the sovereignty of a neighboring state using the federal courts, even if inadvertently, is [not] a wise use of Oklahoma's limited state resources."

Pharmacokinetics

Smoked vs. Eaten

Medical Marijuana: Formulations


Marijuana Through the Lungs

- Similar to IV bolus
- Passive diffusion into alveolar capillaries
- Bioavailability: 2-96%
- Fraction absorbed: 10-20%
- Rapid onset (sec-min)
- Maximal onset 30 minutes and lasting 2-3 hours
- Metabolism in liver, lung, and brain
- Elimination t½ = 20 hrs (2-13 days)
- Elimination primarily via feces (65%) and urine (20%)

Can easily titrate to desired effect
Marijuana Through the Gut

- Variable absorption
- Bioavailability ranges 4-20%
- Onset: 30 minutes-2 hours
- Duration: 5-8 hours
- Metabolized primarily in the liver
  - 11-hydroxy-THC
- Elimination t½ = 20-30 hrs
- High inter- and intra-patient variability

State Marijuana Laws (Colorado)

- Driving
  - Most states have zero tolerance for marijuana (THC) in the blood
  - The fact that a person charged with drugged driving is entitled to use the legal or medical use of marijuana does not constitute a defense against any charge of driving under the influence. Colorado Revised Stat. § 42-4-1301(1)(e).
  - Presumptive impairment 5 ng/ml limit
    - But, woman with 19 ng/ml THC Level Acquitted:

Pharmacology in Action: Oral Formulations

- New Technology to detect THC levels
- Marijuana and Driving Q&A
- Traffic Stop to Evaluate Marijuana Impaired Driving

State Marijuana Laws (Colorado)

Edibles: A growing business

New amendments limit THC content to 10 mg per unit.
Up to 100 mg per package.
Marijuana Through the Mucosa

• Onset: 15-40 minutes
• Duration: 45 minutes-2 hours
• May have inter- and intra-patient variability
• Plasma levels of THC and other cannabinoids are lower compared with the levels achieved following inhalation of cannabinoids at a similar dose (nabiximols)
• Metabolized in the liver
• Elimination via feces (65%) and urine (35%)

Therapeutic Effectiveness of MMJ

MMJ Registrants in CO and OR: Qualifying Conditions

How Should MMJ Be Studied?

Inhaled Cannabis for Neuropathic Pain: Meta-Analysis of Individual Data

Key Point

Given the wide variety of formulations available, it is important to consider various pharmacokinetic and pharmacodynamic parameters.

A patient-determined, self-titrated dosing model should be used. The most effective and tolerable formulation and dose will vary based on body type, weight, and condition.

Providers need to step into a shared decision making model with patients.

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Providers need to step into a shared decision making model with patients.
Crossover Study: Low-dose Vaporized Cannabis

- Objective: evaluate analgesic efficacy in patients with neuropathic pain despite traditional treatments
- Visual analog scale (0-100)
- 39 patients with previous cannabis exposure
  - 28 male/11 female
  - Avg age 50 years
- Vaporized cannabis
  - Medium-dose (3.53%)
  - Low-dose (1.29%)
  - Placebo

<table>
<thead>
<tr>
<th>INHALED CANNABIS</th>
<th>Number of episodes</th>
<th>256</th>
<th>P vs Low: p=0.0069</th>
</tr>
</thead>
<tbody>
<tr>
<td>111</td>
<td>10/38 [26% (15-42%)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>21/37 [57% (41-71%)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-dose</td>
<td>22/36 [61% (45-75%)]</td>
<td></td>
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<th>Statistical significance</th>
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<td>P vs Low: p=0.0069</td>
</tr>
<tr>
<td>P vs Med: p=0.0023</td>
</tr>
<tr>
<td>Low vs Med: p=0.7</td>
</tr>
</tbody>
</table>

| NNT | Low: 3.2 | Med: 2.9 |

J Pain 2013;14:136-48

Smoked Cannabis for Chronic Neuropathic Pain

- 21 adults post-traumatic or post-surgical neuropathic pain
- Cannabis 25 mg at 0%, 2.5%, 6%, and 9.4% THC smoked 3x/day
- Four 14-day periods in crossover trial
- Primary outcome: pain intensity (11-item scale)

<table>
<thead>
<tr>
<th>Number of episodes</th>
<th>≥30% improvement in VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>122</td>
<td>31/61 [≥50% improvement in VAS]</td>
</tr>
<tr>
<td>248</td>
<td>(RR (95% CI) 2.38 (1.38 to 4.10))</td>
</tr>
<tr>
<td>646</td>
<td>(NNT (95% CI) 3.38 (2.19 to 7.50))</td>
</tr>
</tbody>
</table>

MMJ in Painful HIV-Associated Sensory Neuropathy: Systematic Review and Meta-Analysis

- Objective: evaluate clinical effectiveness of various analgesics
- Total of 14 trials evaluated
- Smoked cannabis 1-8% and capsaicin 8% found to be effective

Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders

- Condition Effective Possibly effective Probably or possibly ineffective
- Spasticity OCE Nabiximols, THC
- Central pain or painful spasms OCE Nabiximols, THC
- Urinary dysfunction Nabiximols THC, OCE
- Tremor THC, OCE, nabiximols

"The risks and benefits of medical marijuana should be weighed carefully."

Psychiatric Implications

- Acute cannabis psychosis
  - Very large dose of cannabinoid botanical consumed
  - Typically through oral ingestion (concentrated preparation)
  - Agitation, confusion, sedation
  - Self-limiting and generally disappears after metabolism/excretion

- Acute schizophreniform reaction
  - Young adults under stress and have other vulnerabilities to schizophreniform illness
  - Early and heavy cannabis exposure may increase the risk of developing a psychotic disorder such as schizophrenia
  - Carefully monitor or avoid in early teens or preteens with preexisting symptoms of mental illness or patients with significant family or personal history of mental illness

Pediatric Epilepsy: AES Annual Meeting 2015

- 261 children (average age 11 years)
- Severe epilepsy not responding to other treatments
- Epidiolex given in increasing doses with other AEDs (avg=3)
- After 3 months of treatment
  - 45% lower frequency of seizures
  - 47% experienced ≥50% reduction in seizures
  - 47% seizure-free
  - Dravet syndrome patients: 62% reduction in seizures, 13% seizure free
  - Lennox-Gastaut patients: 71% reduction in atonic seizures
- Frequency of seizures
  - 45% lower frequency of seizures
  - 47% experienced ≥50% reduction in seizures
- Adverse effects (>10%)  
  - Sleepiness, diarrhea, fatigue (4% discontinued treatment)
  - Adverse events
  - Altered liver enzymes, status epilepticus, diarrhea and others
  - Lack of efficacy caused 12% withdrawal

Marijuana Exposure in Childhood and Adolescence

- 3Ds: Dependence – Depression – Dysfunction
- Dunedin Study (Meier 2012)
  - Over 1000 individuals followed from birth ('72/'73) to 38 years
  - Cannabis use ascertained at 18, 21, 26, 32, and 38 years
  - Neuropsychological testing at 13 and 38 years
- Results for persistent adolescent users:
  - Greater decline in IQ (~6 IQ points)
  - Greater neuropsychological impairment
  - Executive functioning and processing speed
  - Informants reported observing significantly more attention and memory problems
- Conclusion:
  - Neurotoxic effects of cannabis on the adolescent brain

Cannabis Treatment for Chronic Pain

- Systematic Review and Meta-Analysis
  - 18 double-blind RCTs
  - Synthetic derivatives included
  - Efficacy outcome: “intensity of pain” by VAS
  - Harms: number of adverse events
  - Concluded moderate efficacy, but risks may be greater than benefit

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>OR (95% CI)</th>
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<tbody>
<tr>
<td>Intensity of pain</td>
<td>-0.61 (-0.84, -0.37)</td>
</tr>
<tr>
<td>Euphoria</td>
<td>4.11 (1.33, 12.72)</td>
</tr>
<tr>
<td>Dysphoria</td>
<td>2.60 (0.66, 9.90)</td>
</tr>
<tr>
<td>Blurred vision</td>
<td>8.34 (4.63, 15.03)</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>2.18 (0.93, 5.11)</td>
</tr>
<tr>
<td>Disorientation/Confusion</td>
<td>3.24 (1.51, 6.97)</td>
</tr>
<tr>
<td>Dissociation/ Acute psychosis</td>
<td>3.18 (0.89, 11.33)</td>
</tr>
<tr>
<td>Speech disorders</td>
<td>4.13 (2.08, 8.20)</td>
</tr>
<tr>
<td>Ataxia, muscle twitching</td>
<td>3.84 (2.49, 5.92)</td>
</tr>
<tr>
<td>Numbness</td>
<td>3.98 (1.87, 8.49)</td>
</tr>
<tr>
<td>Impaired memory</td>
<td>3.45 (1.19, 9.98)</td>
</tr>
<tr>
<td>Attention disturbances</td>
<td>5.12 (2.34, 11.21)</td>
</tr>
</tbody>
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Research Gaps

- **CLINICAL**
  - Specific medical conditions
  - Specific cannabinoid effects
  - Varied formulation and dose-related effects
  - Patient participation (including naïve and regular users)
  - Methodology/design
- **FEDERAL**
  - Investigator must secure a Schedule I research registration from the DEA and often a Schedule I research license from the state-controlled drug agency
  - FDA assesses research and data from clinical studies where research is initiated by either investigator or a pharmaceutical company
  - Investigational new drug application with 1+ protocols must be presented and allowed by the FDA
  - Expanded access may also be allowed for seriously ill patients
  - “Differential scheduling” is possible (e.g., dronabinol – synthetic THC – Schedule III)
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  - Challenges can be overcome with high-quality clinical research by trained individuals

Future Research Improvements

- Report as much as possible about beneficial and harmful effects in medical conditions
- Report as much as possible about strains of cannabis
- Concentration of cannabinoids in plant
- Concentration of cannabinoids in blood of participants
- Do not equate effects of cannabis in human samples with effects of synthetic THC and CBD
- Plant has complex set of interactions with cannabinoids and terpenes (among other components)
- Need to study strains used in “real world”
- Challenges can be overcome with high-quality clinical research by trained individuals
Other Interesting Clinical Findings

- PTSD: cannabis used more frequently for sleep and coping
  - Drug and Alcohol Dependence 2014;136:162-5
  - J Psychoactive Drugs 2014;46:73-7
- IBD: improved pain and diarrheal symptoms
  - Inflamm Bowel Dis 2014;20:472-80
  - Inflamm Bowel Dis 2013;19:2809-14
  - Dig Dis 2014;32:468-74
- Pediatric treatment-resistant epilepsy: parental reports
  - Epilepsy Behav 2015;47:138-41
  - Epilepsy Behav 2015;45:49-52
  - Epilepsy Behav 2013;29:574-7
- Migraine
  - Pharmacotherapy 2016;article online (DOI: 10.1002/phar.1673)

Conclusions

- The endocannabinoid system, including CB1 and CB2 receptors, is the key target for exogenous cannabinoids.
- Psychoactive effects of marijuana related to THC, but other cannabinoids involved with other therapeutic effects
- Many different formulations and variable doses available in “real world” setting; should be individualized
- Clinical studies indicate MMJ may have a role in patients with neuropathic pain and seizures refractory to other treatments.
- Providers should be aware of potential drug interactions and other patient safety issues

Employment and Other Legal Issues

Marijuana and Employment

- State laws vary in their protection of workers
  - Examples of states that provide some protection:
    - Arizona—No discrimination based on status as registered qualified patient
    - Unless an employer would lose a monetary or licensing-related benefit under federal law, an employer may not discriminate against a person in hiring, termination or imposing any term or condition of employment or otherwise penalize a person based upon either:
      1. The person’s status as a cardholder.
      2. A registered qualifying patient’s positive drug test for marijuana components or metabolites, unless the patient used, possessed or was impaired by marijuana on the premises of the place of employment or during the hours of employment.
- Cannot undertake any task under the influence of marijuana that would constitute negligence or professional malpractice. (A.R.S. § 36-2802a)

Marijuana and Employment

- Arizona Continued
  - Employers are not required to:
    - Allow marijuana use at work or
    - Allow any employee to work under the influence of marijuana.
      - But, a registered qualifying patient is not under the influence solely because metabolites or components of marijuana are present in insufficient amounts to cause impairment. (A.R.S. § 36-2814 A.3)
      - Cannot undertake any task under the influence of marijuana that would constitute negligence or professional malpractice. (A.R.S. § 36-2802a)

Marijuana and Employment

- Nevada
  - An employer does not have to allow medical use of marijuana in the workplace.
  - An employer does not have to modify the job or working conditions of a person who engages in the medical use of marijuana that are based upon the reasonable business purposes of the employer.
Marijuana and Employment

Nevada continued

• But an employer must attempt to make reasonable accommodations for the medical needs of an employee who engages in the medical use of marijuana if the employee holds a valid registry identification card, if such reasonable accommodation would not:
  – Pose a threat of harm or danger to persons or property or impose an undue hardship on the employer; or
  – Prohibit the employee from fulfilling any and all of his or her job responsibilities.

NRS 453A.800

Marijuana and Employment (Cases)

  – Held that employees who used marijuana in compliance with the Michigan Medical Marijuana Act (“MMMA”) and who tested positive for marijuana at workplace drug screen could collect unemployment benefits.
  – Reasoned that the MMMA created a broad immunity because under the law, a registered qualified patient “shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege . . . . for medical use of marijuana in accordance with this act.”
  – Denial of unemployment benefits fell within the broad term “penalty.”

• Ross v. Ragingwire Telecommunications, 70 Cal. Rptr. 3d 382 (Cal. 2008)
  – Held that a medical marijuana user who was fired as a result of a positive drug test did not have a claim for disability-based discrimination or for wrongful termination in violation of public policy.

• Emerald Steel Fabricators, Inc. v. Bureau of Labor and Industries, 230 P.3d 518 (Or. 2010)
  – Held that an employer that fired an employee who had a valid registration identification card for marijuana use for a debilitating condition did not violate Oregon law that prohibited discrimination based on disability.
  – Federal law that makes marijuana use illegal preempts Oregon law that allows medical marijuana use. Therefore the employee’s use of marijuana was illegal.

  – RELIEF SOUGHT: Terminated employee appealed dismissal of his suit against employer alleging that his termination was based on his “lawful” state-licensed use of medical marijuana.
  – ISSUE: Was a quadriplegic’s use of medical marijuana under Colorado’s Medical Marijuana Amendment lawful under Colorado’s law that prohibits employment discrimination for “lawful” activities (Colo. Rev. Stat. § 24-34-402.5)?
  – HOLDING: The Colorado Supreme Court affirmed because the employer did not terminate plaintiff for a “lawful activity” (see § 24-34-402.5). The court reasoned that marijuana use is illegal under federal law and nothing in § 24-34-402.5 limited the term “lawful” to state law. The term was used in its general unrestricted sense, indicating that a “lawful” activity is one that complies with all state and federal laws.
  – The U.S. District Court for the District of Colorado relied on Coats to conclude that termination of an employee who tested positive for cannabinoids was not discriminatory because use of marijuana is illegal under federal law and therefore and “illegal activity.”

• Casias v. Wal-Mart Stores, Inc., 695 F.3d 428 (6th Cir. 2012)
  – Employee who had been diagnosed with sinus cancer and an inoperable brain tumor used medical marijuana in compliance with Michigan law. Wal-Mart terminated him after the employee failed a drug test.
  – The MMA prohibited “any civil penalty or disciplinary action by a business” against a registered qualified patient “by a business.”
  – The court held that in the MMA the term “business” did not mean private business, but meant licensing board. Thus, the MMA did not regulate private employers.
Other Legal Issues

- **Banking**: laws have created a cash and carry marijuana industry, see, Criminal Money Laundering Law (18 USC § 1956)
- **Tax**: Illegal income is taxable, but 26 USC § 280E prohibits deductions business trafficking in Schedule I or II controlled substances.
- **Intellectual Property**: Federal law prohibits trademark protection for marijuana products and services that violate federal law (e.g., Cannabis Farmers Market rejected by USPTO)
- **Property Law**: Banks don’t want to lend money for property used to commit federal felony

Property Law Issues

- Landlords have to be cautious about illegal uses of rented premises
  - Could landlord be prosecuted under federal law for possession or distribution?
  - Could landlord be responsible under state laws if tenant is apparently lawful, but in fact is not complying with state marijuana laws?

Ethics—Conflicts of Interest

1. Which of the following forms of marijuana has the slowest onset of action?
   A. Intravenous
   B. Inhaled
   C. Oral
   D. Buccal

2. Which of the following is the most common reason for MMJ use in Colorado?
   A. Cancer
   B. Epilepsy
   C. Glaucoma
   D. Muscle spasms
   E. Nausea
   F. Pain

3. Which is true about a recent federal court case addressing the DOJ’s (and DEA’s) ability to enforce federal controlled substances laws?
   A. The court ruled the DEA cannot impose penalties or shut down dispensaries acting lawfully under state law.
   B. The court ruled the Supremacy Clause of the U.S. Constitution allows the DEA to arrest marijuana dispensaries because marijuana is a schedule I substance.
   C. The court ruled pharmacists were permitted to be involved in marijuana dispensaries because they were acting lawfully under state law.
   D. The court ruled owners of dispensaries could be arrested because of the quantity of marijuana they possessed, but patients could not be arrested.
4. Which of the following is NOT true about federal cannabis law?

A. Marinol (Dronabinol) capsules are available for commercial use.
B. Smoked cannabis is a C-I controlled substance.
C. Pharmacies may not dispense C-I controlled substances.
D. The DEA may not enforce its laws to prevent states from implementing their own state laws.
E. A series of memoranda from the DOJ prohibit the DEA from enforcing federal marijuana laws in states where marijuana is legal for medical use.

5. Which of the following is true?

A. Pharmacists should never ask patients if they are using marijuana or taking illicit drugs.
B. Pharmacists should never put information about patient’s marijuana use in the patient profile.
C. Pharmacists should counsel patients never to use marijuana.
D. Pharmacists should counsel patients about known drug-drug interactions with marijuana.

Questions?

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