Medical Marijuana Legalization and the Implications on the Pharmacy Profession

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Disclosure
- I am not affiliated in any manner with the sale, manufacture, or distribution of cannabis products.
- All of the information provided today is based on scientific evidence.
- References and slides are available upon request.

Pharmacists: Learning Objectives
By the end of this lecture, pharmacists will be able to:
- Outline the role of the pharmacist in the use of medical cannabis in the United States.
- Summarize the history of legalization of marijuana/cannabis.
- Describe the socioeconomic impact of medical and recreational cannabis.
- Describe the implications of evidence-based data on the use of cannabis for medical purposes.
- Explain the challenges in healthcare provisions due to the legalization of medical cannabis.
- Explain the pharmacological mechanisms, side effects, drug interactions and pharmacokinetic features for cannabis.

Pharmacy Technicians: Learning Objectives
By the end of this lecture, pharmacy technicians will be able to:
- Review the role of the pharmacy technician in regards of medical cannabis in the United States.
- Summarize the history of legalization of marijuana/cannabis.
- Describe the socioeconomic impact of medical and recreational cannabis.
- Explain the challenges in healthcare provisions due to the legalization of medical cannabis.

Pre-Test Question #1
Which route of administration of medical cannabis has the quickest "onset of action?"
A. Tablets  B. Edibles  C. Smoking  D. Topical Application

Pre-Test Question #2
Pharmacists are allowed to perform the following services for a patient using medical cannabis.
- Educate  B. Dispense  C. Advise prescribers  D. Qualify patients

Pre-Test Question #3
What is the ratio of CBD:TAC that would result in the greatest amount of psychoactive effects?
- 1:0  B. 1:1  C. 1:2  D. 1:10

How did we get here?
- In 2010, the American Glaucoma Society published its position paper on marijuana, followed by a similar paper from the Canadian Glaucoma Society.

Epidiolex: Approved September, 2018 as CV Scheduled Medication
FDA Approved Cannabinoids

- *Dronabinol (Marinol)* is synthetic THC, approved by FDA in 1985, used to treat AIDS wasting syndrome and nausea/vomiting caused by cancer chemotherapy. (http://www.marinol.com/)

- *Nabilone (Cesamet)* is synthetic THC approved by FDA in 1985 for treatment of chemotherapy induced nausea and vomiting. Also used to treat neuropathic pain (https://www.nlm.nih.gov/medlineplus/druginfo/meds/a607048.html)

Both are highly cost restrictive.

Experimental Cannabis Medications

- *Sativex (nabiximols)* is a whole plant cannabis extract with an equal 1:1 ratio of THC to CBD. Approved in U.K. for M.S. related spasticity & pain. Granted fast track designation by US FDA for cancer related pain.

- KY cancer patient Rob Burgin, was approved for Sativex study & then denied due to being in too much pain following chemotherapy. Shortly before his passing in 2014 his wife testified before our legislators regarding the immediate need for legal medical cannabis in KY.

Other Synthetic THC Products

- Agricultural Improvement Act of 2018 (2018 Farm Bill) Industrial hemp and its derived products are legal on a federal level, and states may choose how to move forward in this exciting new industry. Legalizes the production of industrial hemp (defined as Cannabis sativa L. plants containing less than three-tenths of a percent of tetrahydrocannabinol (THC)). The low concentration of THC makes hemp unsuitable for marijuana production, which remains federally illegal.

State Regulations of Medical Marijuana

**Florida** Qualifying Medical Conditions

- Cancer
- Epilepsy
- Glaucoma
- Human Immune Deficiency Virus (HIV) Acquired Immune Deficiency Syndrome (AIDS)
- Post Traumatic Stress Disorder
- Amyotrophic Lateral Sclerosis (ALS)
- Crohn's Disease
- Parkinson's Disease
- Multiple Sclerosis (MS)
- Terminal Condition
- Chronic Nonmalignant Pain
- Other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.

**Georgia** Qualifying Medical Conditions

- Crohn's Disease
- Epileptic seizure disorders Trauma-related head injuries
- Sickle Cell Disease Severe or terminal PTSD
- Amyotrophic Lateral Sclerosis
- Parkinson's Disease that has become severe or terminal
- Intractable Pain
- Crohn's Disease Mitochondrial disease
- Wasting illness, vomiting, or recurring nausea as a result of cancer treatment
- Multiple Sclerosis

Quality of Evidence for Randomized Placebo Controlled Studies Showing Efficacy

<table>
<thead>
<tr>
<th>Condition</th>
<th>Quality of Evidence</th>
</tr>
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<tbody>
<tr>
<td>Chronic Pain</td>
<td>Moderate to High</td>
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<tr>
<td>GI Disorders</td>
<td>Moderate</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>Low</td>
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<tr>
<td>Spasticity Associated with Multiple Sclerosis</td>
<td>Hill, et. al. Pol Arch Intern Med. doi:10.20452/pamw.4123</td>
</tr>
<tr>
<td>HIV and Acquired Deficiency Syndrome</td>
<td>Low</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>Moderate to High</td>
</tr>
<tr>
<td>Parkinson's disease</td>
<td>High</td>
</tr>
</tbody>
</table>

10 FDA Approved Cannabinoids
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12 Other Synthetic THC Products
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15 State Regulations of Medical Marijuana
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18 Quality of Evidence for Randomized Placebo Controlled Studies Showing Efficacy
What are Pharmacists Doing?

Response from Pharmacy Organizations

- APhA

According to the American Pharmacist Association (APhA), pharmacists are responsible for treating marijuana like any other drug. They need to review patients' medication and medical history, check for drug interactions, and counsel patients on use and adverse effects.

States to Initially Allow Pharmacists to Dispense

- **Connecticut**
  - Reclassified cannabis as a CII
  - Can be sold in plant form for smoking
  - Approved for 15 conditions
  - Use is tracked through the Connecticut Prescription Monitoring and Reporting System

- **New York**
  - Requires pharmacist to dispense
  - Program bans edibles
  - Approved for 10 conditions for which patients may receive a prescription from a physician

- **Minnesota**
  - Cannabis cannot be sold in plant form for smoking
  - Pharmacists select and dispense the product for patients, Minnesota's law authorizes medical cannabis for the treatment of numerous medical conditions
  - Approved for 9 conditions

Additional States that Allow Pharmacists to Dispense

- **Pennsylvania**
  - Act 16 of 2016
  - Physician or pharmacist MUST be on duty during open hours of dispensary
  - Pharmacist must undergo a 4-hour training (approved by Pennsylvania DOH)

- **Ohio**
  - [Source: University of Cincinnati](https://www.usciences.edu/blog/noteworthy/posts/the-pharmacists-role-in-medical-marijuana.html)

Medical Cannabis Use in Oklahoma (2016)


Integrative Medical Cannabis Consulting

- [Rachel A Strand Pharm.D., M.B.A.](http://integrativemcconsulting.com/about/)

- [Patricia C Frye, MD LLC](https://www.bluepointwellnessct.com/wp-content/uploads/2017/12/Bluepoint_WaitingRoom-72dpi.jpg)

Source: Cannabis Science, Inc. March 05, 2018 09:23 ET

Cannabis Science Integrates iCannabinoid Into Pharmacy Openings, While Building, Product Manufacturing, Packaging & Cultivation Procedures are Pending CBIS and City Approvals

IRVINE, CA, March 05, 2018 (GLOBE NEWSWIRE) - Cannabis Science, Inc., a biotechnology company focused on commercializing, producing and marketing cannabinoid-based products, today announced that its wholly-owned subsidiary, Cannabis Science of California, Inc. ("CSC"), has completed its first phase of the construction and outfitting of an integrated cannabis dispensary. The dispensary will serve as the first of several iCannabinoidTM branded dispensaries planned in Southern California, and will be the first of several to be licensed by the California Bureau of Medical Dispensary Licensing ("CBIS").

The dispensary will be located in a 4,000 square foot building in Irvine, California, and will feature a modern retail design concept. The dispensary will offer a wide range of products, including iCannabinoidTM branded products, which are currently undergoing testing and regulatory approval. The dispensary will also feature a state-of-the-art cannabis processing facility, which will include on-site cannabis manufacturing, packaging, and cultivation capabilities.

Cannabis Science of California, Inc. CEO, David Slomski, stated, "We are excited to announce the completion of our first phase of construction and outfitting of our iCannabinoidTM branded dispensary in Irvine, California. This milestone represents a significant step forward in our strategic plan to build a network of integrated cannabis dispensaries in Southern California. We are confident that this dispensary will provide the highest quality cannabis products and an exceptional customer experience to our patients."
Top Barriers to Conducting Research on Medical Cannabis
- Regulatory challenges
- Product standardization
- Variation in administration
- Limited funding

Institutional Policies Pertaining to Medical Cannabis - Hospitals
- Health care institutions should have a policy in place addressing marijuana use, especially in states where it is legal for medical indications.
- The policy should explain who is eligible, storage conditions, indicate who is allowed to administer it, and documentation requirements.
- Hospitals that receive funding from the Centers for Medicare and Medicaid Services could be cited for violations, lose federal funding, and receive fines in the event of permitted cannabis use.

Institutional Policies Pertaining to Medical Cannabis - Hospitals
- Providers with credentials in hospital are not permitted to prescribe or provide it to patients.
- Joint Commission Standards consider medical cannabis a home medication.
- In states without tightly regulated medical marijuana dispensaries, concern exists regarding how to accurately identify the product for labeling when it is brought into a health care facility.

Considerations for Use of Medical Cannabis in Long-Term Care Facilities
- Federal Law trumps Medicare funding may be compromised.
- Nursing Homes vs Assisted Living Facilities vs Independent Living Facilities.

Considerations for Use of Medical Cannabis in Long-Term Care Facilities
- Preferences of Prescribers
- Training of Prescribers
- Delivery Problems
- Storage of Medical Cannabis
- Qualifying Conditions
- Safety Issues
- Health of patient
- Involvement of Caregiver
- Liability of Facility

Knowledge Check: Which of the following access modalities for obtaining cannabis is the least expensive?
A. Retail access
B. Street access
C. Medical access
D. Street and Medical access

Economical Impact of Cannabis Sales
- Colorado: $3.5M in 1st month from medical marijuana tax revenue (2014)
- https://www.ibtimes.com/marijuana-costs-us-how-black-market-retail-medical-pot-prices-compare-1622362
A new report sees the market for edibles growing from about $1B to $4B by 2022, apparently at the cost of smoked marijuana.

Cannabis Edibles Market Set to Quadruple in U.S., Canada to $4B

Published: Stanford Advocate, Friday, November 16, 2018

Constant Contacts Software which had access to the email contact list was obtained from dispensaries.com to 846 pharmacists in the United States. The email contact list was distributed electronically to all pharmacists who served as preceptors or attended continuing education courses at the University of South Florida College of Pharmacy.

Erin Laird, Abigail Anderson, Alexandra Gott, Angela M. Hill, Pharm.D., CRPh.

To determine how demographics play a role in basic knowledge on the subject of medical cannabis and their education received on medical cannabis and their level of pharmacists in appropriately treating patients with medical cannabis.

The percentage of respondents that have received no education regarding medical cannabis was 24.2%. This may be because at least half of the respondents said they had received no education on the use of medical cannabis. This may be because at least half of the respondents said they had received no education on the use of medical cannabis.

Very few of the responding pharmacists felt very or extremely prepared to counsel patients. In addition, 60% reported that they had no role in the use of medical cannabis in healthcare. This may be a result of having received no education on the use of medical cannabis. There has been minimal discussion about the need for the pathway of training that pharmacists currently follow as a result of having received no education on the use of medical cannabis in healthcare. This may be the result of having received no education on the use of medical cannabis.

Concerns regarding numbers of accidents
Concerns regarding variance in state laws and transients
Concerns regarding numbers of accidents
Concerns regarding numbers of accidents
Concerns regarding food safety and contamination

Case: How would you counsel this patient in regards to the use of medical cannabis?

Mr. BB is an 84 y.o. patient who you are performing a comprehensive medication review. He lives in Denver, Colorado and comes to Florida during the winter months. He is taking the following medications: Ramipril, Aspirin, Clopidrogel, Fish Oil, Duloxetine, Centrum Silver, Atenolol, Claritin, Naproxen, Finasteride, Simvastatin, and oxybutynin.

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THC Content of Medical Marijuana

- **Charlotte’s Web**: Lowest THC content; <0.3%
- **Cannabis Indica**: Lower THC content → Greater body high
- **Cannabis sativa**: Higher THC content → Laughy, active, mind high

CBD to THC Ratios

- **CBD:THC Ratio 0:1**: No psychoactive effects; potential for treating epilepsy
- **CBD:THC Ratio 1.0**: Minimal psychoactive effects. May feel relaxed instead of anxious and paranoid
- **CBD:THC Ratio 1:1**: May produce mild psychoactive effects, but promotes relaxation, calmness, euphoria, and tranquility; may help with cancer, insomnia, autism, fibromyalgia, neuropathy
- **CBD:THC Ratio 2:1**: Causes minimal psychoactive effects
- **CBD:THC Ratio greater than 10:1**: May treat depression, anxiety, pediatric seizures, and spasms

Drug Interactions of Medical Cannabis

- **Cannabis is metabolized by CYP4503A4, 2C9, 2C19**
- **Cannabis inhibits CYP4502D6 and may inhibit CYP4503A4**
- **Additive versus Synergistic Interactions**

Key Drug Interactions with Medical Cannabis

- **Alcohol and benzodiazepines**: May ↑ the effects of alcohol and benzodiazepines
- **Anticoagulants, antiplatelets, herbs, and supplements**: May ↑ the risk of bleeding
- **CNS depressants**: May cause additive sedative effect
- **Cannabinoid-opioid interactions**: May cause additive analgesia with greater-than-additive effects
- **Anticholinergic Drugs**: This may ↑ the psychoactive side effects of medical cannabis
- **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**: NSAIDs may antagonize the effects of medical cannabis
- **Protease Inhibitors**: Medical cannabis may reduce their effectiveness
- **Selective serotonin reuptake inhibitors (SSRIs)**: May increase the risk of mania
Pre-Test Question #1
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Pharmacists are allowed to perform the following services for a patient using medical cannabis.
A. Educate
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Pre-Test Question #3
Which CBD:THC ratio could result in the greatest amount of psychoactive effects?
A. 10:1
B. 0:1
C. 1:2
D. 1:0

For further questions:
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