



The Sale of Cannabis in Pharmacies

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Learning Objectives

Upon completion of these knowledge-based activities, the pharmacist will be able to:

1. Describe the pharmacologic and therapeutic differences of the various formulations of cannabis, available scientific evidence and the potential impact on patients.
2. Discuss issues regarding the sale of cannabis in pharmacies and potential roles, if any, for pharmacists.
3. Review the legal and ethical implications related to dispensing cannabis in community pharmacies.

Background Information

- **Marijuana** is a mixture of dried shredded flowers and leaves of the hemp plant *Cannabis sativa*.
 - Other preparations include Keif, Hashish (resin), Tinctures, Oils, and Butters
 - Preparations such as oils and resins can contain THC concentrations of up to 60% which is substantially higher than the 5% commonly seen in the dried and shredded flower
- Cannabis contains chemicals called cannabinoids and several isomers of **tetrahydrocannabinol (THC)**
 - Δ^9 -THC is the active ingredient responsible for the majority of the psychological effects of cannabis.
 - Potency depends on the concentration of THC
- **Dronabinol (Marinol®)** is a synthetic Δ^9 -THC product
 - Only FDA approved THC product on the market today

Tetrahydrocannabinol (THC)

Pharmacological Effects of THC

- Increase pulse rate
- Decrease blood pressure
- Muscle weakening
- Increases appetite
- Causes euphoria
- Decreases memory recollection and learning

Medical Uses of THC

- Muscle spasms caused by MS
- Seizures
- Crohn's disease
- Chronic pain
- Nausea
 - Useful for patients receiving chemotherapy
- Appetite Stimulation
 - Useful for poor appetite and weight loss in patients with advanced human immunodeficiency virus (HIV)
- Glaucoma
 - Decreases IOP

Background Information

- Marijuana is usually **inhaled** or ingested **orally**
 - Inhaled products can be smoked or vaporized
 - Oral products consist of drinks such as teas and edibles
- Inhaled cannabis has been shown to provide a rapid and efficient delivery of THC to the brain
 - THC can be detected in the plasma immediately and peak plasma concentration can be seen within 10 minutes
- Absorption of THC from the gut after oral ingestion of cannabis is much slower
 - Oral ingestion produces a delayed peak plasma concentration of THC compared to inhaled formulations

The Sale of Cannabis in Pharmacies - Overview

- Contradiction between state and federal law
- Efficacy, safety and patient care issues
- Pharmacists' role in the provision of medical/recreational cannabis
- Pharmacists' role in patient education, screening and monitoring
- Social aspects of recreational marijuana use

Background Information

- **The Controlled Substance Act** was signed into law in 1970 by President Richard Nixon, and the legislation defined different classes based upon physical dependence, abuse potential and appropriate medical use.
- **Scheduled I Substances** are defined as substances that have a high potential for abuse, have no current medical use in the United States of America, and have a lack of accepted safety data when used under medical supervision. (Marijuana/Cannabis, Heroin, LSD)
- **Schedule III Controlled Substances** have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence. (Dronabinol or Marinol®)

Background Information

- ***Medicinal***: Indicated for the treatment of a medical condition
- ***Recreational***: Used for its mood altering effects, euphoria, and relaxation.
- 23 states and Washington D.C. have laws and regulations that permit use of ***medicinal*** marijuana
- Two states (Colorado & Washington) have written legislation to decriminalize the ***recreational*** use of marijuana

Connecticut

- Medical Marijuana State Bill of 2012
 - Prescribers will need to certify patients' medical need for the drug before it will be dispensed
 - Patients must register with the Connecticut Department of Consumer Protection
 - Restricts patients to obtain medical marijuana from licensed dispensaries
 - A dispensary is a licensed pharmacist who the Department of Consumer Protection determines to be qualified to acquire, possess, distribute and dispense marijuana
 - Immunity from state prosecution
 - A dispensary must only purchase marijuana products from licensed producers

Variation of State & Federal Laws

- While various states have allowed the use of inhaled cannabis for medical purposes, federal regulation still classifies inhaled cannabis as a **Schedule I Controlled Substance**, indicating the federal government recognizes no medical use.
- In terms of compliance with both state and federal statutes, pharmacists must comply with the law that is most stringent, in this case recognizing inhaled cannabis as a **Schedule I Controlled Substance**.
- Violation of federal statutes can result fines, imprisonment and/or the revocation of the pharmacy's DEA registration, immediately halting the dispensing of controlled substances.

Pharmacists' clinical concerns with the use of Medical Marijuana as a treatment option

- **Product variability in between growers/producers**
- **Limited efficacy and safety data**
 - Lack of scientific data on inhaled cannabis and lack of guidance by the FDA leaves pharmacists ill prepared to make clinically sound decisions when assessing cannabis therapy and inhibits pharmacists ability to educate patients.
- **Legal liability stemming from federal regulation**
 - Pharmacists are hesitant to jeopardize their careers by being involved in dispensing inhaled cannabis

Perspective from AMA

1. Our AMA calls for **further adequate and well-controlled studies** of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Our AMA urges that **marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines**, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to **develop a special schedule and implement administrative procedures** to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility

Policy updated in 2009 and reaffirmed in 2013.

Role of Pharmacists

- As with any substance for medical use, Pharmacists are expected to complete a prospective drug utilization review (DUR) to assess:
 - Appropriateness of Therapy
 - Appropriate Drug, Dose, Route and Duration
 - Allergies & Drug Interactions
 - Contraindications
 - Abuse & Misuse

Role of Pharmacists

- Pharmacists are also expected to provide patient education and counseling.
- Pharmacists are in a unique position to be dispensers and educators of Cannabis.
- Pharmacists must be aware of how cannabis use affects patients, including cognitive effects and drug interactions.

Conclusions

- Inhaled cannabis has very limited published literature on its therapeutic use, but in the literature that is present, efficacy has been shown. However, use of inhaled cannabis has a litany of adverse effects that raise patient safety issues.
- Currently, over twenty states have legalized medical marijuana use, with two of them ceasing to treat the recreational use of marijuana as illegal.
- Federal law still states that marijuana is a Schedule I drug.
- Consistency in quality and purity remain a concern for pharmacists

Conclusions

- There are potential safety concerns for pharmacists and their staff associated with an increase risk for burglaries and robberies working in dispensaries that stock inhaled cannabis.
- Currently, Connecticut is the only state in which a pharmacist dispenses inhaled cannabis for medical use. Connecticut could be viewed as a model for other states evaluating the role of pharmacists in dispensing inhaled cannabis for medical purposes.
- Lack of a credible data causes serious challenges for pharmacists to perform their responsibilities as a pharmacist and advocate for appropriate patient care.

Related APhA Policy

*1980 Medicinal Use of Marijuana**

1. APhA supports research by properly qualified investigators operating under the investigational new drug (IND) process to explore fully the potential medicinal uses of marijuana and its constituents or derivatives.
2. APhA opposes state by state, marijuana specific, or other drug specific legislation intended to circumvent the federal laws and regulations pertaining to (a) marketing approval of new drugs based on demonstrated safety and efficacy, or; (b) control restrictions relating to those substances having a recognized hazard of abuse.

**Reviewed and reaffirmed in 2011*

Related APhA Policy

2003, 1983 The Use of Controlled Substances in the Treatment of Intractable Pain

2012 Controlled Substance Regulation and Patient Care

2014 Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

Assessment Question 1

Which of the following states has placed pharmacists in a key role of dispensing inhaled cannabis?

- a. Washington
- b. Connecticut
- c. New York
- d. Colorado

Assessment Question 2

Under Federal law, inhaled cannabis is a Schedule _____ Controlled Substance, while the orally ingested formulation (dronabinol) is a Schedule _____ Controlled Substance.

- a. I, II
- b. I, III
- c. II, III
- d. II, IV

Assessment Question 3

Which isomer of tetrahydrocannabinol (THC) is responsible for the majority of psychological effects of cannabis?

- a. $\Delta^{6a,7}$ -THC
- b. Δ^7 -THC
- c. Δ^9 -THC
- d. Δ^{10} -THC

QUESTIONS?

What's your perspective?

- What do you envision as pharmacists' role? Dispensing, counseling, etc.
- What are the major patient care challenges related to the use of medical and/or recreational marijuana?
- How should APhA's policy address the various forms of cannabis?

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Thank You!

Contact HOD Staff

or

Submit additional comments/questions

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