MEDICAL CANNABIS IN MARYLAND

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DISCLAIMER

My comments and slides are only informational, and not authoritative.

You should not rely upon these slides or my comments as an authoritative statement of the law or the regulations.

OBJECTIVES

• History and background of medicinal cannabis
• Basic pharmacology and physiology
• Review of clinical evidence
• Medical Cannabis in Maryland
• The Commission and Regulations
WHAT IS MEDICAL CANNABIS?

• Medical marijuana, refers to the use of cannabis and its cannabinoids to treat disease or improve symptoms
• Medical cannabis can be administered:
  • Vaporizing or smoking dried buds
  • Consuming extracts
  • Taking capsules
  • Using oral sprays

HISTORY OF USE OF MEDICAL CANNABIS

• Traditional Chinese medicine — one of the 50 “fundamental” herbs
• Ancient Egypt, Ebers Papyrus (ca. 1550 BCE) — used in suppositories for hemorrhoid pain
• Ancient India — insomnia, headaches, gastrointestinal disorders, and pain (including childbirth)
• Ancient Greece — dress wounds and sores, nose bleeds, and expel tapeworms
• Medieval Islamic world — diuretic, antiemetic, antiepileptic, anti-inflammatory, analgesic and antipyretic properties

MODERN HISTORY OF CANNABIS

• William Brooke O’Shagghesey (1809-1889), an Irish physician introduced cannabis to Western medicine — muscle spasms, stomach cramps and general pain
• Albert Lockhart and Manley West studied the health effects of cannabis use in Jamaican communities — in 1987 introduced the pharmaceutical Canasol
• In the 1970s, a synthetic version of THC was produced and approved for use in the United States as the drug, Marinol
MEDICAL CANNABIS IN THE WORLD

- Medical cannabis legalized throughout the world:
  - Austria, Belgium, Canada, Czech Republic, Finland, Israel, Netherlands, Spain, the UK
  - 23 states and DC in the US, although it is illegal under US federal law
- In the United States:
  - While federal law outlaws all cannabis use, legalized states no longer prosecute individuals for the possession or sale of marijuana, as long as the individuals are in compliance with the state’s marijuana sale regulations

MEDICAL CANNABIS IN THE US

PHARMACOLOGY

- Genus Cannabis
  - Psychoactive Species
  - Cannabis indica
  - Cannabis sativa
  - Less Psychoactive Species
  - Cannabis ruderalis
- 460+ compounds (80+ cannabinoids)
PHARMACOLOGY
- Psychoactive cannabinoid
  - Tetrahydrocannabinol THC (or delta-9-tetrahydrocannabinol)
- Other less psychoactive cannabinoids
  - Cannabidiol (CBD)
  - Cannabiol (CBN)
  - Cannabicyclol (CBL)
  - Cannabichromene (CBC)
  - Cannabigerol (CBG)
- Synergy produces effect
- Different from our classic thinking of pharmaceuticals

ENDOCANNABINOID SYSTEM
- Cannabinoid receptors
  - Predominantly located in the brain
- Cell membrane receptors (G-protein-coupled receptor)

ENDOCANNABINOID SYSTEM (CONT')
- Activators
  - Endocannabinoids (Mammillary body)
  - Plant cannabinoids
  - Synthetic cannabinoids (Marinol)

ENDOCANNABINOID SYSTEM (CONT')
- Receptor Subtypes
  - CB1 receptor
    - Brain (predominantly)
    - Lungs, liver and kidneys
  - CB2 receptor
    - Immune system
    - Hematopoietic cells
  - Novel cannabinoid receptors (non-CB1 and non-CB2)
  - Endothelial cells
ENDOCANNABINOID SYSTEM (CONT’)

• Physiology
  • Central Nervous System
  • Psychoactive
  • Pain perception
  • Appetite
  • Mood
  • Memory

ENDOCANNABINOID SYSTEM (CONT’)

• Gastrointestinal
  • Gastrointestinal activity reduced
• Cardiovascular
  • Cardiomyocytes
• Coronary artery endothelial and inflammatory cells in humans and rodents

• Bone
  • Osteoblasts, osteocytes, osteoclasts
  • Osteoporosis

CANNABINOID FOR MEDICAL USE: A SYSTEMATIC REVIEW AND META-ANALYSIS

• Meta-analysis of randomized controlled studies
• High quality evidence
• Chronic pain
• Involuntary movements
• Muscle spasms

CANNABINOID FOR MEDICAL USE: A SYSTEMATIC REVIEW AND META-ANALYSIS

• Moderate/Low quality evidence
• Fibromyalgia
• HIV-related sensory neuropathy
• HIV-related weight loss
• Multiple sclerosis
• Nausea and vomiting caused by chemotherapy
• Rheumatoid arthritis
• Sleep disorders
CANNABINOIDS FOR MEDICAL USE: A SYSTEMATIC REVIEW AND META-ANALYSIS

RESEARCHERS CONCLUDED

Benefits... judged against the risks of potential side effects, such as:

- Dizziness
- Dry mouth
- Euphoria
- Fatigue
- Nausea

MEDICAL MARIJUANA FOR TREATMENT OF CHRONIC PAIN AND OTHER MEDICAL AND PSYCHIATRIC PROBLEMS: A CLINICAL REVIEW

BACKGROUND OF MMCC

- Critical Leadership
- Delegates Dan Morhaim, M.D., and Cheryl Glenn
- Senator Jamie Raskin
- 2013 Natalie M. LaPrade Medical Cannabis Commission (DHMH)

- Review 28 randomized Clinical Trials approx 6,500 patients.
- High Quality Evidence
  - Chronic Pain
  - Neuropathic Pain
  - Spasticity Associated with MS

- No Evidence
  - Anxiety disorder
  - Depression
  - Eye pressure
  - Psychosis
BACKGROUND OF MMCC (CONT')

• 2013 Initial law created an academic medical center model
• 2014 Program expanded to include non-academic physicians
• 2013-2015 Development of regulations
• 2015 (September) Regulations effective

* Latest version available on Commission website: mmcc.maryland.gov

THE COMMISSION

• An independent Commission
• Develops policies, procedures, guidelines and regulations to implement medical cannabis program
• Chair appointed by the Governor

OVERVIEW OF LICENSEES

• Commission is responsible for
  • Development of regulations
  • Issue licenses
  • Continuous monitoring and oversight
OVERVIEW OF LICENSEES (CON’T)

• 15 licensed growers initially
  • Also eligible for dispensary license

• Licensed processors
  • Leaf and flowers, ointments, salves, lotions, and vaporizable extracts
  • Licensed dispensaries per State senatorial district

OVERVIEW OF LICENSEES (CON’T)

• Independent testing laboratories to inspect all products to confirm specifications:
  • Cannabinoid content
  • THC concentration
  • Contaminants

OVERVIEW OF LICENSEES (CON’T)

• Growers
  • Secure building, green house or secure outdoor field
  • Detailed security requirements
  • Strict controls/standard operating procedures
  • Product quality and consistency

OVERVIEW OF LICENSEES (CON’T)

• Growers (con’t)
  • Facilities and operations inspected by Commission
  • Independent Testing Laboratory
  • Certificate of analysis for each batch
  • Strict inventory control
  • Report annually minority owners and employees
OVERVIEW OF LICENSEES (CON’T)

• Dispensaries
  • Separate from growing/processing facility
  • Strict security and inventory controls
  • Package plain, opaque and tamper-evident

OVERVIEW OF LICENSEES (CON’T)

• Dispensaries (con’t)
  • Label active components and their strength
  • Obtained from dispensary by patient and caregivers
  • Delivered to patient and caregivers by dispensary agents

OVERVIEW OF LICENSEES (CON’T)

• Dispensaries (con’t)
  • Patient education encouraged
  • Record dispensing in Commission database
  • Adverse events reporting

FEES – PROGRAM NOT PAID FOR BY TAXPAYERS

• Applications
  • Grower application:
    • Stage 1: $2,000; Stage 2: $4,000
  • Processor application:
    • Stage 1: $2,000; Stage 2: $4,000
  • Dispensary application:
    • Stage 1: $1,000; Stage 2: $4,000
FEES — PROGRAM NOT PAID FOR BY TAXPAYERS (CONT)

- **Annual Fees:**
  - Grower — $125,000
  - Processor — $40,000
  - Dispensary — $40,000
  - Agent registration — $200
    * (Grower, Processor, Dispenser, laboratory)

- Independent Testing Laboratory — $100 registration

PLAN FOR LICENSE APPLICATION (STAGE 1)

- **September 2015:** Applications and instructions released
- **45 day Application period**
- **Reviewed and ranked according to published rubric by independent review team**
- **December 2015 likely Pre-approval of licenses**

LICENSE APPLICATION (STAGE 2)

- Finalizes capitalization, closes on real estate, zoning and planning approval, constructs facility, installs equipment, finishes Standard Operating Procedure, hires staff, trains staff
- Inspection, license issued, operations commence

QUALIFYING PATIENTS

- "Bona fide physician-patient relationship"
- Register with the Commission
- Establish identity
- Registration number issued
- No charge to register
- Identification card, if requested, costs $50
QUALIFYING PATIENTS (CONT')

• Limited to 30-day supply with written certification
  • 120g "usable cannabis" or 36g of Delta 9-THC in infused products
  • Dispensary tracks quantity dispensed

CERTIFYING PHYSICIAN REQUIREMENTS

• Register with Commission
• Register online at Commission website
• No registration fee
• Valid for two years

CERTIFYING PHYSICIAN REQUIREMENTS (CON'D)

• Physician Attestation
  • Active Medical License
  • Unrestricted
  • In good standing
  • Registered to prescribe controlled dangerous substances in Maryland

CERTIFYING PHYSICIAN REQUIREMENTS (CON'D)

• Bona fide physician patient relationship
• Issue "Written Certification"
PHYSICIAN GENERAL REGISTRATION

Certifying Physicians may register to treat a patient who has a condition:

• That is severe
• For which other medical treatments have been ineffective
• For which symptoms can reasonably be expected to be relieved by medical use of cannabis

CERTIFYING PHYSICIANS ARE ENCOURAGED TO REGISTER TO TREAT CERTAIN CONDITIONS

Chronic or debilitating disease or medical condition, or treatment, that cause:

• Cachexia
• Anorexia
• Wasting Syndrome
• Severe or chronic pain
• Severe nausea
• Seizures
• Severe or persistent muscle spasm
• Glaucoma
• Post Traumatic Stress Disorder (PTSD)

CERTIFYING PHYSICIAN ISSUES WRITTEN CERTIFICATION

• Log on to Commission website
• Provide certifying physician’s name, license number, telephone number
• Provide qualifying patient's name, date of birth, address, county of residence
• Condition(s) requiring medical cannabis
• Written certification good for 30-day supply, up to 120 g usable cannabis or 36 g of Delta 9-THC in a medical cannabis-infused product

QUALIFYING PATIENT GOES TO THE DISPENSARY

• 30 day supply
• Dispensary checks identification
• Goes to Commission website to determine that patient has been issued a written certification
• Dispensary may counsel patient
• Dispensary records batch, lot number, amount on Commission database -- this enables patient to go to any dispensary and obtain what they need up to 30 day supply
• Physicians can monitor patients on database
VIOLATIONS OF MARYLAND MEDICAL CANNABIS LAW

- General Assembly concerned
- Possessing, distributing or using diverted medical cannabis punishable by up to 5 years in prison and up to $10,000 fine
- Health Law penalties in addition

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