

Medical Cannabis:  
Operational Issues  
(Training, Workforce,  
Addiction)



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Financial Disclosures

Rhonda Beck, Pharm.D. and Sara Parsley, BBA, M.Ed IT are Regulatory Consultants with Trinity Herbal Compliance.  
Brandon Thornton, Pharm.D. is owner of Steep Hill Arkansas a cannabis analytical testing laboratory.

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**Learning Objectives**

- ✓ Describe common features of the Cannabis plant
- ✓ Identify major cannabinoids and terpenes
- ✓ Describe the endocannabinoid system
- ✓ Identify modern medications derived from cannabinoids



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### FDA Approval

- Drug Discovery
- Preclinical Research
- Clinical Trials > NDA
- FDA Approval
- Post Market

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### Cannabis

- Drug Discovery
- ~~Preclinical Research~~ Prohibition
- ~~Clinical Trials~~ Black Market
- FDA Anecdotal Clinical Evidence
- Availability Through Legislation

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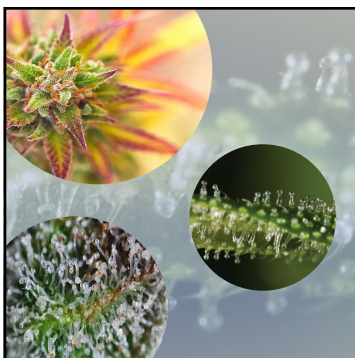
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### Cannabis

- ✓ Indigenous to Asiatic Continent
- ✓ Landrace Varietals
- ✓ Rich in Terpenoids
- ✓ Glandular Trichomes
- ✓ Domestication
- ✓ Strain Names
- ✓ Medical or Recreational
- ✓ Whole Plant Therapy

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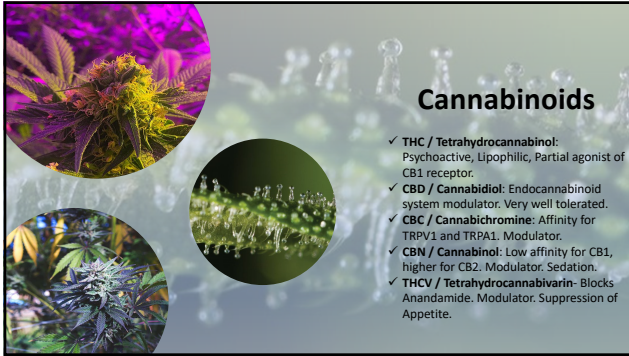
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### Cannabinoids

- ✓ **THC / Tetrahydrocannabinol:** Psychoactive, Lipophilic, Partial agonist of CB1 receptor.
- ✓ **CBD / Cannabidiol:** Endocannabinoid system modulator. Very well tolerated.
- ✓ **CBC / Cannabichromine:** Affinity for TRPV1 and TRPA1. Modulator.
- ✓ **CBN / Cannabinol:** Low affinity for CB1, higher for CB2. Modulator. Sedation.
- ✓ **THCV / Tetrahydrocannabivarin:** Blocks Anandamide. Modulator. Suppression of Appetite.

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### Terpenes

- ✓ **Limonene** – Citrus
- ✓ **Myrcene** - Hops
- ✓ **Pinene** - Conifers
- ✓ **Linalool** - Lavender
- ✓ **Caryophyllene** - Black Pepper

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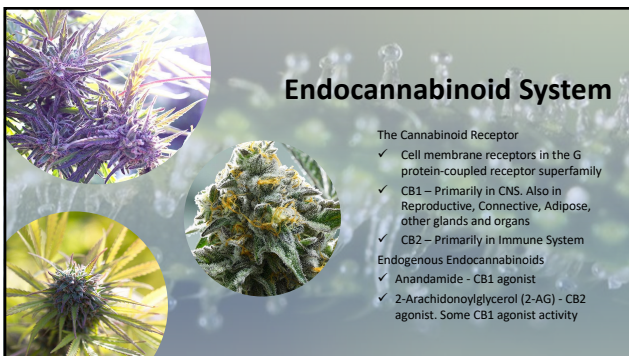
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### Endocannabinoid System

The Cannabinoid Receptor

- ✓ Cell membrane receptors in the G protein-coupled receptor superfamily
- ✓ CB1 – Primarily in CNS. Also in Reproductive, Connective, Adipose, other glands and organs
- ✓ CB2 – Primarily in Immune System

Endogenous Endocannabinoids

- ✓ Anandamide - CB1 agonist
- ✓ 2-Arachidonoylglycerol (2-AG) - CB2 agonist. Some CB1 agonist activity

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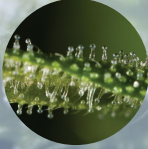

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## Cannabinoid Medications

- ✓ **Dronabinol (Marinol) & Nabilone (Cesamet)**
  - ✓ A synthetic form of THC
  - ✓ Indications:
    - ✓ Appetite stimulation in HIV.
    - ✓ An antiemetic for chemo patients.
- ✓ **Sativex (abiximols in US)**
  - ✓ Natural THC and CBD in a 1:1 ratio available in an oromucosal spray.
  - ✓ Approved in 30 countries for MS
  - ✓ Phase III in the US for MS spasticity

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## Cannabinoid Medications

- ✓ **Epidiolex (cannabidiol)**
  - ✓ CBD Oral Solution
  - ✓ Clinical Trials in US
    - ✓ Dravet Syndrome (Submitted)
    - ✓ Lennox-Gastaut Syndrome (Submitted)
    - ✓ Tuberos Sclerosis (Phase 3)
    - ✓ Infantile Spasms (Phase 2)
- ✓ An FDA advisory panel unanimously recommended approval on 4/18/18

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## Best Practices/Regulatory Requirements

- Personnel Training and Records
- Record Retention
- Inventory
- Inspection/Audits
- Standard Operating Procedures /Process Steps
- Recall Procedure
- Personnel Training and Records
- Sanitation Requirements and Spills
- Packaging and Labeling
- Traceability
- Product Storage
- Waste Management
- Pest Control

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Personnel  
Training  
(RR19.4)  
Record  
Retention  
(RR12.3)

- Job descriptions
- Training Plan
- Personnel file
- On site training and documentation
- Monthly continuous education and improvement
- Signature log

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Inventory  
(RR.10.1.10.2)

- Initial Inventory
- Every 6 month inventory
- Inventory for beginning product (API), in process, finished goods, destruction, retention, sold

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Inspections/Audits  
(RR.4.2.4.3)

- ABC initial inspection
- ABC every 6 month inspection
- Mock audits
- Present at audits

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Standard Operating Procedures/  
Processes Steps  
(RR11.1)

- Ingredient content, instruction (batch record), documentation of safety checks (scale calibration, cleaning equipment, spill cleanup)
- Sanitation process and agents
- Destruction Process
- Inventory Process
- Audit Plan
- Training Plan and Documentation
- Education Program



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Recall Protocol  
(RR15.3)

- Identification and notification of patients and caregivers
- Notify DOH/ABC
- Return and quarantine product
- Retention/Destruction

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Sanitation  
(RR9.6)

- Chemical spill kit and procedure
- Equipment preventative maintenance and calibration
- Cleaning protocol

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**Destruction**  
*(RR18.1)*

- 3 day notification
- Pharmacist sign off

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**Packaging & Labeling**

- Misbranding/Adulterated products
- Child proof packaging
- Product inspection pre-post packaging
- System for prevention of mix-ups/cross contamination
- Label reconciliation
- Excess label destruction

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**Traceability**

- Dispensing logs
- Batch yield analysis and reconciliation
- Retention
- Customer complaint handling

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**Product Storage**

- Quarantine material segregation
- Finished product storage requirements

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**Pest Control**

- Frequency of internal contaminant inspections
- Devices
- Locations
- Monitoring
- Documenting

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**Waste Management**

- Pharmacist to sign-off on destruction of controlled substances
- Documentation required
- Environmental Protection



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### Medical Routes of Administration

**Table 1: Pros and cons of different routes of drug administration**

Route	Advantages	Disadvantages
<b>Oral</b>	<ul style="list-style-type: none"> <li>Easy</li> <li>Preferred by patients</li> <li>"Time-release" preparations may be available to extend duration of action</li> <li>Drugs can be formulated to make it easy to protect them from digestive enzymes, acid, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Unsuitable in patients who are uncooperative, unable to sit or "swallow" or vomiting/vomited or have ileus</li> <li>Most oral administration drugs are absorbed slowly</li> <li>Unpredictable absorption due to degradation by stomach acid and enzymes</li> </ul>
<b>Rectal</b>	<ul style="list-style-type: none"> <li>Good alternative - the haemorrhoidal veins drain directly into the inferior vena cava, avoiding hepatic first pass metabolism</li> </ul>	<ul style="list-style-type: none"> <li>May not be suitable after micturid or anal surgery</li> <li>Some patients dislike suppositories</li> </ul>
<b>Intramuscular or subcutaneous</b>	<ul style="list-style-type: none"> <li>Good alternative, especially for drugs with a slow rate of bioavailability</li> <li>Close to blood vessel than the above routes</li> <li>Depending on formulation can have very long duration of action, e.g. depot antipsychotics and contraceptives</li> </ul>	<ul style="list-style-type: none"> <li>Absorption may still be unpredictable if compliance and veins not used</li> <li>Injection pain, tissue trauma and higher children and needle phobias</li> </ul>
<b>Intravenous</b>	<ul style="list-style-type: none"> <li>Dependable and reproducible effects</li> <li>Drugs administered close to where the systemic circulation immediately - the dose can be accurately related against response</li> </ul>	<ul style="list-style-type: none"> <li>Requires a functioning venous system</li> <li>More expensive and labour intensive than other routes</li> <li>Calculation is demanding to some patients, especially children</li> <li>Calculation are prone to infection</li> <li>Or injection of drugs may cause local reactions</li> </ul>
<b>Inhalant</b>	<ul style="list-style-type: none"> <li>Easy</li> <li>Non-painful</li> <li>High levels of patient satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>Most drugs have a high molecular weight and are poorly lipid soluble, so are not absorbed via cell or mucous membranes</li> <li>Very slow absorption</li> </ul>
<b>Inhaled</b>	<ul style="list-style-type: none"> <li>Very rapid absorption due to the huge surface area of the respiratory membrane</li> <li>Disinfectants and related steroids can be targeted to lungs with the help of systemic absorption</li> </ul>	<ul style="list-style-type: none"> <li>Bioavailability depends on patient's inhaler technique and the size of drug particles generated by the delivery technique</li> </ul>

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### Qualifying Patients

- Person diagnosed by a physician as having a qualifying medical condition and who has registered with the department
- Lawfully engaged in the Medical Use of marijuana while in possession of a registry identification card and possesses an amount that does not exceed 2.5 ounces




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### Patient Population: Qualifying Conditions

- Cancer
- Glaucoma
- HIV/AIDS
- Hepatitis C
- ALS or Lou Gehrig's disease
- Tourette's syndrome
- Crohn's disease
- Ulcerative colitis
- PTSD
- Severe arthritis
- Fibromyalgia
- Alzheimer's disease

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### Patient Population: Qualifying Conditions

A chronic or debilitating disease or treatment that produces one or more of the following:

- Cachexia or wasting syndrome
- Peripheral neuropathy
- Intractable pain
- Severe nausea
- Seizures
- Severe or persistent muscle spasms




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### Patient Population: Emerging Facts

- Overwhelmingly used for severe/chronic pain (70-90%)
- Men vs women
- 18-70 yo
- 60% of patients suffer from two or more qualifying conditions
- Polypharmacy

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### Patient Education: Dispensary Agent

- *Dispensary agent* (information developed by pharmacist)
  - Share good/bad effects of cannabis(heart palp, mood-altering effects)
  - Possible interactions (alcohol, opioids)
  - Encourage patient assessment log (i.e. dose taken, symptom relief, side effects)
  - Information about methods, forms, routes of administration
  - Recognize signs and symptoms of abuse (distorted perceptions, impaired coordination, diff. with thinking/problem solving)




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### Patient Education: Pharmacist Consultant

- Patient specific information
- Detailed drug-drug interactions (polypharmacy)
- Detailed drug-disease information (i.e. liver disease)
- Patient counseling (telephone/video confer.)
- Ongoing materials updates (dispensary feedback)
- Available during operating hours

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### Patient Safety & Cannabis Regulatory Testing in Arkansas

Brandon Thornton, Pharm.D.  
Co-Owner and CEO  
Steep Hill Arkansas

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### Learning Objectives

1. Describe why Cannabis Testing is Important
2. Describe the Arkansas Regulations
3. Identify Equipment used in Testing



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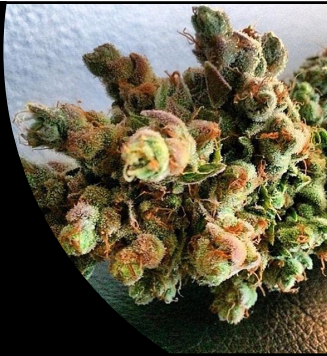
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### Is this Flower Safe?

1. How much THC does it contain?
2. What is the terpene profile?
3. Does it contain any harmful pesticides?
4. Are there any pathogenic organisms present?

While Cannabis is very safe, contaminants on the Cannabis plant can be deadly.




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### Cannabis Testing is Important

#### Testing Protects Public Safety

- Used by immunocompromised and elderly populations.
- Critical since cannabis has no federal oversight or standards.

#### Generates Industry Confidence & Credibility

- Testing separates a medical product from the black market.
- An important factor in building provider trust




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### Cannabis Testing is Important

#### Creates Product Integrity

- Testing safeguards against harmful product reaching patients.
- Provides potency data leading to consistent doses




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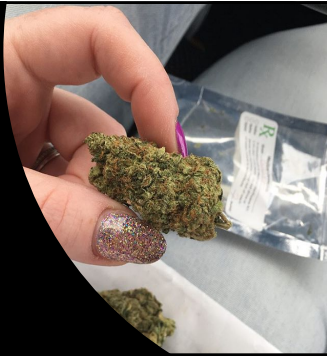
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### Required Cannabis Tests in Arkansas

1. Potency – THCA, THC, CBDA, CBD
2. Pesticides (59)
3. Heavy Metals (4)
4. Residual Solvents (44)
5. Moisture Content (<15%)
6. Water Activity (0.65 Aw)
7. Microbiological - Total coliforms → E. coli (100 CFU)



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### Non-Regulatory Cannabis Tests

- Terpene Profile
- Extended Terpene Profile
- Genetic Tests
  - Sexting
  - Phenohunt
- Environmental Test
  - Grow Environment
  - Processing Equipment
- Mycotoxins



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### Equipment Used in Analytical Testing

- LCMS – Potency, Pesticides (Some)
- GCMS – Solvents, Pesticides (Some)
- ICP – MS - Heavy Metals
- GCMS - Moisture Content, Water Activity
- DNA-Based Microarray Analysis - Micro



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### Contact Information

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