

# Beyond the Green: Navigating Clinical Impacts and Kentucky Cannabis Law

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# Disclosures

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Neither Dr. Dawson nor Dr. Roberts have any relevant financial interests to disclose

# Objectives

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- Evaluate clinical evidence for medicinal cannabis in managing oncology-related symptoms such as chemotherapy-induced nausea and vomiting (CINV), cancer-associated pain, cancer associated cachexia, and depression/anxiety
- Describe medicinal cannabis pharmacokinetics and identify potential drug-drug interactions
- Review Kentucky medicinal cannabis regulations including qualifying conditions, legal possession limits, and professional compliance responsibilities

# Definitions

- **Cannabis:** products from the *Cannabis sativa* plant
- **Cannabinoids:** group of substances in the plant
  - Cannabidiol (CBD)
  - Tetrahydrocannabinol (THC)
- **Marijuana:** parts of the plant that contain THC
- **Delta-9:** most abundant form of THC

Contains ~540 different substances



*Cannabis sativa* plant

# Human Endocannabinoid System (ECS)

**ECS = neuromodulatory system**

CNS development

Synaptic plasticity

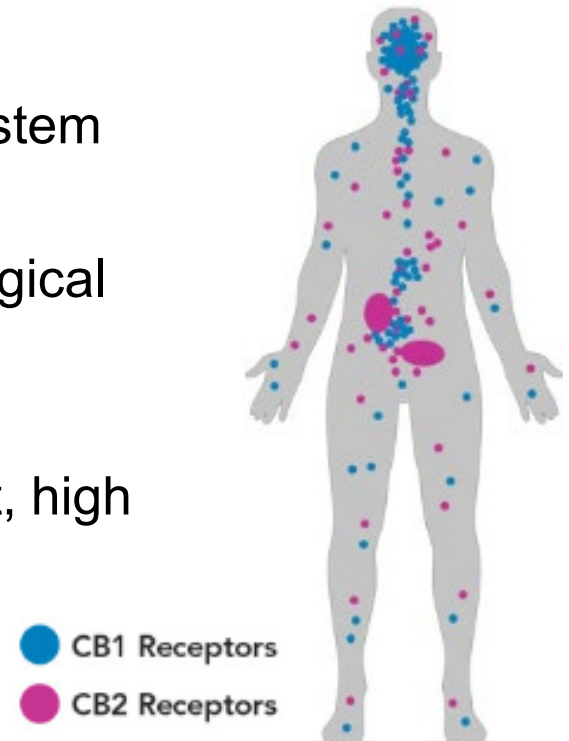
Environmental responses

## Cannabinoid receptors

- CB1: Brain, central, and peripheral nervous system
- CB2: Spleen, cardiovascular system, GI tract
  - Expressed by some neurons under pathological conditions

## Endogenous cannabinoids

- Arachidonylethanolamine (AEA): CB1 agonist, high affinity
- 2-arachidonoyl glycerol (2-AG): CB1 and CB2 agonist, low-moderate affinity

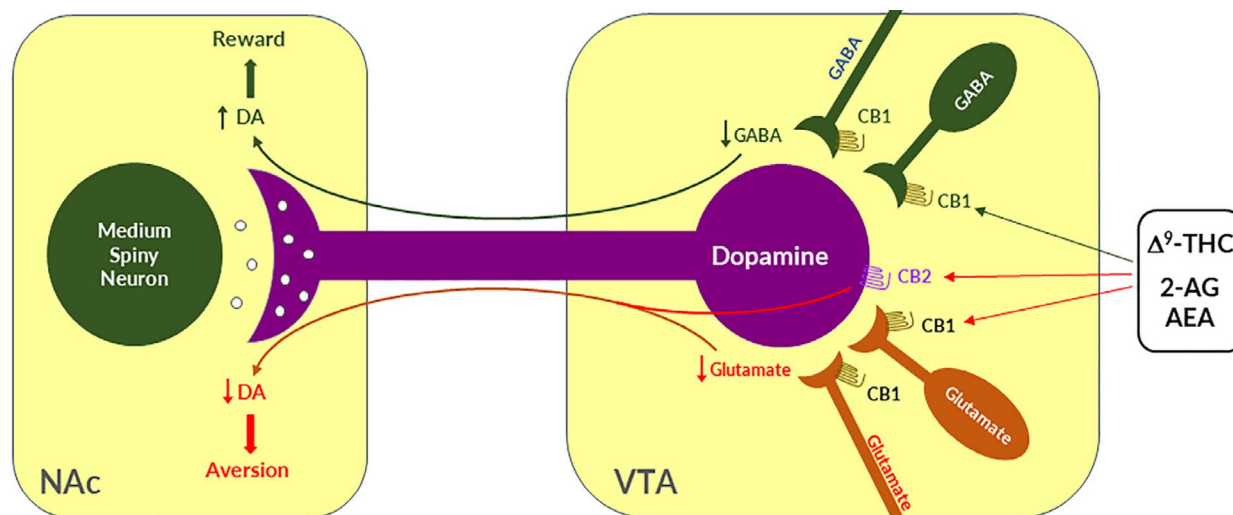


# Human Endocannabinoid System (ECS)

## Endogenous and Exogenous Cannabinoid Signaling

**THC:** Elicits psychoactive effects via CB1 binding

**CBD:** Low CB1/CB2 affinity; may ↑ plasma levels of AEA



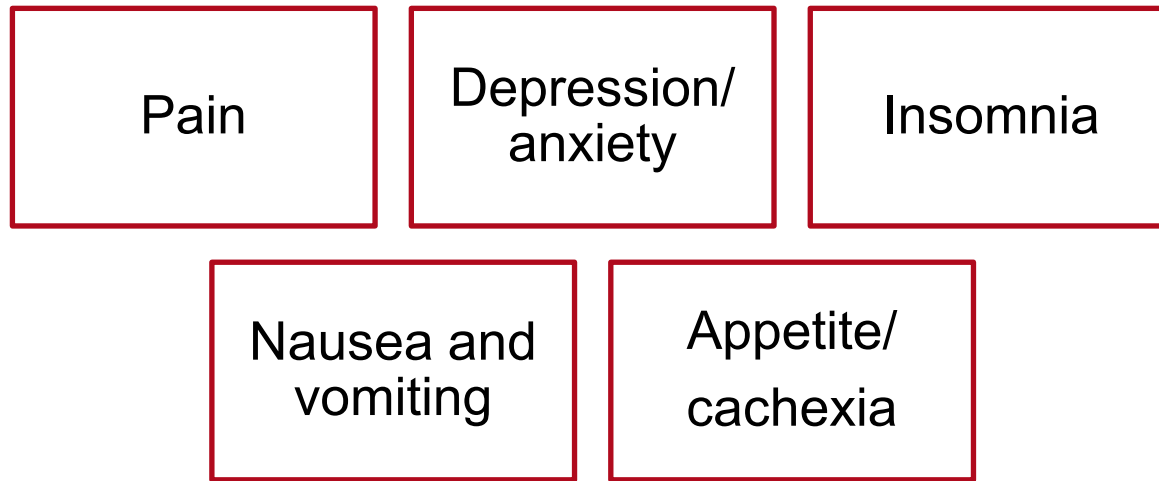
# Medicinal Uses of Cannabinoids

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# Cannabinoids for Medicinal Uses

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## \*Potential Uses:



Survey of medicinal cannabis users, N = 1,429

- 61.2% used for pain, 50.3% for anxiety, 27.4% for nausea

Survey of medicinal cannabis users, N = 808

- Improvement in symptoms: pain (28%), sleep (18%), mood (11%)

# Cannabinoids for Medicinal Uses

## Whiting, et al. 2015 – Meta-Analysis of Cannabinoids for Medical Use

|        |                                                                                                                                                                                                                                                                                                                |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Design | <ul style="list-style-type: none"><li>▪ 79 RCTs of cannabinoids for: CINV, appetite stimulation (HIV/AIDs patients), chronic pain, muscle spasms, mood disorders, sleep, psychosis, glaucoma, and Tourette syndrome</li><li>▪ All compared cannabinoids to placebo or usual care</li><li>▪ N = 6,462</li></ul> |
|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Chronic pain trials (28 studies, n = 2,454)

- Included nabilone, dronabinol, nabiximols, and THC (various routes)

### Results:

- Pain reduction > 30% with CBN: OR 1.41, [95% CI 0.99-2.00] – 8 trials
- Nabiximols > reduction in numerical pain scale ratings: weighted mean difference -0.46, [95% CI -0.80, -0.11] – 6 trials
- No differences in QOL scores – 3 trials

# Cannabinoids for Medicinal Uses

## Whiting, et al. 2015 – Meta-Analysis of Cannabinoids for Medical Use

### Depression trials – No trials met inclusion criteria

- 5 studies of other indications reported depression as an outcome
- 3 studies: no difference
- 1 study: worsened depression with nabiximols (high doses), no difference with other doses

### CINV trials (28 studies, n = 1,772) – 14 nabilone, 6 THC, 3 dronabinol, 5 others

- All studies suggested benefit of cannabinoids vs placebo or active comparator
  - ❑ Did **not** achieve statistical significance
- 3 studies: Complete nausea/vomiting response > with dronabinol than placebo
  - ❑ OR 3.82, [95% CI 1.55-9.42]

# Cannabinoids for Medicinal Uses

## Whiting, et al. 2015 – Meta-Analysis of Cannabinoids for Medical Use

### Sleep trials (2 studies, n = 54)

- 1 study: nabilone improved sleep apnea index, mean difference -19.64, p = 0.02
- 1 study: nabilone compared to amitriptyline, nabilone significantly improved:
  - Insomnia scores, -3.25 from baseline, [95% CI -5.26, -1.24]
  - Restfulness scores, 0.48 from baseline, [95% CI 0.01-0.95]

### Appetite trials (4 studies, n = 255), all assessed dronabinol vs placebo or megestrol

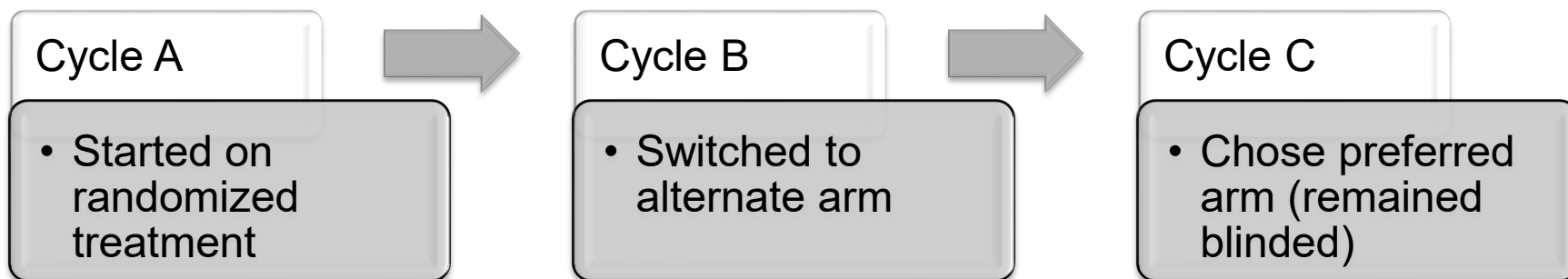
- Some evidence dronabinol increased weight
- Limited evidence for increased appetite

No statistical significance

# Cannabinoids for Medicinal Uses

## Grimison, et al. 2020 – Oral THC:CBD Cannabis for Refractory CINV

|              |                                                                                                                                                                                                                                                          |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Design       | <ul style="list-style-type: none"><li>▪ Multicenter, double-blind, crossover placebo-controlled trial</li></ul> <b><u>Population (N = 81)</u></b><br>Patients receiving IV chemotherapy (moderate to high emesis risk)<br>Refractory CINV, ECOG $\leq 2$ |
| Intervention | <ul style="list-style-type: none"><li>▪ Guideline CINV prophylaxis + THC:CBD (THC) or placebo (PCB) starting day prior to chemo and TID from days 1-5</li><li>▪ THC:CBD 2.5 mg each, titrated from 1-4 capsules/dose</li></ul>                           |



# Cannabinoids for Medicinal Uses

| Grimison, et al. 2020 – Oral THC:CBD Cannabis for Refractory CINV                                                        |                                                                                                                                                             |                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Results (THC:CBD vs Placebo)                                                                                             |                                                                                                                                                             |                                                                                                                                                             |
| Efficacy<br>No. (%)                                                                                                      | <u>Complete response (CR)*</u><br>18 (25) vs 10 (14), RR 1.9, <b>P = 0.04</b><br><br><u>CR + no significant nausea</u><br>9 (13) vs 4 (6), RR 2.1, P = 0.12 | <u>Mean nausea score</u><br>3.2 ± 0.2 vs 4.7 ± 0.2, <b>P &lt; 0.001</b><br><br><u>No significant nausea**</u><br>15 (21) vs 7 (10), RR 2.0, <b>P = 0.03</b> |
| Self-reported cannabinoid-related adverse events (rated as moderate or severe)                                           |                                                                                                                                                             |                                                                                                                                                             |
| No. (%)                                                                                                                  | <u>Any:</u> 22 (31) vs 5 (7), <b>P = 0.002</b><br><br><u>Dizziness:</u> 8 (10) vs 1 (1), <b>P = 0.03</b>                                                    | <u>Sedation:</u> 15 (19) vs 3 (4), <b>P = 0.002</b><br><br><u>Anxiety:</u> 1 (1) vs 1 (1), P = 1.0                                                          |
| <u>Conclusions:</u> THC:CBD <b>decreased</b> vomiting and significant nausea, but had more patient-reported side effects |                                                                                                                                                             |                                                                                                                                                             |

83% preferred THC:CBD combination after cycle B

\*Complete response = no vomiting or rescue medication use during time 0 to 120 hours post chemotherapy

\*\*No significant nausea = nausea < 2 on a 10-point scale

# Cannabinoids for Medicinal Uses

## Hardy, et al. 2022 – CBD Oil for Symptom Relief in Advanced Cancer

### Design

- Single-center, dose-escalated, placebo-controlled trial

### **Population (N = 144)**

Age > 18 years with advanced cancer, TSDS  $\geq$  10/90, negative baseline THC urine test

### Intervention

- CBD oil 100 mg/mL vs placebo
- Starting dose: 0.5 mL (50 mg) once daily
- Titrated to maximum of 2 mL (200 mg) TID
- Standard palliative care provided to **all** participants
- Assessments: phone (every 3-4 days), in-person (week 0, 2, 4)

Primary outcome: TSDS change from baseline to week 2

- Placebo: -6.2 (SD 14.5), CBD: -3.2 (SD 15.2),  $p = 0.24$

\*No differences between arms in TSDS scores in physical, emotional, or well-being subsets

**Conclusions:** CBD oil did not reduce TSDS scores compared to palliative care alone

# Cannabinoids for Medicinal Uses

## Boland, et al. 2020 – Meta-Analysis – Cannabinoids for Cancer-related Pain

### Design

- 5 RCTs, N = 1,442 patients
- Included cannabinoids (THC:CBD oromucosal spray, THC extract) vs other active agents for pain (or placebo)

### Results:

#### Neuropathic Pain:

- 1 study (n = 18), compared nabiximols vs placebo for chemotherapy-induced neuropathic pain
- Mean pre-treatment NRS for pain intensity: 6.75
- Mean post-treatment (4 weeks) NRS for pain intensity: 6.00 (nabiximols vs 6.38, P = 0.29)

#### Pain Intensity

- Change in mean NRS pain score: -0.21 (-0.48-0.07, p = 0.14)

#### ADEs

##### Cannabinoid arms:

- Higher odds of somnolence (OR 2.69, **P < 0.001**), and dizziness: (OR 1.58, **P = 0.05**)
- Numerically higher, not significant: nausea (OR 1.41, P = 0.08), vomiting (OR 1.34, P = 0.21)

# Cannabinoids for Medicinal Uses

## Simon, et al. 2021 – Meta-Analysis – Cannabinoids for Cancer-related Cachexia

### Design

- 10 studies (4 RCTs, 6 NSRIs, N = 804 patients)
- Included medical marijuana (smoked, ingested), THC, CBD, and synthetic cannabinoids (dronabinol, nabilone)

### Results:

### Weight

- 8 trials evaluated weight change
- 1 RCT: megestrol resulted in > weight gain compared to dronabinol (**P = 0.02**)
- 1 RCT: **No difference** between placebo vs nabilone in weight gain
- 4 NRSTs: Slight weight gain in experimental arms (1 trial: mean ↑ 0.3 kg, 1 trial: median ↑ 1-1.3 kg, 2 reported ↑ of 7.7-21.6%)

### Appetite

- 3 RCTs (n = 297), no change in appetite with cannabinoids vs placebo, SMD -0.02, P = 0.93)
- \*7 NRSTs evaluated appetite, data not suitable for statistical analysis
- 2 trials: greater appetite improvement in control arm
- 3 trials: Experimental arm: improvement in appetite and calorie counts, less complaints appetite loss

# Cannabinoids for Cancer Symptoms

## 2024 ASCO Guidelines:

| Outcome              | Certainty of Evidence                                  | Direction of Effect                  | Recommendation |
|----------------------|--------------------------------------------------------|--------------------------------------|----------------|
| CINV                 | Moderate: Dronabinol, nabilone<br>Low: THC:CBD extract | Benefit                              | Weakly favor   |
| Total Symptom Burden | Low: Oral CBD                                          | No clear evidence of benefit or harm | Weakly against |
| Cancer Pain          | Moderate: Nabiximols                                   | No clear evidence of benefit or harm | None           |
| Sleep                | Moderate: Nabiximols, nabilone                         | No clear evidence of benefit or harm | None           |
| Weight/poor appetite | Low: Dronabinol, nabilone, THC/CBD extract, THC        | No clear evidence of benefit or harm | None           |
| Anxiety/depression   | Very low: THC, THC:CBD, dronabinol, nabiximols         | No clear evidence of benefit or harm | None           |

# Cannabinoids and Drug Interactions

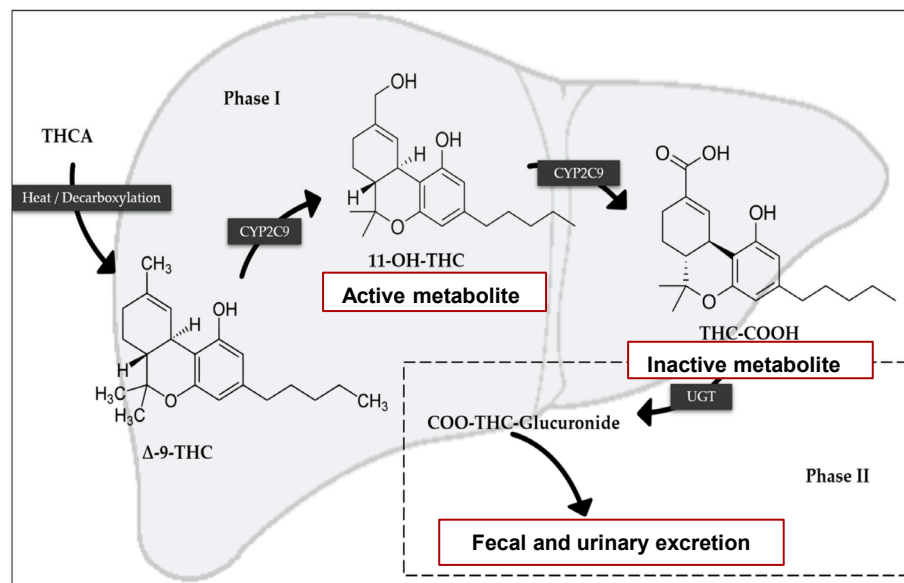
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# Cannabinoid Pharmacokinetics

## THC

- **Bioavailability:** 4-12% (oral), 10-35% (inhaled)
- **Distribution:** Lipophilic → accumulates in fat, released slowly into bloodstream
- **Metabolism:** Primarily CYP2C9, CYP2C19, CYP3A4 in liver, undergoes hydroxylation and glucuronidation into active and inactive metabolites
- **Excretion:** Feces (65-80%), urine (20-35%)
- **Half-life:** 1-3 days (occasional use), 5-13 days (chronic use)

### Main Metabolic Pathways:

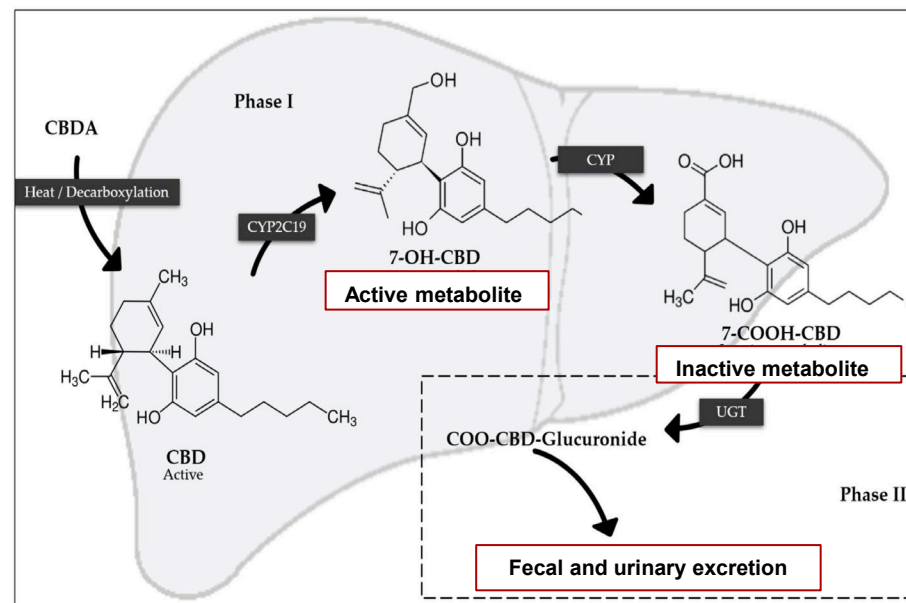


# Cannabinoid Pharmacokinetics

## CBD

- **Bioavailability:** variable, ~6% (oral), 11-45% (inhaled)
- **Distribution:** Brain, adipose tissue; low water-solubility
- **Metabolism:** Primarily CYP2C19 and CYP3A4, undergoes hydroxylation into active and inactive metabolites
- **Excretion:** Feces, unchanged (~33%), remaining active and inactive excreted via urine
- **Half-life:** 18-32 hours

### Main Metabolic Pathways:



# Cannabinoid Pharmacokinetics

| CBD and THC's Impact on Metabolic Enzymes:                           |                                                                                                                                                                                                                                                                                                                     |                                                                                                                                   |
|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
|                                                                      | Competitive Inhibition                                                                                                                                                                                                                                                                                              | Time-Dependent Inhibition                                                                                                         |
| <b>CBD</b>                                                           | CYP2E1 ( $K_{i,u}$ : 0.021 $\mu\text{M}$ )<br><b>CYP2D6</b> ( $K_{i,u}$ : 0.074 $\mu\text{M}$ )<br><b>CYP2C19</b> ( $K_{i,u}$ : 0.050–1.1 $\mu\text{M}$ )<br><b>CYP3A4</b> ( $K_{i,u}$ : 0.093 $\mu\text{M}$ )<br><b>CYP2C9</b> ( $K_{i,u}$ : 0.093–1.3 $\mu\text{M}$ )<br>CYP2B6 ( $K_{i,u}$ : 3.4 $\mu\text{M}$ ) | <b>CYP1A2</b> ( $K_i$ : 0.11–0.59 $\mu\text{M}$ )<br>CYP1B1 ( $K_i$ : 3.1 $\mu\text{M}$ )<br>CYP1A1 ( $K_i$ : 5.9 $\mu\text{M}$ ) |
| <b>THC</b>                                                           | <b>CYP2C9</b> ( $K_{i,u}$ : 0.073 $\mu\text{M}$ )<br><b>CYP1A2</b> ( $K_{i,u}$ : 0.090 $\mu\text{M}$ )<br><b>CYP2D6</b> ( $K_{i,u}$ : 0.11 $\mu\text{M}$ )<br>CYP2B6 ( $K_{i,u}$ : 0.25 $\mu\text{M}$ )                                                                                                             | CYP2A6 ( $K_i$ : 0.86 $\mu\text{M}$ )<br>CYP1A1 ( $K_i$ : 1.2 $\mu\text{M}$ )                                                     |
| $K_i$ = inhibition constant (lower number = higher binding affinity) |                                                                                                                                                                                                                                                                                                                     |                                                                                                                                   |

\*Other studies note THC may inhibit CYP3A4 as well, but likely weaker inhibition compared to CBD

## Clinical Impact?

- CBD: Moderate to strong increase in substrate's AUC at doses > 300 mg/day
- THC: Minimal impact observed at oral doses < 30 mg/day

# Cannabinoids and Drug Interactions

## 2024 ASCO Guidelines:

### Statements:

- Cannabinoids may inhibit: CYP3A4, UGT1A9, UGT2B7, CYP1A2, CYP2B6, CYP2C8, CYP2C9, and CYP2C19
- “Potential for drug interactions through altered metabolism pharmacokinetics”
- Warfarin = “very high-risk” drug interaction
- Buprenorphine, tacrolimus = “high risk” drug interaction
- “Scant” data available, unable to provide “informed, scientifically supported answers” on potential interaction with anticancer drugs

# Cannabinoids and Immunotherapy

## 2024 ASCO Guidelines:

### Recommendations:

- Preliminary data indicates potential poor clinical outcomes in patients receiving immunotherapy and using cannabis
- Advise caution in patients receiving immunotherapy and considering using cannabis

### Rationale:

- Cannabis alters various components of the immune system:

Proliferation,  
activation, and  
cytotoxic activity  
of T cells

Production of  
cytokines and  
chemokines

Function of  
dendritic and  
NK cells

Recruitment of  
immuno-  
suppressive  
myeloid cells

# Cannabinoids and Immunotherapy

| Taha, et al. 2019 – Cannabis Impacts Tumor Response Rate to Nivolumab                                                                                                                                                      |                                                                                                                                                                                                                                                    |                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Design                                                                                                                                                                                                                     | Retrospective, observational study, single-center                                                                                                                                                                                                  |                                                                                     |
| Population/<br>Intervention                                                                                                                                                                                                | Adults, stage IV NSCLC, RCC or advanced melanoma, newly on nivolumab <ul style="list-style-type: none"><li>Compared cannabis users (both THC and CBD) to non-users</li><li>N = 140 (IO alone = 89 patients, IO + Cannabis = 51 patients)</li></ul> |                                                                                     |
| Results: IO alone vs IO + Cannabis:                                                                                                                                                                                        |                                                                                                                                                                                                                                                    |                                                                                     |
| Response<br>Rate:                                                                                                                                                                                                          | <u>NSCLC:</u><br>33% vs 17.6%<br>p = 0.128, OR = 0.43<br>95% CI 0.14-1.28)                                                                                                                                                                         | <u>RCC + Melanoma:</u><br>43.3% vs 10%<br>p = 0.084, OR = 0.15<br>(95% CI 0.02-1.3) |
| Multivariate analysis: Only factor affecting treatment was cannabis, p = 0.031, adjusted OR 2.74, (95% CI 1.09-6.85)                                                                                                       |                                                                                                                                                                                                                                                    |                                                                                     |
| No impact on RR: THC or CBD percentages, method of use (smoked/inhaled vs CBD oil)                                                                                                                                         |                                                                                                                                                                                                                                                    |                                                                                     |
| Conclusions: <ul style="list-style-type: none"><li>Cannabis use correlated with decreased RR to nivolumab (not statistically significant)</li><li>Limitations: Small study, larger study needed to valid results</li></ul> |                                                                                                                                                                                                                                                    |                                                                                     |

# Cannabinoids and Immunotherapy

## Bar-Sela, et al. 2020 – Cannabis Consumption during Immunotherapy Correlates with Poor Clinical Outcomes

|                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Design</b>                                                                                                                                                                                           | Prospective (September 2016-September 2018), single-center                                                                                                                                                                                                                                                                                                                |
| <b>Population/<br/>Intervention</b>                                                                                                                                                                     | Adults, stage IV malignancy, initiated on any immunotherapy <ul style="list-style-type: none"><li>• Compared cannabis users (both THC and CBD) to non-users</li><li>• N = 102 (IO alone = 68 patients, IO + Cannabis = 34 patients)</li><li>• Significant differences between: site of metastases, line of treatment, single agent vs combination immunotherapy</li></ul> |
| <b>Results:</b> IO alone vs IO + Cannabis:                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                           |
| <b>TTP</b><br>(1° endpoint)                                                                                                                                                                             | 13.1 months vs 3.4 months, <b>p = 0.025</b>                                                                                                                                                                                                                                                                                                                               |
| <b>OS</b>                                                                                                                                                                                               | 28.5 months vs 6,4 months, <b>p = 0.00094</b>                                                                                                                                                                                                                                                                                                                             |
| <b>ORR</b>                                                                                                                                                                                              | 59% vs 39%, <b>p = 0.035</b>                                                                                                                                                                                                                                                                                                                                              |
| <b>Conclusions:</b> <ul style="list-style-type: none"><li>• Cannabis use associated with decreased TTP, OS, ORR</li><li>• Limitations: Small study, heterogenous population (unbalanced arms)</li></ul> |                                                                                                                                                                                                                                                                                                                                                                           |

# Cannabinoids and Immunotherapy

**Xiong X, et al. 2022:**

**Cannabis Suppresses Antitumor Immunity by Inhibiting JAK/STAT Signaling in T-cells**

## Methods:

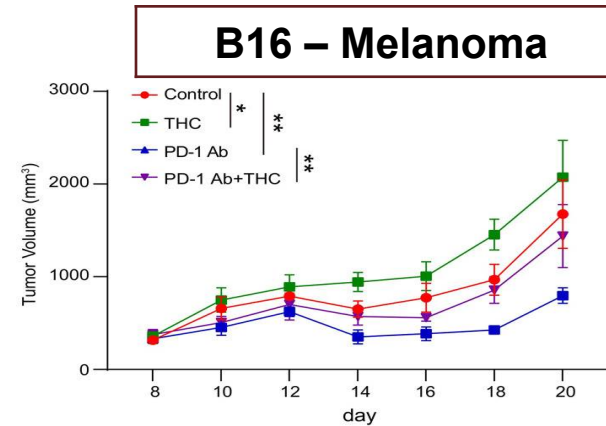
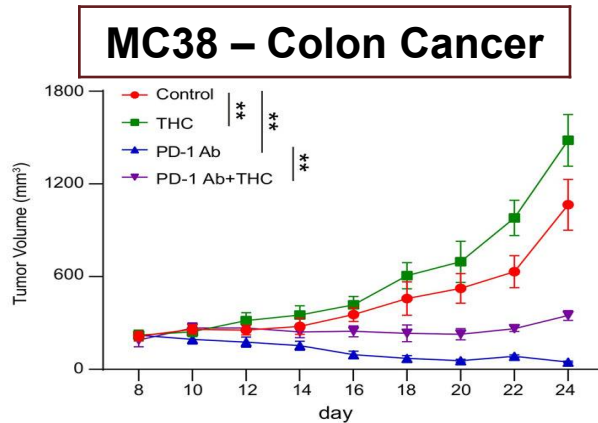
- Population: Mice with MC38 cell (colon carcinoma) or B16 cells (melanoma)
- Intervention:
  - Administered PD-1 antibodies  $\pm$  THC or AEA

| <b>Control:</b>                                                                                                                                   | <b>THC:</b>  | <b>PD-1:</b> | <b>Combination:</b> |
|---------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|---------------------|
| No treatment                                                                                                                                      | THC, no PD-1 | PD-1, no THC | PD-1 and THC        |
| <ul style="list-style-type: none"><li>• PD-1 antibodies: 200 mcg given 2x weekly</li><li>• THC and AEA: 10 mg/kg every 2 days x 2 weeks</li></ul> |              |              |                     |

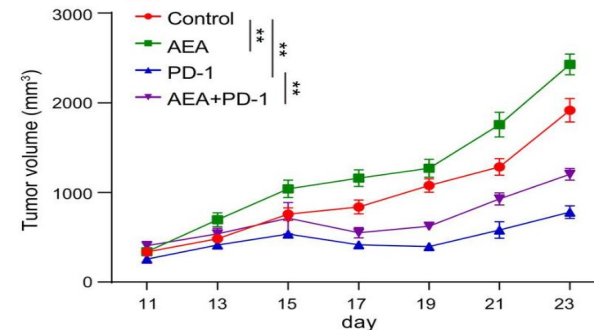
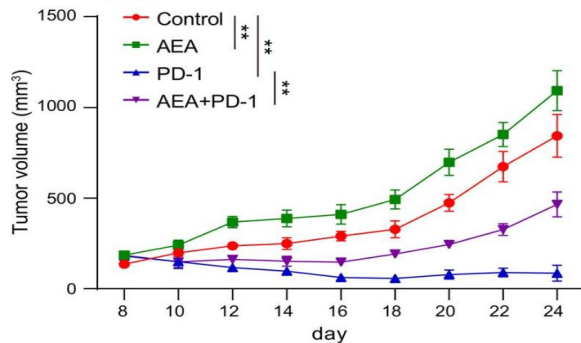
- Tumor volume measured every other day

# Cannabinoids and Immunotherapy

## Tumor Volume after THC Administration:



## Tumor Volume after AEA Administration:



## Conclusions:

- THC and AEA reduced efficacy of PD-1 blockade
- Molecular analysis: cannabis inhibited JAK1-STAT signaling in T cells via CNR2

# 2024 ASCO Guidelines

## Recommendation:

- Avoid  **$\geq 300$  mg** oral CBD per day due to lack of efficacy and possible liver dysfunction

## Data:

- 2023 meta-analysis; N = 28 trials (1,533 patients on CBD vs 494 on placebo)
  - 89% administered CBD via oral solution
- Liver enzyme elevation:
  - CBD: n = 159 cases (10.5%); Placebo: n = 2 cases (0.40%)
  - OR 5.85 (95% CI 3.84-8.92), **p < 0.001**
- DILI:
  - CBD: n = 57 cases (4.43%); Placebo: n = 1 (0.20%)
  - OR 4.82 (95% CI 2.46-9.45), **p < 0.001**



No DILI cases reported at doses < 300 mg/day

# Summary and Current Limitations

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- Medicinal cannabis may be useful in alleviating some cancer-related symptoms, but clinical data is limited by many factors:
  - Small sample sizes, primarily observational data, no standardized dosing/formulation, lack of long term follow up
- Cannabis may negatively impact efficacy of immunotherapy and clinicians should discuss with patients
- THC and CBD inhibit many CYP 450 isoenzymes which may impact antineoplastic drug metabolism; data on clinical impact is lacking

# Medicinal Cannabis Regulations

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# Disclosure

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None of the comments and material provided regarding legal content constitutes legal advice and should not be utilized as such.

# Timeline of Legislation

Executive  
order 2022-  
798 signed by  
Governor  
Beshear  
**November  
2022**

Medicinal  
cannabis  
program goes  
live  
**January 2025**

Applicable  
medical  
conditions  
expanded  
**June 2026**

**March 2023**  
Senate bill 47  
signed into law

**April 2026**  
U.S. Attorney  
General  
proposes  
reclassification  
of medical  
cannabis  
products to  
Schedule III

**July 2026**  
Executive  
order 2022-  
798 rescinded

# Application Process

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Obtain a written certification from a medical cannabis practitioner in person



Create an account on the patient and caregiver registration portal and start an application



Submit the application with a notarized signature form



Application will be reviewed and accepted by the CHFS

Cabinet will acknowledge receipt of the application within 15 calendar days

Cabinet will approve or deny the application within 30 calendar days of receiving an application

Approved applicants will receive registry ID cards within 5 days of approval

# Medical Cannabis Practitioners

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- Physician or an Advanced Practice Registered Nurse who is authorized to prescribe controlled substances
- Authorized through their respective licensing boards
- Eligibility requirements:
  - Good standing with DEA credentials
  - Access to the state's PDMP
  - Six hours of continued medical education on medical cannabis
  - NO ownership, investment in or compensation agreement with a licensed medical cannabis business

# Applicable Medical Conditions

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- Any type or form of cancer
- Chronic or severe pain
- Epilepsy or other intractable seizure disorder
- Multiple sclerosis, muscle spasms, or spasticity
- Chronic nausea or cyclical vomiting syndrome
- Post-traumatic stress disorder

# New Additions

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- “Terminal Illness”
- Sickle Cell Anemia
- ALS
- HIV/AIDS
- Huntington’s Disease
- Muscular Dystrophy
- Cachexia/Wasting Syndrome
- Crohn’s Disease
- Ulcerative Colitis
- Neuropathies
- Severe arthritis
- Fibromyalgia
- Glaucoma

# Cards and Fees

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- In-state registry ID card
- Minor patient registry ID card
  - In-state individual less than 18 years of age
- Designated caregiver registry ID cards
- Visiting patient registry ID cards
  - Individual out-of-state registry card and documentation of a qualifying medical condition
  - In KY for less than 30 days and at least 21 years old
- All cards: \$25
- Cards expire 1 year from the date of issuance
  - Ability to purchase medical cannabis expire on date of written certification
  - Applications must be complete no later than 30 calendar days prior to expiration date on the card

## Registry Requirements

|                                                                                                                                                                   | In-state qualified patient <sup>17</sup> | In-state minor qualified patient <sup>18</sup> | Designated caregiver <sup>19</sup> | Visiting qualified patient <sup>20</sup> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|------------------------------------------------|------------------------------------|------------------------------------------|
|  Applicant's identifiable information                                             | X                                        | X                                              | X                                  | X                                        |
|  Name and registry ID card number of qualified patient                            |                                          |                                                | X                                  |                                          |
|  Written certification from medical cannabis practitioner                         | X                                        | X                                              |                                    |                                          |
|  Medical cannabis practitioner information                                        | X                                        | X                                              |                                    |                                          |
|  Designated caregiver information and attestation (if applicable)                 | X<br>(If applicable)                     | X                                              | X                                  |                                          |
|  Notification of clinical trials                                                  | X                                        | X                                              |                                    |                                          |
|  Attestation of information sharing                                               | X                                        | X                                              | X                                  | X                                        |
|  Notarized signature form                                                         | X                                        | X                                              | X                                  | X                                        |
|  Documentation that the applicant has been diagnosed with a qualifying condition* |                                          | X                                              |                                    | X                                        |
|  Statement from custodial parent or legal guardian                              |                                          | X                                              |                                    |                                          |
|  Copy of valid out-of-state registry ID card                                    |                                          |                                                |                                    | X                                        |

\* This documentation must consist of one (1) or more medical records containing an express statement of diagnosis from a physician or advanced practice registered nurse (APRN) of a qualifying medical condition.<sup>1</sup> For in-state minor patients, this documentation must be provided from a practitioner other than the medical cannabis practitioner who provided the written certification for the use of medical cannabis.

# Product Packaging and Labeling

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## Packaging

- Tamper-evident and child resistant seal
- Light resistant, opaque, and minimizes oxygen exposure
- Provides telephone number for National Poison Control Center



## Labeling

- Total mg of THC/CBD per serving/package
- Data of harvest, processing, and packaging
- Manufacturer name, batch ID, expiration
- Directions for use
- QR code linking directly to certificates of analysis to verify safety

# Allowable Medical Cannabis Products

| Form of medical cannabis          | 10-day supply limit | 30-day supply limit* | Example products                                                                                                                                                                                                                 |
|-----------------------------------|---------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Raw plant material                | 37.5 grams          | 112 grams            | N/A                                                                                                                                                                                                                              |
| Concentrates                      | 9.5 grams           | 28 grams             | <ul style="list-style-type: none"> <li>▶ Vape cartridges</li> <li>▶ Nebulizer solutions</li> </ul>                                                                                                                               |
| THC-infused products              | 1,300 milligrams    | 3,900 milligrams     | <ul style="list-style-type: none"> <li>▶ Edibles</li> <li>▶ Pills</li> <li>▶ Capsules</li> <li>▶ Oils</li> <li>▶ Liquids</li> <li>▶ Beverages</li> <li>▶ Tinctures</li> <li>▶ Suppositories</li> <li>▶ Dermal patches</li> </ul> |
| Non-consumable (topical) products | N/A**               |                      | <ul style="list-style-type: none"> <li>▶ Gels</li> <li>▶ Creams/lotions</li> <li>▶ Ointments</li> <li>▶ Cosmetics</li> <li>▶ Soaps</li> </ul>                                                                                    |

# Required Notifications

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- Cardholders are required to make the following notifications (notification time):
  - Change in name/address (10 days)
  - Loss of the card (10 days)
  - Termination of a designated caregiver relationship (10 days)
  - Cardholder ceases to suffer from the medical condition (30 days)
  - Designated caregiver becomes aware that patient is deceased (30 days)
- New registry ID cards will be issued within 10 days of receiving updated information
- **When a cardholder provides the cabinet with any of the notifications above, the cardholder must, within ten (10) days of notification, return any unused medical cannabis products to a licensed dispensary for destruction.**

# Purchasing Restrictions



In-state qualified patients are permitted to purchase the amount of medical cannabis specified by the patient's medical cannabis practitioner, **up to a thirty (30) day supply** during a twenty-five (25) day period.<sup>32</sup>



Designated caregivers are permitted to purchase the amount of medical cannabis specified by the medical cannabis practitioner for the qualified patient(s) they assist, **up to a thirty (30) day supply per each registered qualified patient** during a twenty-five (25) day period.<sup>33</sup>



Visiting qualified patients are permitted to purchase an amount of medical cannabis **up to a ten (10) day supply** as specified by the program supply limits during an eight (8) day period.<sup>34</sup>

The following medical cannabis consumption methods are **prohibited** by KRS Chapter 218B:



- ▶ Consuming medical cannabis by combustion, such as smoking, by any patient<sup>35</sup>
- ▶ For patients under 21 years old, medical cannabis products intended for consumption by vaporizing are not allowed<sup>36</sup>

**Packages for medical cannabis products cultivated, processed, produced, tested, and sold in the Commonwealth will have the standardized symbol below indicating that the products contain THC and were made and sold by licensed cannabis business in Kentucky.**

# Restrictions for Use

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- **Medical cannabis cardholders may not:**
  - Operate vehicles or machinery while under the influence of medical cannabis
  - Keep medical cannabis in arm's reach when operating machinery
  - Use medical cannabis if it impairs their ability to perform tasks safely
  - Possess or use medical cannabis on school property
  - Possess or use medical cannabis at correctional facilities, or on federal property
  - Consume medical cannabis by combustion
  - Grow their own medical cannabis without a cannabis business license

# Open Dispensary Locations

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- Bowling Green
- Elizabethtown
- Georgetown
- Florence
- Frankfort
- Nicholasville
- Nortonville
- London
- Lexington
- Oak Grove
- Paducah
- Louisville
- Ferguson
- Princeton
- Beaver Dam
- Erlanger
- Ashland
- Corbin

# Schedule III Status

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- Strictly applies to FDA approved drug products containing marijuana (i.e. Dronabinol) and any form of cannabis for anyone holding a qualified state medical marijuana license
  - **Requires DEA registration**
- Benefits:
  - Tax relief for those registering
  - **Broader access to research**
- The BIG problem
  - Only schedule 3 medications are available at pharmacies and only pursuant to a prescription
- Hearing on July 10, 2026
  - Post hearing briefs to be posted August 17, 2026

# 21 U.S.C. § 811(c)

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## **Considerations for Scheduling**

1. Its actual or relative potential for abuse.
2. Scientific evidence of its pharmacological effect, if known.
3. The state of current scientific knowledge regarding the drug or other substance.
4. Its history and current pattern of abuse.
5. The scope, duration, and significance of abuse.
6. What, if any, risk there is to the public health.
7. Its psychic or physiological dependence liability.
8. Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

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# Key Takeaways

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- Consider optimal dosing recommendations based on THC/CBD content
- Carefully examine drug metabolism when reviewing medication lists for interactions
- Expect a minimum 35-day processing to obtain medicinal cannabis
- Cannabis dispensed is still federally a Schedule I substance

# Beyond the Green: Navigating Clinical Impacts and Kentucky Cannabis Law

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