

Medical Marijuana in Ohio – Considerations for Our Aging and Disabled Populations

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Disclosures

- Relevant Financial Relationships: State of Ohio Medical Marijuana Advisory Board Member.
- This continuing education activity contains discussion of published and/or investigational uses that are not indicated by the FDA. Please refer to the official prescribing information for each product for discussion of approved indication, contraindications, and warnings.



Objectives

- Describe the Medical Marijuana Control Program in the State of Ohio
- Identify adverse effects and precautions for marijuana use
- Relate proposed considerations of medical marijuana in the elderly and disabled to your patient population



History of Marijuana Use

**2700 BC:
Chinese Use
Marijuana
for Medicinal
Purposes**

**1850:
Marijuana
added to US
Pharmacopeia**

**1970:
Federal
Controlled
Substance
Act**

**1619:
Jamestown
settlers
required to
grow
cannabis**

**1937:
Marijuana
Tax Act**

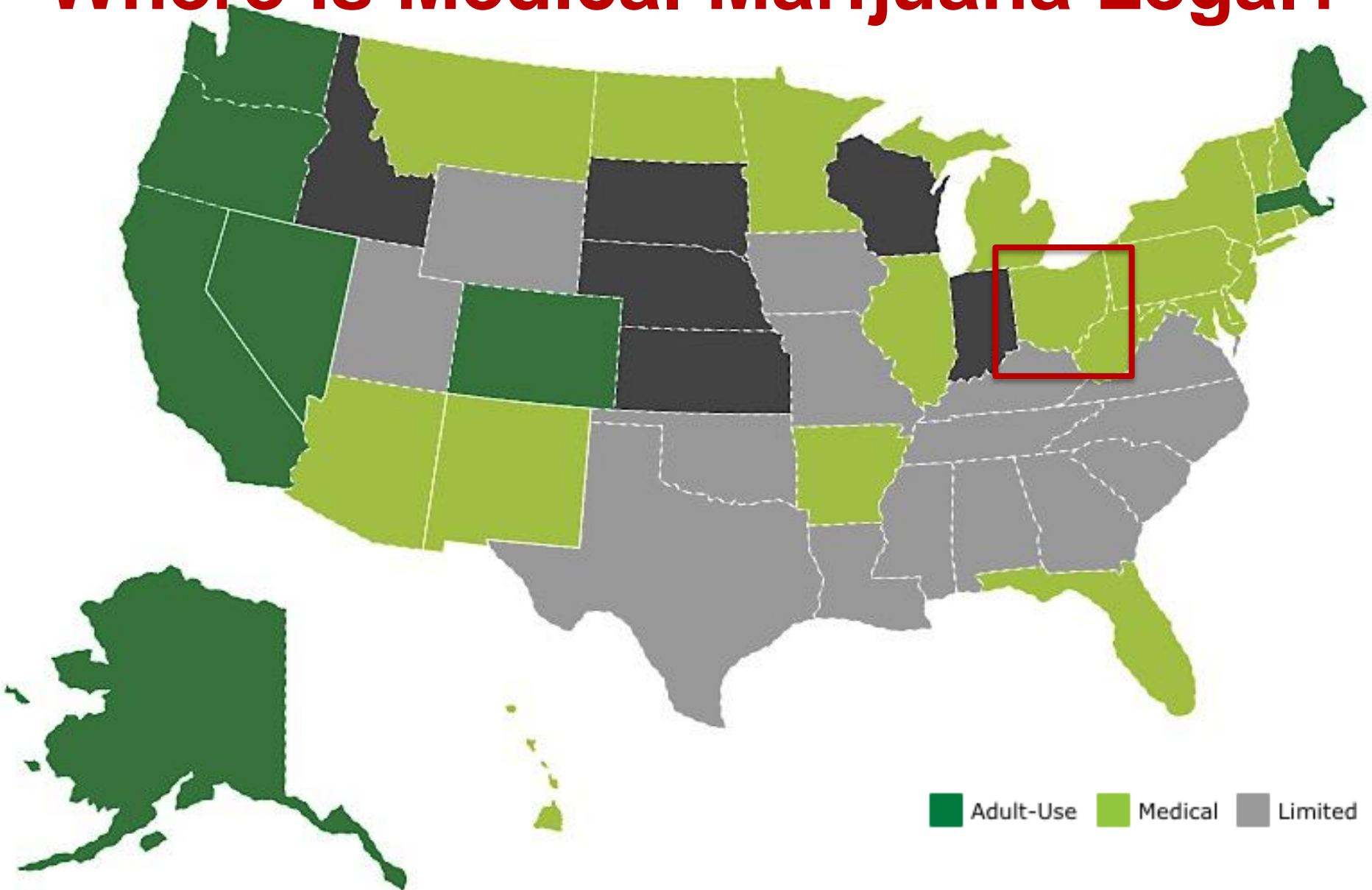
**1996:
Proposition
215**

Public Opinion

- 85% of Americans believe adults should be allowed to use cannabis for medical purposes – Fox News 2013
- 75% of Americans believe federal legalization of cannabis is inevitable – Pew Research, April 2014
- 69% of Americans believe alcohol is more harmful to a person's health than marijuana – Pew Research, April 2014
- 58% of Americans believe recreational cannabis should be legal – Gallup, October 2013



Where is Medical Marijuana Legal?



Adult-Use Medical Limited



Background

- **Federal Controlled Substance Act:**
 - “Marihuana” means all parts of a plant of the genus *cannabis*, whether growing or not; the seed of a plant of that type; the resin extracted from a part of a plant of that type; and every compound, manufacture, salt, derivative, mixture, or preparation of a plant of that type or of its seeds or resin.



Regulatory Status in Ohio

- September 8, 2016
 - House Bill 523 effective date
- September 2017 rules adopted:
 - Processor
 - Testing laboratory
 - Dispensary
 - Patient/caregiver
 - Physician certificate to recommend
- September 2018
 - Program fully functional



Who is Responsible?

Department of Commerce

- Cultivators
- Processors
- Testing laboratories

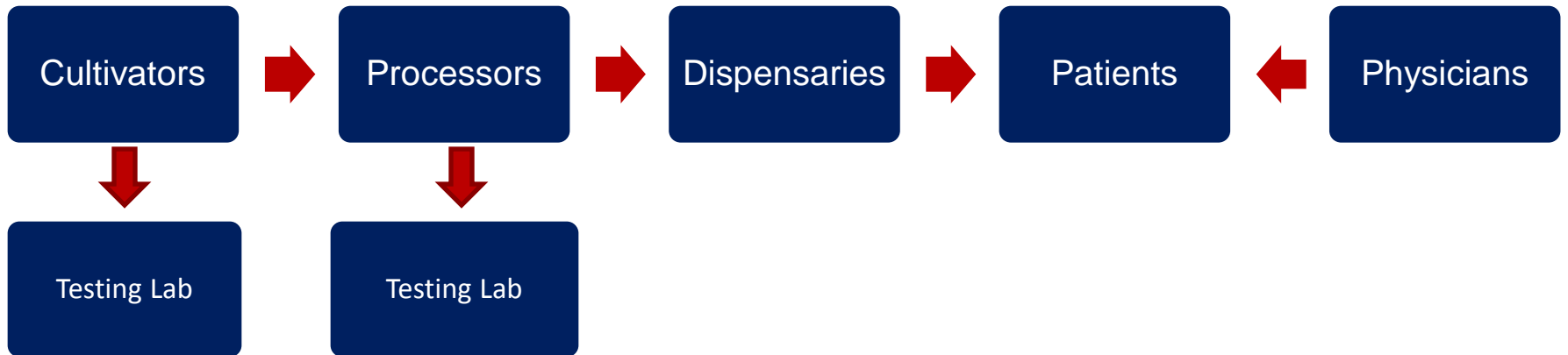
State Board of Pharmacy

- Dispensaries
- Patients/Caregivers
- New forms and methods of medical marijuana

Medical Board

- Certified physicians
- New qualifying conditions

Medical Marijuana Process Flow Chart



Dispensaries

- Up to 60 licenses issued by State Board of Pharmacy
- Must have proof of registration and recommendation prior to dispensing
- Must submit data to Ohio Automated Rx Reporting System (OARRS)
- No healthcare professional required to dispense
 - Policy must exist for education of patients
 - Employee must have documented training
 - Must maintain 16 CE hours/2 year licensing period



House Bill 523-Approved Forms

Oils

Tinctures

Plant
material

Edibles

Patches

House Bill 523 Prohibitions on Form and Method of Administration

Forms and methods considered attractive to children

Forms that require smoking or combustion

THC Content

- Responsible for most of the psychoactive effects of cannabis
- Best available clinical data is for $\leq 23\%$ THC
 - Data focuses on efficacy based on THC content
 - Does not take into account the “Ensemble Effect” (also known as the Entourage Effect)
 - Limited studies demonstrate this effect at this time

90-Day Supply of Plant Material

Tier	THC Content	Maximum 90-Day Supply	THC Medical Efficacy	Adverse Events
Tier 1	0 – 23%	8 oz. 10 oz. (terminal exception)	+	+
Tier 2	23.1 – 35%	5.3 oz. 6.6 oz. (terminal exception)		+

90-Day Supply of MM based on THC Content

Form	90-Day Supply
Tier I plant material (up to 23% THC)	8 ounces of plant material; 10 ounces for terminal exception
Tier II plant material (over 23% THC)	5.3 ounces of plant material; 6.6 ounces for terminal exception
Oils for vaporizing	53.1 grams of THC; 65.7 grams for terminal exception
Patches for transdermal administration	26.6 grams of THC; 33.3 grams for terminal exception
Edibles, oils, and tinctures for oral administration	9.9 grams of THC; 11.7 grams for terminal exception

Importance of Constituents

- THC trends over time
 - 1980s ~4%
 - 2012 average concentration from police confiscation ~15%
 - 2015 ~20% with potencies up to 30%
- Percentage of constituents play a role in therapeutic applications, adverse effects, etc.

Patients and Caregivers

- Patients and caregivers must register with the Board of Pharmacy
 - Electronic
 - Can be submitted by a patient's recommending physician or physician's delegate
 - Annual registration fee is \$50 for patients and \$25 for caregivers
- Patients under 18 must have a parent or legal representative as a caregiver
- A person must be 21 to serve as a caregiver and patient can have up to 2 caregivers; each caregiver can have up to 2 patients

Certificate to Recommend (CTR) Eligibility

- Active, unrestricted license
- OARRS registration
- DEA registration
- No prior action on license from DEA or any licensing entity for inappropriate prescribing
- 2 hours of approved CME
- No defined conflict of interest
 - Ownership/investment in or compensation agreement with a medical marijuana entity/applicant



CTR Standard of Care

- Bona fide physician-patient relationship
- Create and maintain medical record
 - Similar to standards for pain management
 - Standard medical treatment attempted or considered
- Ensure patient is registered or submit application



Components of Recommendation

- Statement from physician certifying:
 - Bona-fide physician-patient relationship
 - Diagnosis of at least one qualifying medical condition
 - Description of qualifying condition and indicate if terminal
 - OARRS report run
 - Risks and benefits outlined



Qualifying Medical Conditions

AIDS	Amyotrophic Lateral Sclerosis	Alzheimer's Disease
Cancer	Chronic Traumatic Encephalopathy	Crohn's Disease
Epilepsy / Seizure Disorder	Fibromyalgia	Glaucoma
Hepatitis C	Inflammatory Bowel Disease	Multiple Sclerosis
Pain (chronic & severe / intractable)	Parkinson's Disease	HIV
Post-Traumatic Stress Disorder	Sickle Cell Anemia	Spinal Cord Disease / Injury
Tourettes's Syndrome	Traumatic Brain Injury	Ulcerative Colitis


Employment Law- 3796.28

House Bill 523 does not require or prohibit the following:

- An employer to permit or accommodate an employee's use, possession, or distribution of medical marijuana;
- An employer from refusing to hire, discharging, disciplining, or otherwise taking an adverse employment action because of that person's use, possession, or distribution of medical marijuana;
- An employer from establishing and enforcing a drug testing policy, drug-free workplace policy, or zero-tolerance drug policy;
- Interfere with any federal restrictions on employment;

Employment Law- 3796.28

- Permit a person to commence a cause of action against an employer for refusing to hire, discharging, disciplining, discriminating, retaliating, or otherwise taking an adverse employment action against a person with respect to hire, tenure, terms, conditions, or privileges of employment related to medical marijuana;
- Affect the authority of the administrator of workers' compensation to grant rebates or discounts on premium rates to employers that participate in a drug-free workplace program



Pharmacology of Cannabinoids



Types of Cannabinoids

- Endocannabinoids
- Phytocannabinoids
 - Δ -9 tetrahydrocannabinol (THC)
 - Cannabidiol (CBD)
 - Cannabinol (CBN)
- Synthetic

Primary Clinical Implications of THC and CBD

- THC
 - Psychoactive
 - emotional and cognitive changes, analgesia, hypothermia and appetite stimulation
- CBD
 - Non-psychotropic
 - Modulation of behavioral effects

Modes of Administration

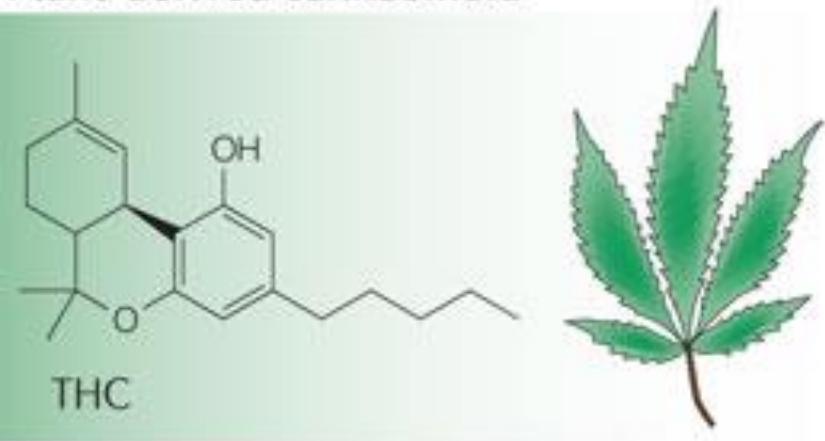
- Marijuana/cannabis
 - Smoking
 - Vaporization
 - Oral ingestion
- Synthetic cannabinoids
 - Oral ingestion
 - Oromucosal spray



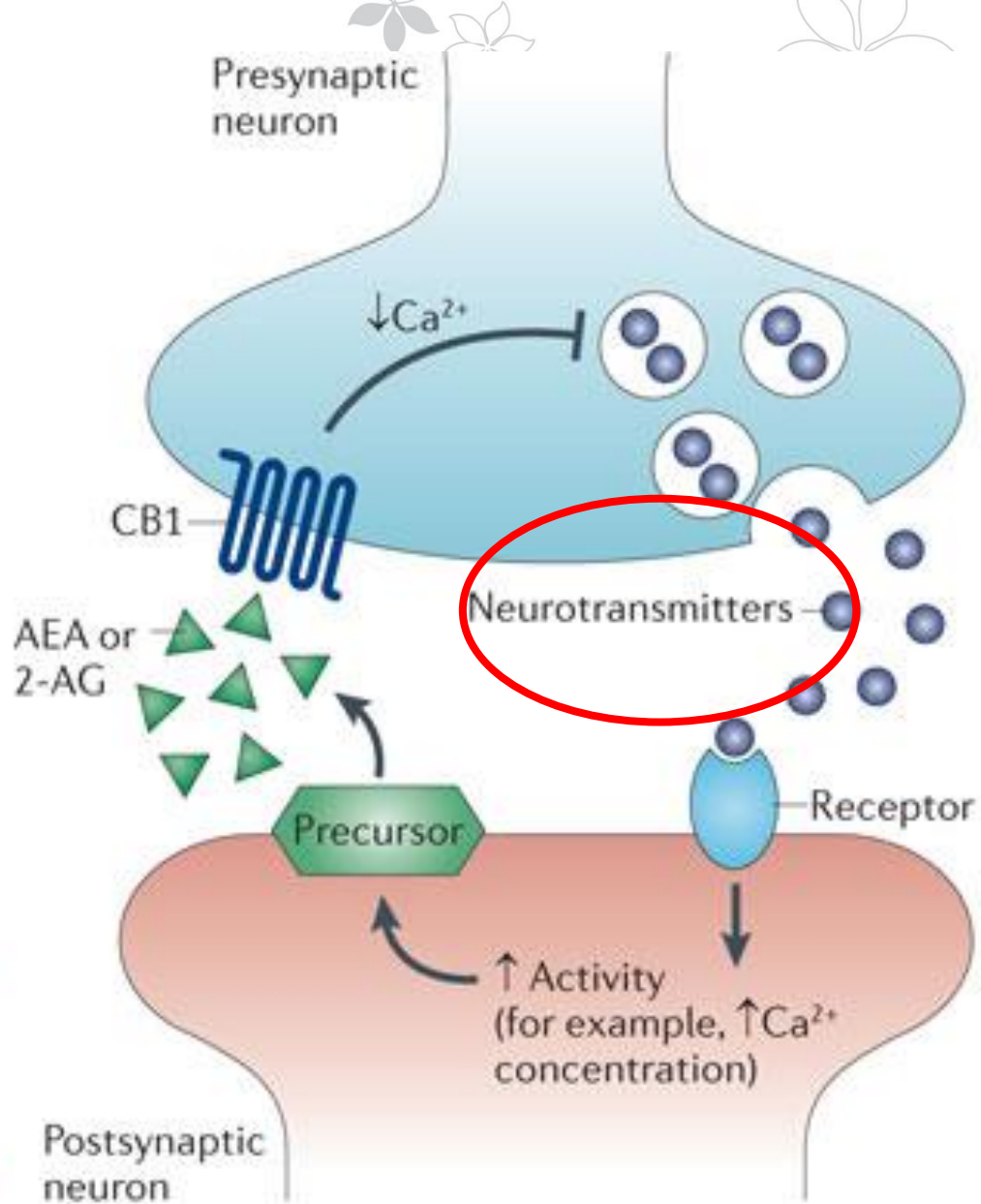
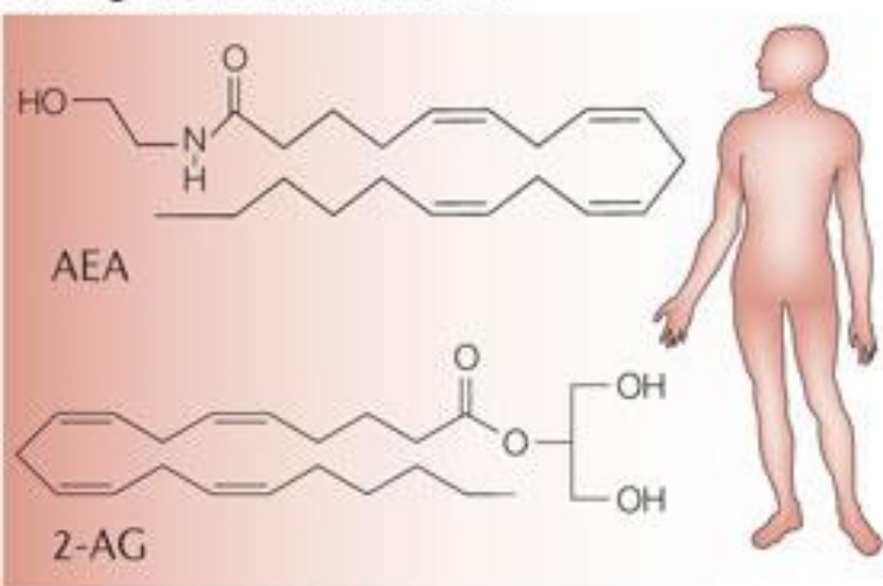
Quantity Definitions and Effective Doses of Cannabis

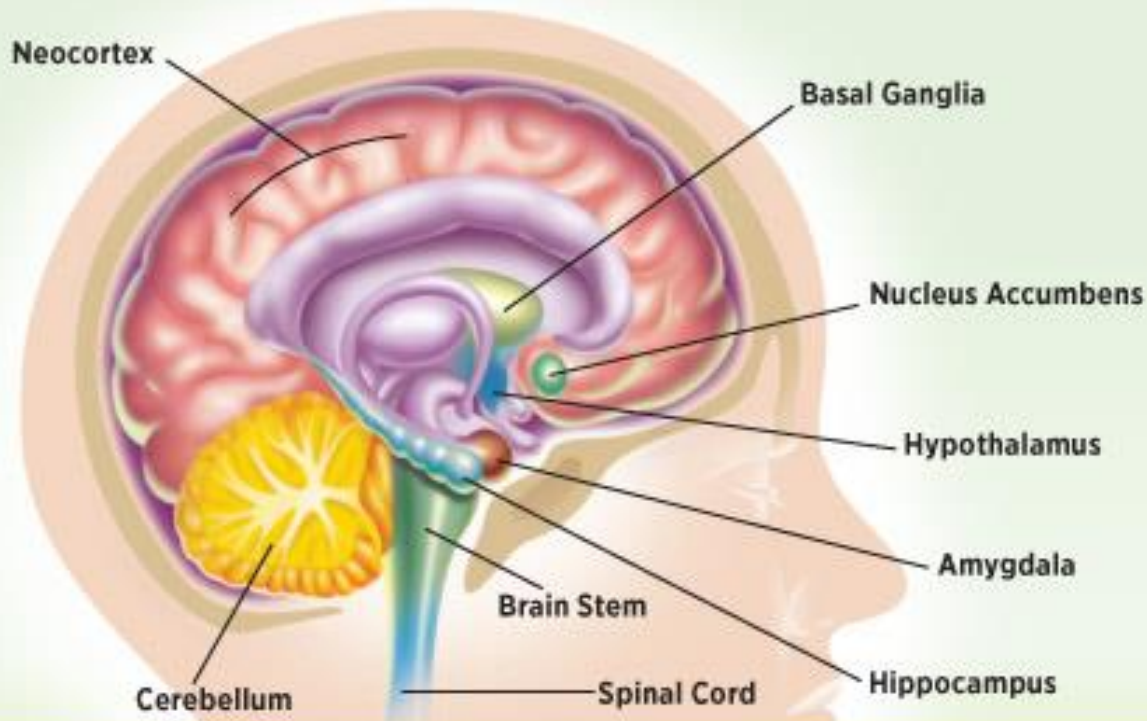
- 1 “joint” = 500 mg
- Effective doses
 - Smoked
 - 1 – 3 grams per day
 - Vaporized
 - 8 – 12 inhalations of 800 mg over a 2 hour period
 - Oral
 - 5 – 20% bioavailability of smoked cannabis
 - Magnitude is 10% of smoked

Plant-derived cannabinoid



Endogenous cannabinoids






Brain Structure	Regulates	THC Effect on User
Amygdala	emotions, fear, anxiety	panic/paranoia
Basal Ganglia	planning/starting a movement	slowed reaction time
Brain Stem	information between brain and spinal column	antinausea effects
Cerebellum	motor coordination, balance	impaired coordination
Hippocampus	learning new information	impaired memory
Hypothalamus	eating, sexual behavior	increased appetite
Neocortex	complex thinking, feeling, and movement	altered thinking, judgment, and sensation
Nucleus Accumbens	motivation and reward	euphoria (feeling good)
Spinal Cord	transmission of information between body and brain	altered pain sensitivity

The brain structures illustrated above all contain high numbers of CB receptors

JAMA 2015 Meta-analysis Summary of Parallel-Group Studies

Indication	# of Studies (# patients)	Cannabinoid (# studies)	Comparator	Outcome Favors
Neuropathic and cancer pain	31 (4535)	Smoked THC (1), Nabiximols (29), Nabilone (1)	Placebo	Majority cannabinoid
Spasticity	21 (5371)	Nabiximols (13), THC/CBD (2), Dronabinol (2), Nabilone (3)	Placebo	Majority cannabinoid
Depression	3 (408)	Nabiximols	Placebo	Placebo
Anxiety disorder	1 (24)	Cannabidiol	Placebo	Cannabidiol
Sleep disorder	1 primary (22); 11 in other indications (2167)	Nabilone (1), Nabiximols (10), THC/CBD (1)	Placebo	Cannabinoids
Psychosis	2 (70)	Cannabidiol	Amisulpride	1 st study: CBD; 2 nd study: Amisulpride
Tourette syndrome	4 (69)	THC capsules	Placebo	THC
CINV	3 (102)	Dronabinol (2), Nabiximols (1)	Placebo	Cannabinoids
HIV/AIDS	1 (88)	Dronabinol	Placebo	Dronabinol



Cannabinoids Used with Opioids



Boehnke et al, 2016

- Results (n = 185)
 - 64% self-reported opioid use reduction
 - Mean # medication classes reduced (2.38 vs 1.81)



Perron et al, 2015

- 40% combined cannabis with alcohol
- No difference in lifetime or past-3-month use of other drugs
- PPM users favored cannabis for pain efficacy
- PPM users noted a strong desire to reduce PPM usage



Bachhuber et al, 2014

- States with medical cannabis laws had 24.8% lower mean annual opioid overdose mortality rate
- Lower rates of overdose mortality strengthened over time



Adverse Effects and Precautions



Use in the Aging Population

- ~110.9 million Americans >50 use marijuana
- 600 million \geq 60 years of age
 - Double by 2025

Drug/Drug Interactions

- Metabolism
 - THC and CBN
 - CYP 3A4 & 2C9
 - CBD
 - CYP 3A4 & 2C19
- Synergy with CNS depressants
- Opioids: Cross tolerance and mutual potentiation



Medical Marijuana Adverse Effects

System Affected	Adverse Effects
Central Nervous System	Dizziness, numbness, nightmares, visual disturbances, headache, feeling intoxicated, drowsiness, anxiety, cognitive impairment, emotional changes, mental slowness, impaired reaction time, dysphoria
Cardiovascular	Tachycardia, orthostatic hypotension, hypertension, palpitations, paroxysmal atrial fibrillation, peripheral vasodilation
Other	Dry mouth, nausea, syncope, hyperemesis, exacerbation of immunosuppression, fertility



Acute Effects of Marijuana

- Alterations in short-term memory
- Coordination
- Judgment
- Elderly may suffer from concurrent conditions
 - Dementia
 - Vision/hearing changes
 - Mobility issues

Driving Impairment

- Independent risk factor for motor vehicle accidents (MVA)
- Associated with increased fatality in MVA
- Avoid driving
 - Inhalation – 4 hours
 - Oral ingestion – 6 hours
 - Euphoria experienced – 8 hours

Controversial Adverse Effects

- Cognitive impairment
 - Importance of age 25
- Mental Illness
 - Role of pre-existing/family history
- Gateway Hypothesis
 - Direct cause vs association

Cannabis Use Disorder

- 10 – 30 % of users will develop
 - Most common age and timeframe
- DSM-5 Diagnostic Criteria (at least two within previous 12 months):
 - Tolerance
 - Withdrawal
 - Increasing amounts of use over time
 - Inability to control consumption
 - Craving
 - Recurrent use causing negative impacts on social, professional, and educational life

Acute Toxicity and Overdose

- Acute psychosis
- CNS depression
- Cardiovascular and neurologic toxicity
- Pharmacokinetic differences between inhaled and edible formulations
 - Oral more likely to cause toxicity with redosing or accidental ingestion
 - Educate elderly who have children/grandchildren

Cannabis Withdrawal Syndrome

- Symptoms
 - Nightmares and strange dreams
 - Trouble sleeping
 - Anxiety
 - Irritability
 - Physical tension
 - Low mood and depression
 - Reduced appetite
- Symptom appearance and duration

Considerations for Patients with Disabilities

- Social Security Disability is a federal program
- Americans with Disabilities Act
- Administration
 - Routes
 - Caregivers

Take Home Points

- Medical Marijuana available 09/2018 in Ohio
 - Must have a recommendation from a physician
 - Role of caregivers
- Considerations for elderly
- Considerations for disabled



Helpful Resources

- **State Regulatory Status/Updates:**
<http://medicalmarijuana.ohio.gov/>
- **Overview and counseling points:** Parmar JR, Forrest BD, Freeman RA. [Medical marijuana patient counseling points for health care professionals based on trends in the medical uses, efficacy, and adverse effects of cannabis-based pharmaceutical drugs.](#) Res Social Adm Pharm. 2015 Sep 16. pii: S1551-7411(15)00170-9. doi: 10.1016/j.sapharm.2015.09.002. [Epub ahead of print] PubMed PMID: 26443472.
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Cannabinoids and Medical Marijuana: What You Need to Know for Legalization in Ohio

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