

# **Cannabis:**

## **History, Trends, Tensions**

**Presented By**



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# Cannabis: History, Trends, Tensions

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## In the Court of Public Opinion



62% of Americans favor  
legalization

Compared to 31% in 2000



By Age

Millennials 74%

Gen Xers 63%

Baby Boomers 54%



By Party

D: 69%; D-Independents: 75%

R: 45%; R-Independents: 59%

<https://www.pewresearch.org/fact-tank/2018/10/08/americans-support-marijuana-legalization/>

## Pre-20<sup>th</sup> Century



- 8000 BC: Discovered at archeological site in Japan
- 2900 BC: 1<sup>st</sup> written reference to cannabis in China
- 1300 AD: 1<sup>st</sup> restrictions on cannabis in Islamic world
- Believed to be 1<sup>st</sup> ever domesticated crop
- **Pre-20<sup>th</sup> Century U.S.**
  - Freely cultivated & exported to England
  - Exchanged as tender & embraced as medicinal
  - Used to produce rope & fabric

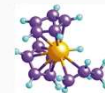
## 20<sup>th</sup> Century U.S.

- 1906 Pure Food & Drug Act
  - 1<sup>st</sup> Fed safety regs
  - OTC remedies must be labelled
- 1930's Great Depression
  - 29 states outlawed
- 1937 Marijuana Tax Act
  - Opposed by AMA
- 1950's Sentencing Laws
  - 1<sup>st</sup> offense = 2-10yrs, \$20,000
- 1960's Counterculture Movement
  - Widespread use among affluent
- 1970 Controlled Substances Act
  - Cannabis = Schedule I (Heroin)
  - Hemp/Marijuana treated same
- 1986 Anti-Drug Abuse Act
  - Mandatory Sentencing
- 1996 California legalizes medicinal

## Current State of the Law

- 2018 Farm Bill legalized hemp agriculture & sales
- 2019 Congress acts to block enforcement of federal law
  - House passed; pending in Senate
- Secure and Fair Enforcement Banking Act of 2019
  - Passed House w/bipartisan support: over 2/3 majority
  - Protects banks & other firms from prosecution

## Cannabis 101



*Cannabis*  
is a plant of the  
Cannabaceae  
family

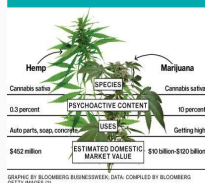
100+ biologically active  
compounds

Two Most Commonly Known:  
Delta-9 tetrahydrocannabinol (THC)  
& cannabidiol (CBD)

*THC = psychoactive*  
*CBD = non-psychoactive*

## Hemp v Marijuana

- Can grow to 20'
- .3% or less of THC
- **No** psychoactive properties
- Grows easily in most climates
- Requires little care
- Used to make rope, fabric, soaps, food



- Shorter, bush-like plant
- Between 5-35% THC
- Psychoactive properties
- Requires more care
- Susceptible to cross-pollination
- Used for medicinal & recreational purposes

## Hemp Products



**CBD from Hemp no longer considered a controlled substance under federal law**



amazon

- Cannabis plants/derivatives w/ no more than 0.3% THC;
- Hemp seed, protein powder, oil recognized by FDA as safe and can be legally marketed in food.

## The FDA



APPROVED ONLY 1 CANNABIS-DERIVED AND SYNTHETIC CANNABIS-RELATED DRUG PRODUCTS



ONLY AVAILABLE WITH PRESCRIPTION FROM LICENSED HEALTHCARE PROVIDER



NO OTHER FDA-APPROVED DRUG PRODUCTS THAT CONTAIN CBD

## FDA-Approved Drug Products

### • Epidiolex (CBD) oral solution

- Approved 6/26/2018
- **Indication:** treatment of seizures associated with 2 rare, severe forms of epilepsy (Lennox-Gastaut syndrome and Dravet syndrome)
- **Intended Population:** 2 years of age or older
- **Safety Risks:** included potential for liver injury
- First FDA-approved drug containing a purified drug substance derived from marijuana



## FDA-Approved Drug Products

- **Marinol & Syndros** (dronabinol, synthetic THC)
  - Approved May 1985 and in 2017 respectively
  - **Indication:** nausea/vomiting due to chemo; anorexia due to HIV
  - **Risks:** exacerbate mania, depression, schizophrenia.
- **Cesamet** (nabilone, synthetic THC)
  - Approved 1985
  - **Indication:** nausea/vomiting due to chemo
  - **Risks:** exacerbate mania, depression, schizophrenia.
- **Synthetic** → risks r/t lack of biological complexity



## The FDA & CBD



"CBD" products may be sold depending on marketed use; may not be labeled as a "drug," must meet the definition of "hemp," i.e. <= 0.3% THC



CBD products cannot be sold as "dietary supplements;" can be identified as an "herbal."



CBD cannot be added to food which is sold in interstate commerce. Hemp seeds, powder, etc., can be sold as a food product.



FDA position → such products have not been evaluated as to efficacy, proper dosage, potential drug interactions and other side effects/safety concerns.

## The FDA & CBD



Why does FDA prohibit marketing CBD as a "dietary" supplement?



CBD is an active ingredient in an FDA approved "drug" Epidiolex



CBD has been "authorized for investigation as a new drug."



By definition CBD cannot be a "dietary supplement."

## Cannabis Research: U.S.

- U.S. slow to approve drugs
- Influenced by:
  - Cultural & political bias
  - lobbyists & special interests: pharmaceutical, corporate agriculture, religious
- Regulatory obstacles to research
  - Only 1 authorized grower; very poor quality; not reflective of end market product
- International Research
  - U.S. funded; U.S. researchers



6/2019

## Cannabis Research in the U.S.

**Rigorous process that involves multiple federal agencies:**

**FDA** Provides a process through which researchers submit an Investigational New Drug (IND) application to the Center for Drug Evaluation and Research

**NIH (NIDA)**

Research-grade cannabis  
Oversees cultivation @ Univ.  
of Mississippi  
Controls for varying  
potencies & compositions



**DEA**

Investigator & protocol  
registrations;  
Schedule I-level security at  
research sites.

## Cannabis Research: Worldwide

- **Israel**
  - Raphael Mechoulam discovered endocannabinoid system in 1960's
  - 110 clinical trials underway in 2018
  - U.S. provides researchers & funds
- **Netherlands, Uruguay, Czech Republic, Canada & Spain**
- Research Findings:
  - THC influences programmed cell death in brain tumor cells without negatively impacting surrounding cells.
    - *J Clin Invest.* 2009 May 1; 119(5): 1359-1372. doi: 10.1172/JCI37948
  - CBD strengthens bones, accelerates healing of fractures.
    - *J Bone Miner Res.* 2015 Oct; 30(10):1905-13. doi: 10.1002/jbmr.2513.
  - CBD reduces severity of spinal cord injury induced sublesional cancellous bone loss.
    - *Euro J Pharm.* 2017 May3; 809:13-19. doi: 10.1016/j.ejphar.2017.05.011

Multiple studies demonstrate conclusive/substantive evidence that cannabinoids are effective in treating a variety of conditions and symptoms

## U.S. Cannabis Research: Looking Ahead



Over 75 clinical trial studies listed on clinicaltrials.gov as actively recruiting or active with "the" or "cbd" keyword search



Farm Bill 2018 reclassification—streamlines process for researchers to study hemp and derivatives (CBD)



FDA public hearing 5/31/2019 for marijuana stakeholders to solicit input relevant to regulatory strategy



FDA had an open docket for public to submit comments (7/2019)

## Tensions



- **Federal v State**
  - Federal rules apply when:
    - Preemption; Interstate commerce; Feds are paying
- Facility licensure/certification actions
  - Risk is small, but exists
- Provider licensure/scope of practice concerns
  - DEA
  - State Board

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graph LR; A[Other Considerations] --> B[Patients' rights under state law]; A --> C[Discrimination concerns]; A --> D[Ethical issues];
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Other Considerations

Patients' rights under state law

- Hospitals lack legal authority to deny rights under state law;
- Healthcare providers should not act as agent of police
  - Potential constitutional issues
  - Privacy concerns

Discrimination concerns


- Does denying patient right to use medical marijuana constitute discrimination?
  - Does documenting marijuana use label patient as "drug seeking"?
- Should patients be denied treatment because they use marijuana?
  - i.e. transplant

Ethical issues

- Patient autonomy
- Relief of pain & suffering
- Denial of preferred treatment in favor of pharmaceutical
  - Conflict of interest?
- Paternalism, beneficence & non-maleficance...who decides?

## Property or Contraband

- It depends → What does your state law say?
- Should healthcare providers “police” patients?
- If property → how to handle, store, return
- If contraband → how to dispose

A green icon of a balance scale, symbolizing justice or law, enclosed in a thin black rectangular frame.


# Patients & Cannabis

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*Should your institution have a formal policy on patient cannabis use?*






Considerations:

- Your **state's** laws and consequent patient perceptions of their rights to possess & use
- **Overarching Federal laws**
  - Example – the VA Health Administration DIRECTIVE 1315 (Dec. 2017)
  - VA providers are not permitted to refer veterans to state-approved medical marijuana programs
- Your **institution's** values & risk tolerance

A green silhouette of a person's head and shoulders, facing forward. A white stethoscope is draped around the neck, with the earpieces visible. The icon is centered within a white square frame that has a thin grey border.

## Patients & Cannabis

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-  Your current non-smoking policy
-  Current Security/contraband policy
-  Broaden existing policies on alcohol & cigarettes to include marijuana
-  Securing, storing & disposing of marijuana (medical or otherwise)
-  Communicating with patients regarding possession and use on premises

## Provider Perspectives

- Majority of doctors support legalization
  - over 1500 physicians across 12 specialties<sup>1</sup>
- A look at the numbers:
  - 69% say it helps with certain treatments & conditions;
  - 67% say it should be a medical option for patients;
  - 56% support making it legal nationwide;
  - 50% in states where it is illegal say it should be legal;
  - 52% in states considering legalization support it.

<sup>1</sup> <http://www.amlivestates.com/wp-content/uploads/downloads/2014/03/amlivestates-physicians-survey-2014.pdf>

## Physician Barriers

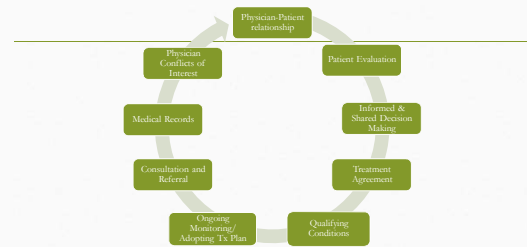
- DEA license actions
- Quasi-medical drug dealer reputation
- Illegal to prescribe a Schedule 1 drug
  - Prescribing constitutes aiding/abetting acquisition
- Lack of hard data re: efficacy for certain conditions
- Difficult to specify contents, dose and type
  - Evolving in states where legal
  - Safety concerns—contaminants, quality control
    - Less of a concern in states where regulated
  - Lack of clinical training

## Provider Perspectives

- In states where marijuana is legal, doctors can write a *recommendation* if patient meets criteria
- Physicians' 1st Amendment rights**
- Conant v Walters*<sup>2</sup>
  - Physicians have a right to recommend medical marijuana to patients
  - Within a bona fide doctor-patient relationship
  - But physician may not assist patients in obtaining medical marijuana (e.g. cannot prescribe it)



## Model Guidelines for Physicians



Federation of State Medical Boards, April, 2016 <https://www.fsmb.org/advocacy/advocacy-and-policy/medical-marijuana-guidelines>  
<https://www.fsmb.org/advocacy/advocacy-and-policy/medical-marijuana-guidelines> Accessed 05/25/2021

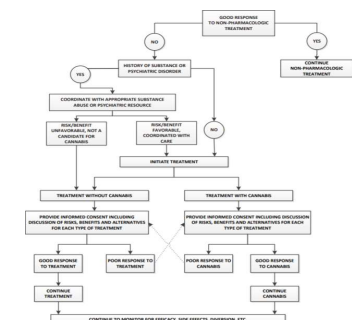
## State Medical Board



- Common Factors oversight agencies reference for possible abuse of marijuana recommendations:
  - Physician caseload (high caseload >3,521/year for GP per CDC)
  - Plant & Ounce Recommendations
  - Age Demographics of Patient Caseload
  - Evidence of Potential Violation of Medical Practice Act, state medical board regulations, statutes

Federation of State Medical Boards (April 2016) guidance

## Sample Decision Tree



Medical Board of CA, Guidelines for the Recommendation of Cannabis for Medical Purpose (April 2018)

## Recommendations for Physicians

- Establish physician-patient relationship
- Perform/document comprehensive Medical Exam
- Documented discussion of risks/benefits/alternatives
- Develop assessment/plan if history of substance abuse or mental health disorder
  - Ensure appropriate follow-up & monitoring of effects
- Document written treatment plan & agreement
  - Is informed consent process appropriate?
- Ensure regular follow-up
  - Establish procedures to proactively contact patients
- Document assessment of patient response
- Identify/avoid personal conflicts of interest
  - e.g. financial interest in dispensary

## Thank You

Please Complete Your Evaluation