



# Medical Marijuana, Hemp And the FDA

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# Conditions

- ▶ ALS
- ▶ Autism
- ▶ Cancer
- ▶ Chronic Inflammatory Demyelinating Polyneuropathy
- ▶ Crohn's Disease
- ▶ Dyskinetic and Spastic Movement Disorders
- ▶ Intractable Spasticity
- ▶ Epilepsy/Seizures
- ▶ Glaucoma
- ▶ Huntington's Disease
- ▶ Inflammatory Bowel Disease (Colitis and Crohn's)
- ▶ HIV/AIDS
- ▶ Intractable Seizures
- ▶ Multiple Sclerosis
- ▶ Neurodegenerative Diseases
- ▶ Neuropathies
- ▶ Opioid-Use Disorder
- ▶ Parkinson's Disease
- ▶ Post-Traumatic Stress Disorder (PTSD)
- ▶ Severe Chronic/Intractable Pain
- ▶ Sickle Cell Anemia
- ▶ Terminal Illness
- ▶ Ulcerative Colitis

# New forms of medicine

Dry Leaf or Plant - aka Flower



Ability for Dispensaries to purchase, from entities other than G/P, devices that administer mmj

Not yet - cannabis infused foods



# Federal vs. State Authority

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## FEDERAL AUTHORITY

- ❑ FDA - Federal Agency
- ❑ CSA – Federal Law
- ❑ DEA - Enforcer

## STATE AUTHORITY

- ❖ Pa. DOH – State Agency
- ❖ Medical Marijuana Act.35 P.S. § 10231.101 – 10231.2110
- ❖ 28 Pa.Code § 1131.1 et. seq.

# Federal Roadblocks to Research

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## Federal Food & Drug Administration (FDA)

- Research application review and approval



## Drug Enforcement Administration (DEA)

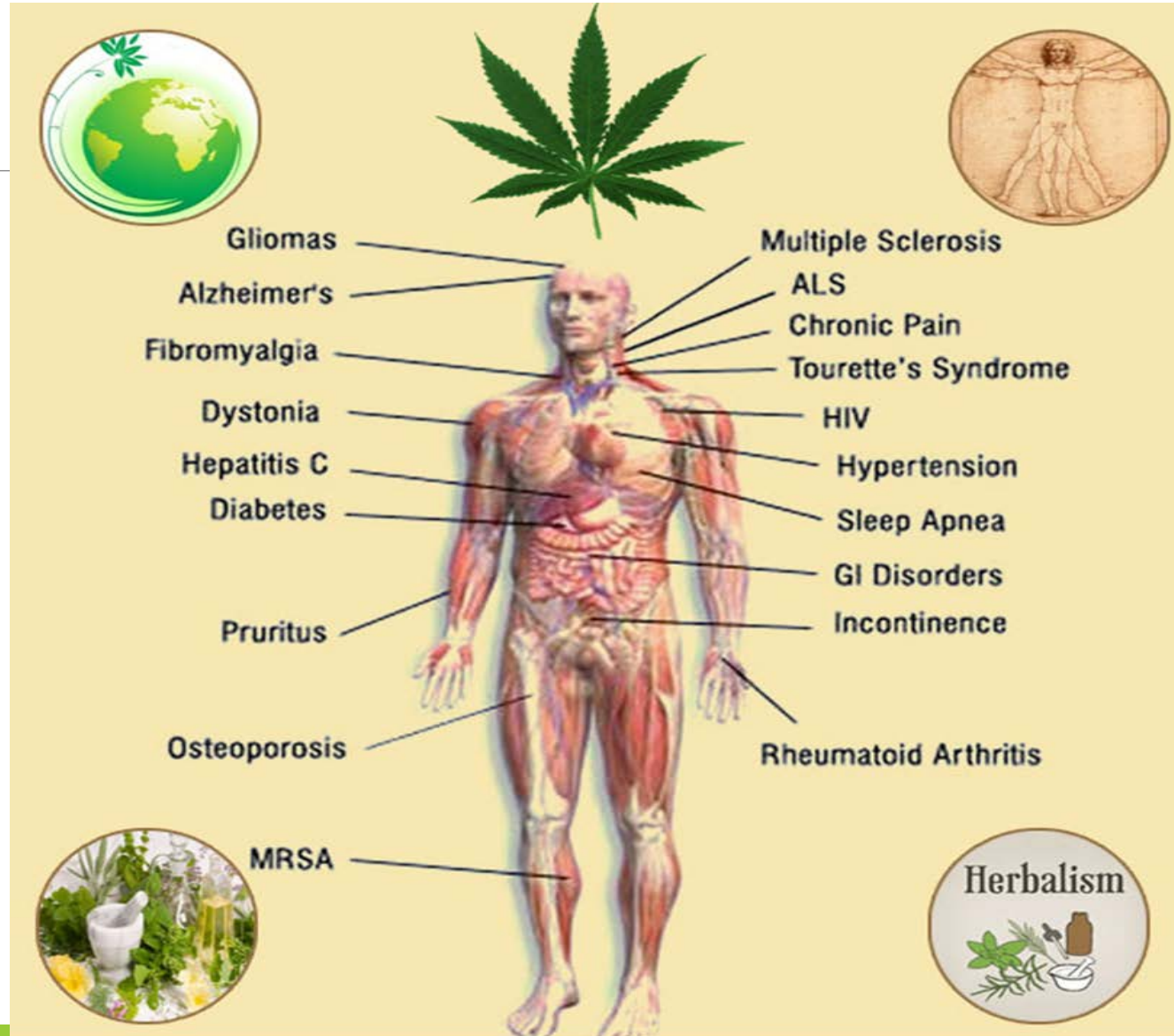
- Researcher registration application review
- Approval of additional research marijuana providers

## National Institute on Drug Abuse (NIDA)

- Responsible for overseeing the cultivation of marijuana for medical research



# Research



**Potential Therapeutic Uses of Medical Marijuana**

# Is it or isn't it?



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## FDA Says...

The FDA has not approved marijuana as a safe and effective drug for any indication. The agency has, however, approved one specific drug product that contains the purified substance cannabidiol, one of more than 80 active chemicals in marijuana, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

# FDA approves first MMJ drug for epilepsy



# Agricultural Improvements Act of 2018

## aka

# Farm Bill

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- < .3% THC
- Not just for pilot programs anymore
- Transport a/c State Lines
- Removes restrictions on sale, transport, and possession
- PA Dept. of Agriculture & USDA
- Research – Still Important Component

# Medical Marijuana & the Opioid Epidemic

Original Investigation

## Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010

Marcus A. Bachhuber, MD; Brendan Saloner, PhD; Chinazo O. Cunningham, MD, MS; Colleen L. Barry, PhD, MPP

 Invited Commentary  
page 1673

**IMPORTANCE** Opioid analgesic overdose mortality continues to rise in the United States, driven by increases in prescribing for chronic pain. Because chronic pain is a major indication for medical cannabis, laws that establish access to medical cannabis may change overdose mortality related to opioid analgesics in states that have enacted them.

**OBJECTIVE** To determine the association between the presence of state medical cannabis laws and opioid analgesic overdose mortality.

**DESIGN, SETTING, AND PARTICIPANTS** A time-series analysis was conducted of medical cannabis laws and state-level death certificate data in the United States from 1999 to 2010; all 50 states were included.

**EXPOSURES** Presence of a law establishing a medical cannabis program in the state.

**MAIN OUTCOMES AND MEASURES** Age-adjusted opioid analgesic overdose death rate per 100 000 population in each state. Regression models were developed including state and year fixed effects, the presence of 3 different policies regarding opioid analgesics, and the state-specific unemployment rate.

**RESULTS** Three states (California, Oregon, and Washington) had medical cannabis laws effective prior to 1999. Ten states (Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont) enacted medical cannabis laws between 1999 and 2010. States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI, -37.5% to -9.5%;  $P = .003$ ) compared with states without medical cannabis laws. Examination of the association between medical cannabis laws and opioid analgesic overdose mortality in each year after implementation of the law showed that such laws were associated with a lower rate of overdose mortality that generally strengthened over time: year 1 (-19.9%; 95% CI, -30.6% to -7.7%;  $P = .002$ ), year 2 (-25.2%; 95% CI, -40.6% to -5.9%;  $P = .01$ ), year 3 (-23.6%; 95% CI, -41.1% to -1.0%;  $P = .04$ ), year 4 (-20.2%; 95% CI, -33.6% to -4.0%;  $P = .02$ ), year 5 (-33.7%; 95% CI, -50.9% to -10.4%;  $P = .008$ ), and year 6 (-33.3%; 95% CI, -44.7% to -19.6%;  $P < .001$ ). In secondary analyses, the findings remained similar.

**CONCLUSIONS AND RELEVANCE** Medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates. Further investigation is required to determine how medical cannabis laws may interact with policies aimed at preventing opioid analgesic overdose.

October 2014 Study Published in *JAMA Internal Medicine*

**60% of all opioid overdoses** were among patients having legitimate prescriptions from a single provider

Found states with medical cannabis laws had a **24.8% lower mean annual opioid overdose mortality rate** compared with states without medical cannabis laws.

Mortality rates continued to **decline each year** after the implementation of the law.

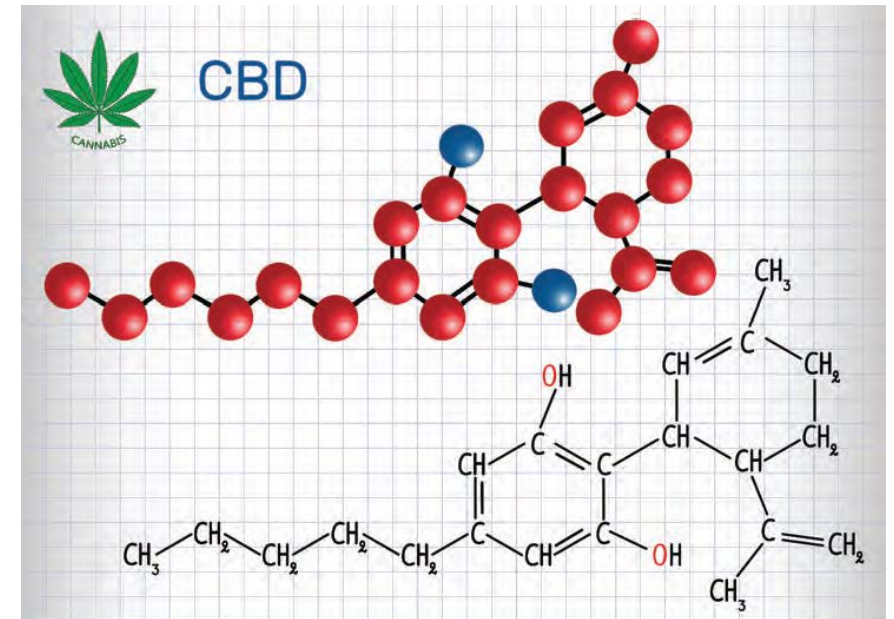
# Medical Marijuana & the Opioid Epidemic

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*Journal of Neuroscience Study – CBD and Opioids*

By Dr. Yasmin L. Hurd - practitioner at the Friedman Brain Institute of Mount Sinai Medical Health Systems

CBD has a “protracted neurobiological effect to counter long-lasting neuroadaptations that specifically govern conditioned cue-induced drug-seeking behavior and relapse.”



# Medical Marijuana & the Opioid Epidemic

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## Medicaid/Medicare Patient Research



Results of two five-year studies published in April 2018 in the *JAMA Internal Medicine Journal*

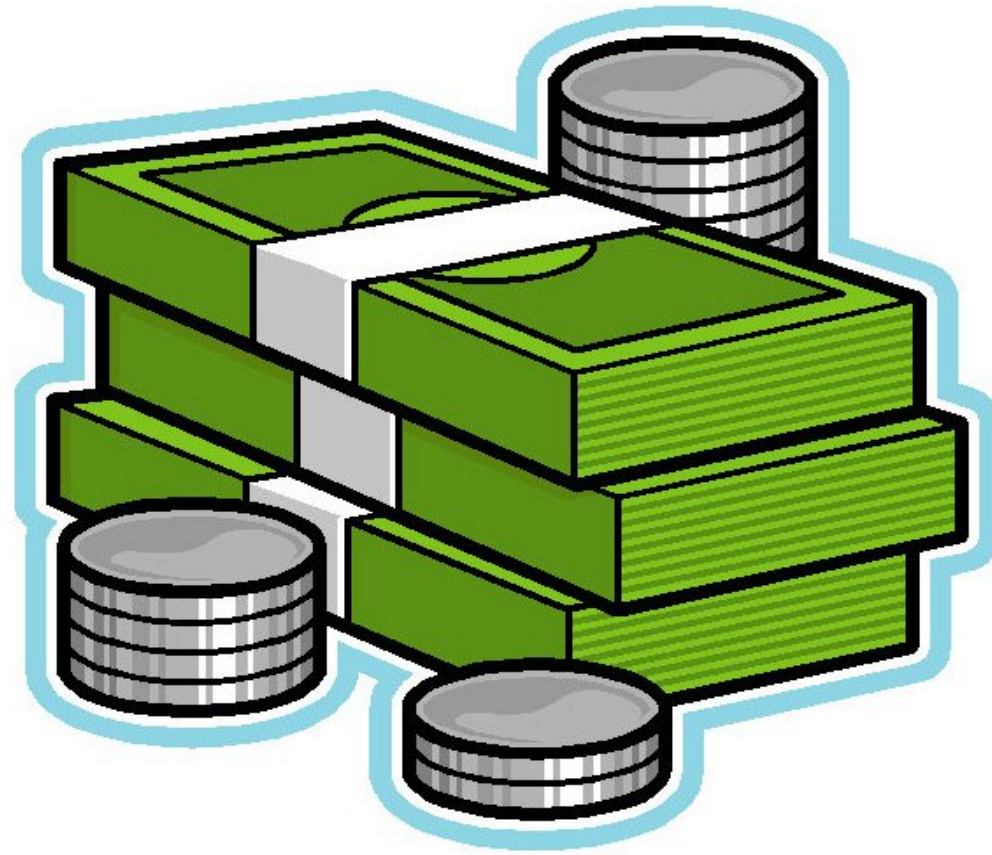
**1<sup>st</sup> Study** - Researchers found that states with medical marijuana laws had about **6 % fewer opioid prescriptions** among Medicaid patients compared with states without such laws.

**2<sup>nd</sup> Study** - Looked at Medicare Part D patients, found a **drop of 8.5% in opioid prescriptions** in medical marijuana states.

# Other Key Developments 2018 -2019

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- Rohrabacher –  
Blumenauer
- Safe Banking
- Farm Bill



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