

*Presentation AH #1*

# The Argument for FDA-Approved CBD Drug Studies in Idaho

Governor's Office of Drug Policy

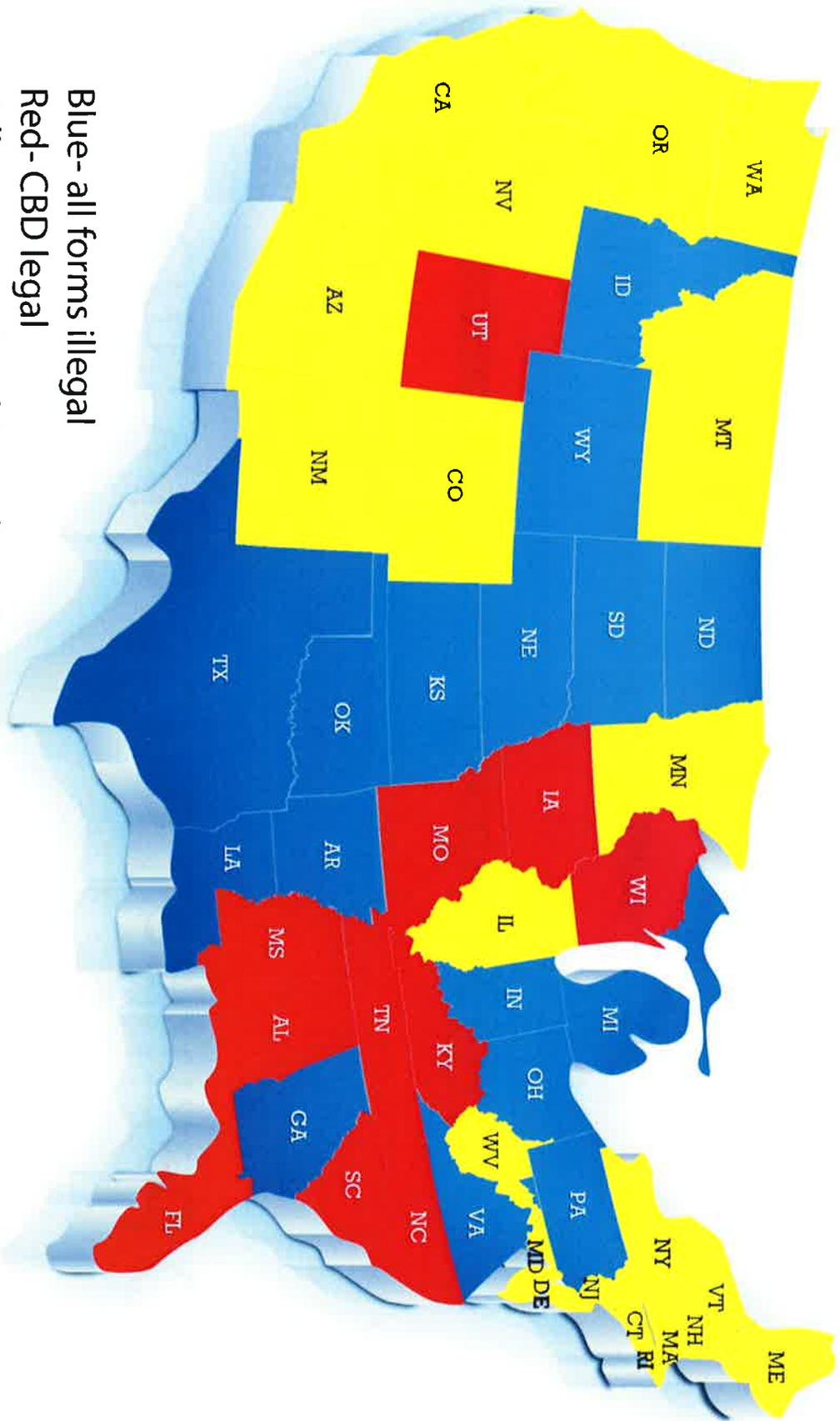


## Cannabidiol Oil (CBD)

- One of many components of cannabis plant
- No psychoactive effects
- May show some benefit for intractable seizures
- Administered orally in oil form

# Marijuana States

Blue- all forms illegal  
Red- CBD legal  
Yellow- recreational & 'medicinal'





# Concerns with State Legalized CBD

- Schedule I drug
- Not deemed safe and effective by FDA
- Very limited unbiased studies
- Accessed through “budtenders”

- Rely on advice of “budtenders” regarding strain and dosage
- Product purity concerns
- Unregulated extraction process allows for unknown amounts of THC which can cause seizures
- Contaminants such as mold, fungi, E Coli, other toxins (New Haven University)
- May cause negative drug interactions



“Buddender Derek Richards, left, helps Carson Jones of Lincoln, Neb., while Jones’ brother Jack, also of Lincoln, finishes his order and security guard Dirk Smith, back, signals to buddenders how many customers are waiting inside the store. KAI-HUEI YAU — Tri-City Herald”

Daniel Friedman, M.D.,  
epileptologist and a clinical  
neurophysiologist at the NYU  
Comprehensive Epilepsy Center  
opined, “More studies are needed  
to understand the potentially  
complex interactions between  
CBD and other drugs but in the  
meantime, frequent monitoring  
of drug levels is warranted in  
children taking CBD-containing  
products, including medicinal  
cannabis” .

American Epilepsy  
Society (2014) New  
reports of Epidiolex  
efficacy and safety  
presented at the  
American Epilepsy  
Society Annual  
Meeting. Retrieved  
from:

<http://www.newswise.com/articles/view/626892/>

# Research Reported December 2014

## American Epilepsy Society

- After 3 months, 39% of parents reported CBD reduced seizures by more than 50%
- 3 of 5 patients showed decreased seizure frequency
- 4% Experienced more seizures
- 1 of 5 showed increased frequency by 5%

Devinsky, O., Sullivan, J., Friedman, E. T., March, E., Laux, L., Hedlund, J., ... & Cilio, M. (2014). Efficacy and safety of Epidiolex (cannabidiol) in children and young adults with treatment-resistant epilepsy: Initial data from an expanded access program, 3.303, American Epilepsy Society Annual Meeting.

[www.aesnet.org](http://www.aesnet.org)

Geffrey, A., Pollack, S., Paolini, J., Bruno, P., & Thiele, E. (2014). Cannabidiol (CBD) treatment for refractory epilepsy in tuberous sclerosis complex (TSC). 2.427, American Epilepsy Society Annual Meeting. [www.aesnet.org](http://www.aesnet.org)

\*Both studies lack appropriate research rigor for conclusive results.

# Questions that Arise

- How can a state pass a law in clear violation of federal drug laws?
- How does a state prevent their conflicting drug laws from negatively impacting neighboring states?
- If a municipality does not want legal pot in their city, can they opt out of the state law?
- What does an employer do when employees with “medical” marijuana cards have a positive drug test?



# FDA Process

FDA Process in place for over 100 years

Rigorous, scientific process

Dose

Efficacy

Condition

Clean and Pure

System for Recall

Drug Interactions

# Pharmaceutical Companies

## GW Pharmaceuticals – Epidiolex

Dravet and LGS

Second phase of three phase clinical trial

Expanded Access Programs

New York, California,  
Iowa, Minnesota,  
Pennsylvania, North  
Carolina, Maryland

## Insys Therapeutics

January 2015 – pharmacokinetic study

March/April 2015 – Phase 3 Clinical Trials on Dravet and LGS



# Research Reported

- Promising signals of efficacy and safety on 58 treatment-resistant children and young adults
- Approximately 410 children and young adults now authorized for treatment with Epidiolex®
- 20 expanded access Investigational New Drug Applications (INDs)
- Approximately 200 children now receiving Epidiolex® treatment under expanded access INDs at 11 clinical sites in the U.S.

## FDA Approved Medications

## CBD/"Medical" Marijuana

V  
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Pure

May Not Be Pure

Safe

Not Proven Safe

Effective

No Evidence of Effectiveness

Tested by Randomized Controlled Trials

Not Tested by Randomized Controlled Trials

Capacity for Emergency Recall

No Capacity for Emergency Recall

Physician Prescription Required

Physician Prescription Not Required

Sold in Pharmacies

Sold in Marijuana Dispensaries

Dispensed by Licensed Pharmacists

Dispensed by "Budtenders"



## Concerns with FDA-Approved CBD Studies

“Not every child is eligible to receive medication.”

“I don’t want my child to receive the placebo during the study.”

“I don’t want to be limited to one formula of CBD.”

“It’ll take too long.”

“Pharmaceutical drugs are too expensive, and marijuana is cheap.”

## If CBD Legalized in Idaho

- Idaho will be in violation of Federal law
  - **Nominee for new Attorney General**
- The medical community is bypassed because it is not an FDA-approved medication
- The safety and efficacy of the product will be unknown
- The purity of the product will be unknown

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- Patients will have to rely on “buddtenders” to advise regarding dosing the drug
  - Negative drug interactions are unknown
  - Possible side effects are unknown
  - Idaho will be forced to expand government to administer and fund a CBD program

## FDA approved studies of CBD in Idaho will:

- Provide a method for sick Idahoans to access safe, effective medication

- Adhere to the FDA process instead of legislating medicine and expanding state government

- Allow for the compassionate care of Idahoans while adhering to Federal drug laws
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## Concerns from Utah

- “The law provides a false hope for families.”
- “Colorado can’t meet the supply of all that want to participate.”
- “As a state, we are recommending something we don’t know enough about.”
- “Who is liable when something goes wrong?”

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