

# Marijuana Legalization: from pipe-dream to panacea

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# Federal Guidelines

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Controlled Substances Act of 1970

The Cole Memo

2018 United States Farm Bill

CARERS Act

# Federal Guidelines

## Controlled Substances Act of 1970

- Attempt to consolidate numerous pre-existing laws & regulations
- Foundation of the federal “war on drugs”
- Defines Drug Schedules (I-V)
- DEA and FDA responsible for adding/removing substances

# Federal Guidelines

## Schedule I:

- High potential for abuse
- No currently accepted medical use in treatment in the United States
- Lack of accepted safety for use of the drug or substance under medical supervision

It is this third facet, in particular, which has led to attempts to re- or de-Schedule marijuana since passage of the CSA.

# Federal Guidelines

## The Cole Memo

- Aug 29, 2013 – US Deputy AG James M. Cole under presidency of Barack Obama

# Federal Guidelines

## The Cole Memo

De-emphasized federal marijuana prohibition except for

- Distribution to minors
- Revenue going to gangs, cartels, criminal enterprises
- Diversion from states where it is legal to those where it is not
- Use as a cover for other trafficking or illegal activity
- Violence and/or use of firearms
- Drugged driving and other public health consequences
- Growing of marijuana on public lands
- Marijuana use or possession on federal property

# Federal Guidelines

## The Cole Memo

- Rescinded Jan 2018 by AG Jeff Sessions under presidency of Donald Trump

# Federal Guidelines

## 2018 United States Farm Bill

- Incorporated some aspects of the “Hemp Farming Act of 2018”
- Hemp = cannabis with <0.3% THC
- Removing Hemp from Schedule I
- Redefine as an ordinary agricultural commodity

# Federal Guidelines

## Compassionate Access, Research Expansion, and Respect States (CAREERS) Act

- Amend federal law to allow states to set their own medical marijuana policies
- Allow physicians within the VA to prescribe medical marijuana
- Does NOT legalize marijuana
- Broad bipartisan support, but not yet passed or signed

## New York State Guidelines

### Compassionate Care Act

“Relates to the medical use of marihuana; legalizes the possession, manufacture, use, delivery, transport or administration of medical marihuana by a designated caregiver for a certified medical use; prescribes procedures for such possession, acquisition, etc. including certification of patients by their practitioner, and that, in the practitioner's professional judgment, the patient would receive therapeutic or palliative benefit from use of medical marihuana.”

# New York State Guidelines

## Compassionate Care Act

Very tight controls of MM

- Certifying of providers
- Certifying of patients
- Location of providers, manufacturers, distributors
  - Cannot be at same site
  - Cannot be within certain distance from school, church, synagogue, or place of worship
- Licensing manufacturers/distributors
- Manufacturing requirements

# New York State Guidelines

## Compassionate Care Act

Very tight controls of MM

- Approved formulations
- Routes of administrations
- Quality assurance
  - Saving samples from each lot
  - Consistency of concentrations of cannabinoids
- Price setting
- Marketing regulations
- Packaging requirements

# New York State Guidelines

## Compassionate Care Act

Very tight controls of MM

- PMP Reporting
- Where products can be used
- How products can be used (eg. No smoking)
- Reporting requirements
  - Deaths
  - Adverse Effects
- Disposal of MM products by patients vs organizations

# NYS Indications for Medical Marijuana

- ◆Cancer
- ◆HIV/AIDS
- ◆ALS
- ◆Parkinson's
- ◆Multiple Sclerosis
- ◆Spinal cord injury with intractable spasticity
- ◆Epilepsy
- ◆Inflammatory Bowel Disease
- ◆Neuropathies\*
- ◆Huntington's Disease
- ◆Severe debilitating pain\*
- ◆PTSD\*
- ◆Pain, alternative to opioids\*
- ◆Substance Use Disorder\*

# I know what you're thinking...

You're NOT going to talk about all the other indications?

No. I'm not.



Sorta.

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# Underlying Mechanisms

## **Appetite Stimulant**

- ◆ Cancer, HIV/AIDS

## **Anti-inflammatory**

- ◆ Inflammatory Bowel Disease, Multiple Sclerosis,
- ◆ Pain, alternative to opioids\*

## **Antispasmodic & Neuromodulator**

- ◆ ALS, Parkinson's, Multiple Sclerosis, Spinal cord injury with intractable spasticity, Epilepsy, Huntington's Disease
- ◆ Neuropathies\*

# Pain, alternative to opioids

Definitive answers are still emerging, but there seems to be growing consensus that medical cannabis

- MAY be an effective alternative to opioids for acute pain
- MAY be an effective alternative to opioids for chronic pain
- MAY help some chronic pain patients decrease or cease opioid use

Remember, this is not addressing those with opioid use disorder. The majority of patients in the studies showing benefit were patients with chronic pain who did not show clinical signs of addiction.

Side effect profile for co-administration of marijuana and opioids is largely unknown.

# Neuropathies

Limited but convincing evidence of clinically significant effect.

Not all Neuropathies are made equal, and each study tends to focus on a particular one:

- HIV-associated sensory neuropathy
- Diabetic Neuropathy
- Chemotherapy-induced peripheral neuropathy

Mechanism may be related to CB1 receptors in nociceptive terminals of PNS and CB2 receptors on immune cells (activation of which decreases release of nociceptive agents).

# Then there are the others...

Severe debilitating pain\*

PTSD\*

Substance Use Disorder\*

# Severe debilitating pain

Let me be clear, this CAN BE and IS a valid indication. **BUT...**

Must be very clearly defined, and is open to wide-ranging interpretation.

“Indication creep”

Need clarification on where cannabinoids fall in the pain management algorithm.

# PTSD

Mechanistic plausibility for beneficial effect

Inadequate evidence to support beneficial effect in PTSD

Copious evidence of risk for psychosis & SUD

Moderate evidence of risk for depression & anxiety

Associated with worse treatment outcomes in naturalistic studies, along with reinforcement of maladaptive coping styles common in PTSD.

# Substance Use Disorder

# Cannabis Taxation and Regulation Act

Likely to pass this year and be implemented either late this year or in 2020.

Legalization of marijuana and cannabis products for persons age 21 and over, with numerous caveats and regulations.

Essentially, legalized recreational cannabis.



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