

# Grandma Wants Special Brownies?

## Preparing for Medical Marijuana and Cannabidiol Products

### *Legal Implications and Regulatory Compliance*



“Mother, are you sure your marijuana use is purely medicinal?”

# The “Science” of Marijuana

- **Cannabis Sativa** is the species of the plant.
- **Cannabinoids**
  - There are over 100 “cannabinoids” or classes of chemical compounds found in Cannabis Sativa.  
Most talked about:
    - **Tetrahydrocannabinol (THC)** – primarily psychoactive/hallucinogenic cannabinoid
    - **Cannabidiol (CBD)** – other major cannabinoid; analgesic; anti-inflammatory and anti-anxiety properties without the psychoactive effects.

# Differentiating Cannabis, Hemp, and CBD

- **Cannabis:** Cannabis sativa, is a genus of flowering plants of the family Cannabaceae, the hemp family, that has a tough fiber and is often separated into a tall loosely branched species (C. sativa) and a low-growing densely branched species (C. indica). The term “Cannabis” refers to the whole plant.

# Differentiating Cannabis, Hemp, and CBD (Con't)

- **Hemp:** Hemp is the non-psychoactive, genetically distinct variety of the plant *Cannabis sativa*. Hemp is low in tetrahydrocannabinol (THC), which is the principal psychoactive constituent of cannabis. Hemp has no use as a recreational drug and is typically grown for its fiber, seed, and oil.

# Differentiating Cannabis, Hemp, and CBD (Con't)

- **Cannabidiol (CBD):** CBD is a naturally occurring, non-intoxicating cannabinoid constituent of cannabis. After THC, CBD is the second most prevalent chemical constituent in cannabis. Proponents of CBD claim that it can be used to treat ailments such as inflammation, pain, acne, anxiety, insomnia, depression, and post-traumatic stress.

# Legalization of Hemp

## 2014 Farm Bill

- Gave discretion to states to adopt regulations governing hemp activity
  - Cultivation allowed
    - By institutions of higher education or state departments of agriculture (and their designees)
    - For research purposes (which some argue includes market research)
    - As part of an “agriculture pilot program” or other agricultural or academic research
- Strictly defines hemp to include any part of the cannabis plant, whether growing or not, with a delta -9 THC concentration of not more than 0.3% on a dry weight basis
- 40 U.S. states implemented legalization pursuant to the 2014 Farm Bill (including N.D. in 2017)
- Hemp progress vary from state to state

# Legalization of Hemp (Con't)

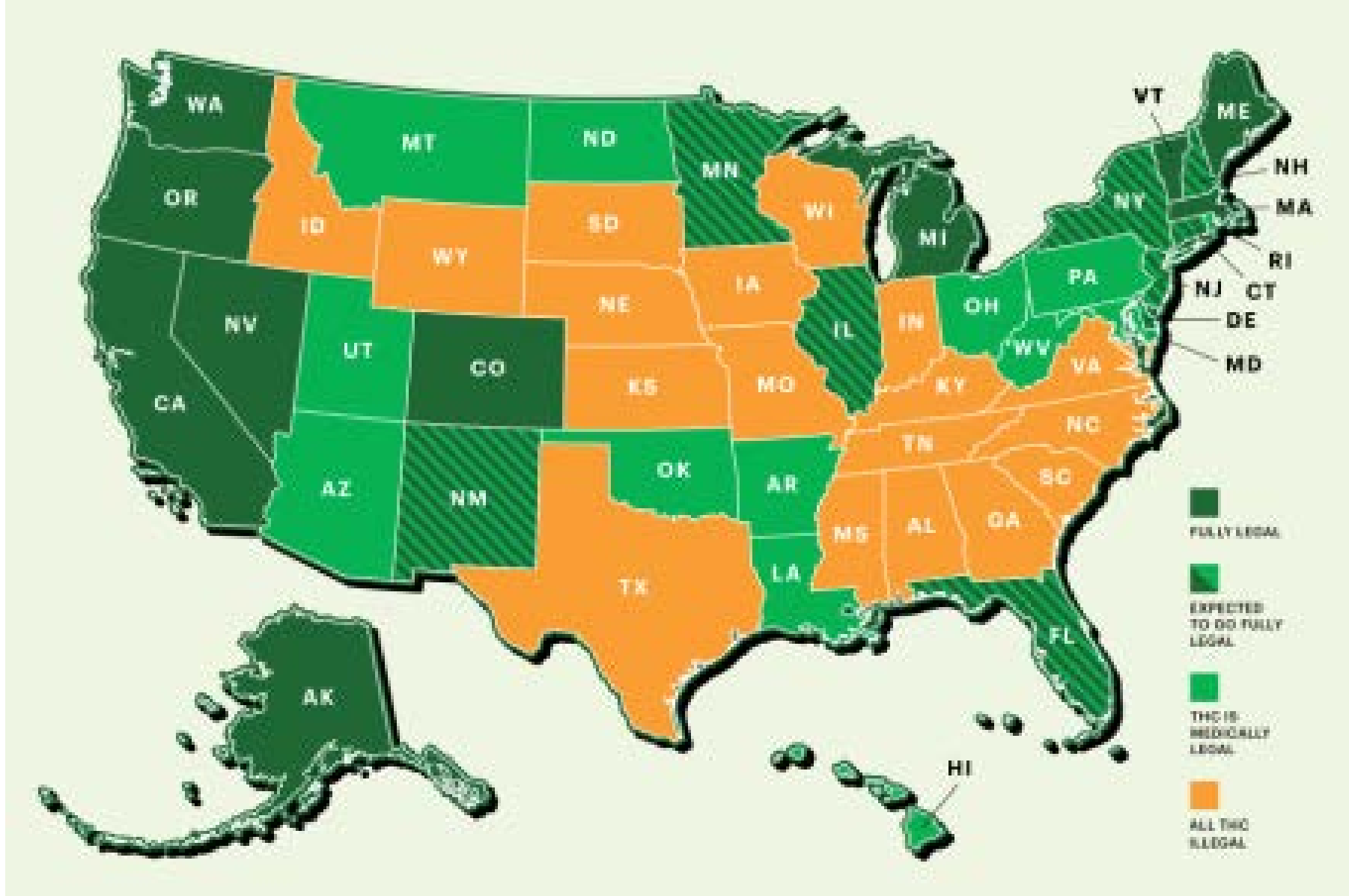
## 2018 Farm Bill

- Expanded the definition of “industrial hemp” from the definition of the 2014 Farm Bill, removing the qualifier “industrial” and including derivatives, extracts, and cannabinoids;
- Explicitly removed hemp from the CSA;
- Removed the requirement that hemp only be grown as part of a pilot program designed to study aspects of the hemp industry;
- Explicitly permits interstate transportation of hemp.



# Current Regulatory Framework - States

- 33 states (and DC, Guam, and Puerto Rico) have legal medical cannabis
- 10 states (and DC) have legal adult use cannabis
- Programs vary widely – issues include residency, vertical integration, taxes, number of licenses, conviction expungement



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# Public Attitudes Toward Medical Marijuana

- A 2014 CBS News poll found that 86% of Americans believe doctors should be able to prescribe marijuana to their patients.
- The federal government continues to classify the plant among the most “dangerous” substances alongside heroine and LSD with “no currently accepted medical use.”

# THE PROBLEM – U.S. Federal Law

- In the United States, federal prohibitions outlawing cannabis' recreational, industrial, and therapeutic use were first imposed by Congress under the “Marihuana Tax Act of 1937” and then later reaffirmed by federal lawmakers' decision to classify marijuana – as well as all of the plant's organic compounds (known as Cannabinoids) – as a Schedule I substance under the Controlled Substances Act of 1970.

# U.S. Federal Law

- Controlled Substances Act classification, asserts that cannabis is equally as dangerous to the public as is heroin, defines cannabis and its distinct cannabinoids as possessing “a high potential for abuse,...no currently acceptable medical use,...[and] a lack of accepted safety for the use of the drug under medical supervision.” (By contrast, cocaine and methamphetamine – which remain illicit for recreational use but may be consumed under a doctor’s supervision – are classified as Schedule II drugs; examples of Schedule III and IV substances include anabolic steroids and valium respectively, while codeine-containing analgesics are referred by law as Schedule V drugs, the federal government’s most lenient classification.)

# Federal Prohibition of Cannabis

- Currently, cannabis is a Schedule I drug under the CSA. Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
- It is therefore unlawful to “manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense,” cannabis.

# Federal Prohibition of Cannabis (Con't)

- Other prohibited acts under federal law:
  - Conspiring to violate the CSA
  - Money-laundering
  - Racketeering
- Risks for companies and their employees
- Penalties for violations of the CSA
  - Imprisonment
  - Fines
  - Forfeiture

# Federal Enforcement

- Still a Schedule I drug under Controlled Substances Act in 2018
- In 2009, the Department of Justice issued a memorandum (**The Cole Memorandum**):
  - Confirms that state laws have no effect on marijuana's illegal status under federal law
  - Directs U.S. attorneys to utilize their resources prudently, and to use discretion before prosecuting those using medical marijuana in compliance with their state's laws.



# Federal Enforcement (Con't)

- U.S. Attorney Eric Holder had commented that state legalized medical marijuana statutes would be a low priority to prosecute at the federal level.
- Cole Memo was the current enforcement position of the DOJ **UNTIL** U.S. Attorney General Jeff Sessions changes **EVERYTHING** with his “Marijuana Enforcement” Memo of January 4, 2018:

“These statutes reflect Congress’s determination that marijuana is a dangerous drug and that marijuana activity is a serious crime.”

# Attorney General Barr on Cannabis

- Testimony before the Senate Judiciary Committee hearing on January 15, 2019:
  - “To the extent that people are complying with state laws with distribution and production and so forth [of cannabis], I don’t intend to go after those.”
  - Barr said that he does not intend to step up efforts to crack down on legal states.
  - “I’m not going to go after companies that have relied on the Cole Memorandum,” Barr told the Committee.
  - Rescinding the Cole Memo was not the right decision – “My approach to this would be not to upset settled expectations and the reliance interests that have arisen as a result of the Cole Memoranda. Investments have been made. So, there’s been a reliance on it. I don’t think it’s appropriate to upset those interests.”

# Federal Legislative Update

- The Joyce Amendment (f/k/a “Rohrabacher – Blumenauer” and “Rohrabacher – Farr”)
  - Prohibits the DOJ from using federal funds to interfere with the implementation of state medical cannabis laws.
  - Protection from prosecution extends to medical cannabis patients, growers and distributors that are in compliance with state laws (9<sup>th</sup> Circuit).
  - First introduced in 2001 and became law in 2014 after six failed attempts at passage.
  - Included in federal spending bills since and is part of current spending bill set to expire on September 30, 2019.
  - Similar attempts to protect adult use cannabis have failed (McClintock-Polis).

# Federal Legislative Update (Con't)

- The STATES Act (proposed):
  - Would remove state-lawful cannabis from the purview of the CSA, such that activities lawfully conducted pursuant to a state's cannabis regulations, and proceeds generated therefrom, would not be a violation of the CSA or related federal prohibitions on cannabis.
  - Would allow tax deductions and credits for cannabis businesses currently prohibited under federal law (IRC Sec. 280E).
  - Would allow financial institutions to transact with cannabis businesses without the threat of criminal prosecution.
  - President Trump will “probably” support the bill if passed and sent to his desk for signature – Senate resistance remains. (206 cosponsors in the House and 30 in the Senate as of June 5, 2019.)

# Current Regulatory Framework - Federal

- Schedule I drug under Controlled Substances Act – as dangerous as heroin and LSD – no known medical benefit
- Cole Memo – rescinded but Barr supports
- Joyce Amendment prevents medical cannabis enforcement
- Farm Bill of 2018 – legalized industrial hemp – USDA/FDA
- Potential STATES Act
- 66% now favor full legalization including majority of Republicans.

# Federal Enforcement under Trump

- Trump Position (**confirmed?**)
  - **April 13, 2018 – “Trump agrees to leave state-legal marijuana programs alone,” USA Today:**

Republican Sen. Cory Gardner announced he'd received assurances from the President that federal agents would leave alone states like Colorado that have legalized recreational cannabis.

# Current Landscape

- April 20, 2018
  - Trevor Hughes, “Industry Growing Like Weeds,” USA Today
    - \$25 Billion projected in 2025
    - \$8.3 Billion sold in 2017
    - \$11.7 Billion in sales expected in 2018

# Where's the FDA?

- Douglas C. Throckmorton, MD, Deputy Center Director for Regulatory Programs, CDER, FDA
  - “We will work as hard as we can to support new marijuana drugs that are safe, effective, and manufactured to a high quality.”
  - “FDA is committed to making the drug development process as efficient as possible and looking for ways to speed the availability of new drugs from marijuana for the American public.”
  - Regulation of Cannabis in FDA-Regulated Products, July 19, 2017.



# Where's the FDA? (Con't)

- Drug Enforcement Administration (DEA)
  - August 2016: DEA declines to reschedule marijuana. It remains a Schedule I controlled substance.
- Food and Drug Administration (FDA)
  - In 2016, FDA completed a review of published literature and did **NOT** recommend that marijuana come off of its Schedule I designation.

# Where's the FDA? (Con't)

- FDA approved drugs (synthetic THC and Epidiolex):
  - Marinol (dronabinol) (1985): treats nausea from cancer chemotherapy.
  - Cesamet (nabilone) (2006): treats nausea and neuropathic pain
  - Syndros (dronabinol) (2017): treats nausea and vomiting from chemotherapy, and helps treat weight loss
  - Epidiolex (cannabidiol) (June 25, 2018): unprecedented FDA approval of this oral seizure medication containing a **natural**, purified substance from marijuana.

# FDA Regulation of CBD

- Farm Bill recognized authority of FDA to promulgate rules and regulations related to products containing cannabis or cannabis derived compounds.
- FDA approved CBD in Epidiolex in 2018 and now recognizes CBD to be an active pharmaceutical ingredient (“API”).
- FDA’s position: Companies may not sell, distribute, or market products containing CBD in interstate commerce, or market CBD products as being dietary supplements or having any therapeutic benefit.
- Public hearing was held by the FDA on regulation of CBD in May of 2019.
- Hearing covered topics including (1) health and safety, (2) manufacturing and product quality, and (3) marketing / labeling / sales.

# FDA Regulation of CBD (Con't)

- Evaluation Considerations
  - Safe or effective to treat any particular disease
  - What proper dosage is
  - Interaction with other foods or drugs
  - Dangerous side effects or other safety concerns
  - Current CBD products with misleading or false claims
  - Warnings issued to companies claiming their products prevent, treat, diagnose, or cure serious diseases such as cancer, Alzheimer's disease, psychiatric disorders, and diabetes.
  - FDA has tested certain CBD products to discover they contain no levels of CBD
  - Reports of CBD containing contaminants (e.g., pesticides, and heavy metals)

# FDA Regulation of CBD (Con't)

- Evaluating Regulatory Framework
  - Continues to believe drug approval process is best practice (This will take years)
  - Currently illegal to market CBD as a food or dietary supplement
  - FDA is evaluating how to update its regulations as well as evaluating new potential legislation
  - New legislation is being evaluated to classify CBD according to defined concentration levels, whereby CBD would be classified as a dietary supplement up to a defined concentration above which it would be considered a pharmaceutical drug. This is how fish oil has been regulated.
  - Currently neither THC or CBD has been approved by the FDA

# FDA Regulation of CBD (Con't)

- Most CBD products are illegal but only if someone is checking. [Most illegal activity is from companies distributing products versus individuals possessing the product.]
  - Low quality and tainted products are flooding the market.
  - Could contain more than .3% THC if extracted incorrectly.
  - FDA has prohibited the sale of CBD in any unapproved health products, dietary supplements or food – which literally means everything except for the drug Epidiolex.
  - FDA can go after companies improperly selling or marketing products that make health claims about CBD especially products in interstate trade.
  - FDA has limited staff – only two warning letters have been issued. It has hinted at pursuing broader enforcement with federal and state partners if CBD craze continues.

# FDA / CBD Blind Spot

- Can sell as much CBD as stores or retailers want as long as it doesn't make any health claims about the products put in food nor add it to dietary supplements.

# Status of CBD Under North Dakota Law

- Definition of Schedule I controlled substance includes marijuana (excludes medical marijuana) but was amended in 2019 to exclude hemp.
  - Hemp under North Dakota law is the cannabis sativa plant or any part of the plant whether growing or not with a THC concentration of not more than .3% on a dry weight basis. N.D. Cent. Code § 4.1-18.1-01.
- In North Dakota a Schedule V controlled substance includes an FDA approved cannabidiol drug product in finished dosage formulation which has no more than .1% weight for weight residual THC.
  - Still requires willfulness to possess (intentional, knowingly, or recklessly) without a valid prescription is a Class A misdemeanor. N.D. Cent. Code § 19-03.1-23 Subd. 7 a. and b.



# CBD Recap

- Illegal under FDA regulations for companies to improperly sell or market CBD in unapproved health products, dietary supplements, or food – which is basically everything except the drug Epidiolex.
- Illegal to have CBD in North Dakota that is an FDA approved drug product in finished dosage formulation and more than .1% THC without a valid prescription. N.D. Cent. Code § 19-03.1-13 Subd. 5(c) and 19-03.1-23.
- However hemp derived CBD with no more than .3% THC is removed from the Controlled Substances Act under North Dakota law and federal law.

# Hemposium aims to answer questions about growing CBD hemp



Jay Alsop, one of the partners in CBD hemp-grower Plantology, stands in a sea of hemp plants in the company's field in Leonard, N.D. A Hemposium is planned Thursday, Aug. 29 at the Leonard Country Club. Plantology Photo/ Special to The Forum

# Medical Marijuana

- **The Nursing Home Dilemma:**
  - Any patient using medical marijuana breaks federal law.
  - Residents/patients are increasingly using medical marijuana to ease their pain.
  - But many health care facilities in which they reside or will reside receive federal funding through Medicare or Medicaid.
  - Many facility administrators wonder how they can comply with federal law and preserve their Medicare/Medicaid reimbursements, but at the same time permit residents to medicate with marijuana.
  - Also staff members may not want to be a “Designated Caregiver” because of the inherent fear of prosecution because federal law still considers possession of marijuana a crime.

# Medical Marijuana (Con't)

- Administrators and Executive Directors need to decide how and if they should allow medical marijuana in their homes and communities.
- Delicate Balance:
  - Resident rights
  - Risk of prosecution
  - Risk of loss of Medicare/Medicaid reimbursement
  - Risk of abuse, sale, or theft of marijuana by Designated Caregivers/Residents? (How do you track marijuana in the nursing home? No bubble packs here.)
  - Therapeutic benefit?
    - What to do? – More clarification is needed by state public health departments to help direct use in nursing homes, and at the federal level by Centers for Medicare and Medicaid Services (“CMS”) to clarify Medicare/Medicaid issues.

# Medical Marijuana in the Nursing Home

- Facility Restrictions in North Dakota
  - Basic care, nursing, assisted living, adult daycare, or adult foster care homes may have “reasonable restrictions” including:
    - No storage or maintenance
    - No administering medical marijuana
    - No vaping or combustion restrictions
    - Consumption limited to a place specified by the facility

A facility listed in subsection 1 may not unreasonably limit a registered qualifying patient’s medical use of marijuana as authorized unless failing to do so would cause the facility to lose a monetary or licensing-related benefit under federal law or regulations.

N.D. cent. Code § 19-24.1-35

# Medical Marijuana in the Nursing Home (Con't)

- Practical Considerations
  - Numerous facilities have drafted policies governing use of medical marijuana in nursing homes which comply with both federal and state law (ex. Hebrew Home at Riverdale JAMADA 20 (2019) 94-98.
  - Numerous considerations and training and education of staff.
  - Consider risk of possession and improper use if zero tolerance position not enforced.
  - Determination needs to be made by board and administration with input from stakeholders.

# Questions?





# Contact Info

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