Marijuana (Cannabis) Part 1: Legal Aspects

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Marijuana use, possession, and/or cultivation for medical purposes is referred to as "*medical marijuana*" (or *medicinal cannabis*). This article (Part 1) highlights federal and state marijuana (cannabis) laws, principally Cannabidiol (CBD) and Tetrahydrocannabinol (THC), and summarizes the Oklahoma Medical Marijuana Act of 2018. Part 2 depicts the pharmacodynamics, pharmacokinetics, and medical aspects of CBD and THC.

In 2011, the OSMA Journal published the 100-year-history of U.S. drug enforcement of controlled substances, including opioids and marijuana, in the *War on Doctors*,[2] and the 21st century initiatives, policies and developing national guidelines pertaining to appropriate pain management.[3] Presently, the marijuana statutes are perhaps best described as characterized by behaviorally inconsistent or comprising contradictory elements (i.e. schizophrenic). To date, the FDA (Food and Drug Administration) has *not* recognized or approved the marijuana plant as medicine. Nevertheless, as of December 2018, a total of 33 states, and the District of Columbia, Guam and Puerto Rico have approved comprehensive public medical marijuana programs.[4] Thirteen states, including Oklahoma, allow the use of "low THC, high CBD" products for medical reasons in limited situations or as a legal defense. In October 2018, Canada legalized nationally recreational use of cannabis,[5] and the Mexico Supreme Court[6] legalized cannabis for non-commercial recreational use.

EVOLUTION OF MARJUANA LAWS

- In 1906, Congress enacted federal legislation imposing labeling regulations on narcotics, including opioids and marijuana, and prohibiting the manufacture or shipment of any adulterated or misbranded drug traveling in interstate commerce.[7]
- In 1913, California was one of the first States to prohibit the sale and possession of marijuana.[8]

- In 1914, the Harrison Narcotics Act[9] sought to exert control over the possession and sale of narcotics, specifically cocaine, opiates, and marijuana.
- In 1937, Congress passed the Marihuana Tax Act,[10] and imposed registration and reporting requirements for all individuals importing, producing, selling, or dealing in marijuana, and required the payment of annual taxes in addition to transfer taxes whenever the drug changed hands. The Marihuana Tax Act did not declare the drug illegal *per se.*
- In 1969, the U.S. Supreme Court held in *Leary* v. *United States*[11] that certain provisions of the Marihuana Tax Act and other narcotics legislation were unconstitutional.
- In 1969, President Nixon declared a national *war on drugs* and reorganized the federal drug control agencies. Congress also passed the Comprehensive Drug Abuse Prevention and Control Act of 1970,[12] making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by Title II, which is the CSA (Controlled Substances Act).[13] The latter repealed most of the earlier antidrug laws. Marijuana was classified as a Schedule I drug, and the manufacture, distribution, or possession of marijuana became a criminal offense. The CSA designated marijuana as contraband for *any* purpose and Congress expressly found no acceptable medical uses for the drug.
- In 1972, the National Commission on Marijuana and Drug Abuse released a report favoring decriminalization of cannabis, but no action was taken.[14]
- In 1996, California was the first state to allow for the medical use of marijuana under the Compassionate Use Act.
- As late as 2005, the federal Supreme Court stated in *Gonzales v. Raich*[15] that it is illegal to use, sell or possess marijuana, even for medical use.
- But in 2009, the Obama administration sent a memo to federal prosecutors encouraging them not to prosecute people who distribute marijuana for medical purposes in accordance with state law.
- In 2012, Colorado and Washington became the first two states in the Union to legalize recreational marijuana.
- In 2013, the U.S. Department of Justice announced an update to their marijuana enforcement policy,[16] stating that while marijuana remains illegal federally, the US Department of Justice expects states like Colorado and Washington to create "strong, state-based enforcement

efforts … and will defer the right to challenge their legalization laws at this time." The department reserved the right to challenge the states at any time they felt it was necessary.

- In 2017, the National Academies of Sciences, Engineering, and Medicine released a report[17] based on the review of over 10,000 scientific abstracts from marijuana health research. They made 100 conclusions[18] related to health and suggested ways to improve cannabis research.
- In early 2018, Attorney General Sessions issued a Marijuana Enforcement Memorandum[19] that rescinded the previous Memorandum, and allowed federal prosecutors to decide how to prioritize enforcement of federal marijuana laws.

WHAT HAS BEEN DRIVING THE LEGALIZATION OF MARIJUANA?

- Illegal marijuana sales are estimated at $40 billion. Legalizing marijuana should reduce illegal sales, decrease marijuana sentencing to a lower charge, and diminish the number of incarcerated offenders.
- A mature marijuana industry could generate up to $28 billion in tax revenues for federal, state, and local governments, including $7 billion in federal revenue: $5.5 billion from business taxes and $1.5 billion from income and payroll taxes.[20]
- Legalizing and taxing use of marijuana brings governments more money than it costs to regulate it. Legalizing marijuana boosts revenue for state and local governments. For example, tax income is equivalent to 1.2 in Washington state of the general fund revenue from marijuana sales and about 2% of the Colorado state budget. New Jersey is planning on having an additional $60 million in taxes from legalized marijuana in 2019.[21]
- Investors in marijuana stocks expect to earn substantial interest. In December 2018, Banyan Hill Publishing, a network of global experts in asset protection, reported that as medical marijuana begins legalizing in all 50 states, an expected 4,067% industry boom will transform the average American's savings into early retirement nest eggs.[22] They also noted that:
    - In 2016, campaign President Trump commented about medical marijuana: "I'm in favor of it 100%."

  - Former Speaker of the House John Boehner, who once stated he was "unalterably opposed" to legalization, now sits on the advisory board of a major marijuana company and admits: "My thinking on cannabis has evolved."
  - United States Attorney General Jeff Sessions, once completely against legislation favoring marijuana, later said: "There may well be some benefits from medical marijuana." And,
  - A recent poll shows 93% of Americans are in 2018 favoring legalization of marijuana.
- Legalization of marihuana may be of help in alleviating the opioid crises, as noted next.

IMPACT OF CANNABIS LEGALIZATION ON PRESCRIPTION OPIOIDS

- In 2018, Wen and Hockenberry[23] examined the opioid prescribing rates among Medicaid enrollees in the context of state marijuana liberalization policies between 2011 and 2016, using State Drug Utilization Data from the Centers for Medicare and Medicaid Services (CMS). The results showed that that the implementation of medical marijuana laws was associated with a 5.88% lower rate of Medicaid-covered prescriptions for all opioids. When states with existing medical marijuana laws implemented adult-use marijuana laws, the change was associated with an additional 6.38% lower opioid prescription rate. The lower rate of opioid prescribing associated with adult-use marijuana laws was mainly concentrated in Schedule II opioids (morphine, meperidine, hydrocodone with acetaminophen, oxycodone, and others). Additionally, the implementation of adult-use marijuana laws was associated with a 9.78% lower Medicaid spending on prescription opioids, equivalent to an annual saving of $1,815 in Medicaid spending per 1,000 enrollees. There was also a lower rate of Medicaid-covered prescriptions for nonopioid pain medications of 8.36%. The authors concluded that medical and adult-use marijuana laws have the potential to reduce opioid prescribing for Medicaid enrollees, opioid use disorder, and opioid overdose. Thus, marijuana liberalization may be one potential aspect of a comprehensive approach to tackle the opioid crisis.

- In 2018, Bradford *et al*[24] examined the association between prescribing patterns for opioids in Medicare Part D and the implementation of states' medical cannabis laws. They analyzed the daily doses of opioids filled in the Medicare Part D plan for all opioids as a group and by states from 2010 through 2015. They used data from the Medicare Part D Prescription Drug Event Standard Analytic Files.[25] The results showed that medical cannabis laws of any sort were associated with a 2.211 million daily dose decrease in filled opioid prescriptions compared with states that did not have active medical cannabis laws; statistically significant decreases were observed for hydrocodone and morphine. When compared with having no medical cannabis law, the authors found that permitting access via a dispensary was significantly associated with a decrease in prescribing of 3.742 million daily doses (or 14.4 % decrease) annually. However, access via home cultivation only was associated with a decrease of 1.792 million annual daily doses (or 6.9% decrease).
- Hill and Saxon[26] commented on the above studies and stated that (1) both medical and recreational cannabis laws were associated with annual reductions in opioid prescribing rates, (b) cannabis legalization may play a beneficial role in the opioid crisis by reducing opioid use and mortality, and (c) the results dovetailed with preclinical research showing that cannabinoid and opioid receptor systems mediate common signaling pathways central to clinical issues of tolerance, dependence, and addiction.

PRESENT FEDERAL LAW GOVERNING MARIJUANA

The Controlled Substances Act (CSA)[27] governs federal drug control and enforcement. It sets forth "a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA."[28]

Marijuana is classified as a Schedule I drug under the CSA, meaning it (1) has a high potential for abuse, (2) does not have a currently accepted medical use for treatment, and (3) poses an unacceptable safety risk even when used under medical supervision.[29] Under federal law, the growth, distribution, possession and use of marijuana is illegal, regardless of conflicting state laws.[30] But the U.S. Department of Justice ("DOJ") is prohibited from using any of the funding it receives from Congress to prosecute individuals and businesses that operate in the

medical marijuana industry in compliance with state medical marijuana laws.[31] No agency is going after physicians unless they are running the marijuana equivalent of a "pill mill."

FDA APPROVED MARIJUANA DRUGS

Medical marijuana refers to treating symptoms of illness and other conditions with the whole, unprocessed marijuana plant or its basic extracts. Scientific study of the chemicals in the *Cannabis* plant has led the FDA to approve the following drugs:

- **Epidiolex®**, a cannabidiol (CBD) oral solution product for controlling seizures in people with difficult-to-treat childhood-onset epilepsy. It was approved In June 2018. It the first FDA approved drug that contains a purified substance derived from marijuana. It is indicated for the treatment of seizures associated with two rare and severe forms of epilepsy: (1) Lennox-Gastaut syndrome which begins usually between ages 3 and 5and manifests multiple types of seizures, more than three-quarters are tonic seizures. The patients develop learning problems, intellectual disability, delayed development of motor skills such as sitting and crawling, requiring help with usual activities of daily living. And (2) Dravet syndrome, a rare genetic disorder that appears during the first year of life with frequent fever-related seizures (febrile seizures). Other types of seizures also develop, including myoclonic seizures (involuntary muscle spasms), and status epilepticus. The patients experience poor development of language and motor skills, hyperactivity and difficulty relating to others.

  The U.S. Drug Enforcement Administration (DEA) has assigned **Epidiolex®** a Schedule V classification. Non-Epidiolex CBD remains a Schedule I drug prohibited for any use. Of note, CBD is not scheduled under any United Nations drug control treaties, and in 2018, the World Health Organization recommended that it remain unscheduled.
- **Cesamet®** (nabilone), **Marinol®** (dronabinol capsules) and **Syndros®** (dronabinol oral solution) are orally active synthetic cannabinoids containing THC, the psychogenic component of marijuana, to treat nausea and boost appetite caused by chemotherapy and increase appetite in patients with extreme weight loss caused by AIDS.

The United Kingdom, Canada, and several European countries have approved nabiximol (**Sativex®**), a mouth spray containing THC and CBD. It treats muscle control problems caused by Multiple Sclerosis, but it is not FDA-approved.

FDA WARNING

In July 2018, the FDA became aware of reports of severe illnesses and deaths resulting from the use of synthetic cannabinoid (marijuana) products that had been contaminated with brodifacoum, a very long-acting anticoagulant commonly used in rat poison.[32] These FDA-*unapproved* products were being sold in convenience stores and gas stations as substitutes for standard marijuana under names such as "K2" and "Spice." The FDA report warned that the sale and use of these products is illegal and unsafe. They pose significant public health concerns for both individuals who may use the contaminated products and the U.S. blood supply, as there is the potential for contamination of blood products donated by those individuals who have used these substances.

OKLAHOMA MARIJUAN LAW

- In 1933, Oklahoma banned the drug, marijuana, as part of a larger trend nationwide to restrict cannabis.
- In 2011, new penalties were enacted for possession or making of hashish, a grinder, or brownies that may include life imprisonment.
- As of 2013, a person will be jailed for no less than 10 days or more than 1 year if: he or she "has any amount of a Schedule I chemical or controlled substance, as defined in Section 2-204 of Title 63 of the Oklahoma Statutes, or one of its metabolites or analogs in the person's blood, saliva, urine or any other bodily fluid at the time of a test of such person's blood, saliva, urine or any other bodily fluid administered within two (2) hours after the arrest of such person." A second offense will have longer sentencing.
- Most recently, in 2014, Oklahoma State Attorney General Scott Pruitt and Nebraska Attorney General Bruning announced their states' lawsuit in federal court against Colorado over marijuana legalization, in an effort to stop the commercial production and sale of

marijuana.[33] The following year, Governor Mary Fallin signed into law a bill which allows clinical trials of CBD oil.

- In 2018, Oklahoma voters approved State Question 788 legalizing medical marijuana and liberalized the fines for a non-license holder, reducing the crime of "simple possession" (without intent to distribute) of up to 1 1/2 ounces. This misdemeanor carries a $400 maximum fine. A person who obtains an Oklahoma Medical Marijuana License may consume marijuana legally and may legally possess up to: 3 ounces of marijuana; 6 mature marijuana plants; 6 seeding plants; 1 ounce of concentrated marijuana; 72 ounces of edible marijuana; and 8 ounces of marijuana at the residence.

THE OKLAHOMA MEDICAL MARIJUANA ACT (OMMA)[34]

Despite contrary federal law, the OMMA allows the cultivation, processing, distribution, prescribing, possession, and use of medical marijuana, provided that such activities are conducted within the framework established by the Oklahoma Medical Marijuana Authority and the implementing regulations adopted by the Oklahoma State Department of Health (OSDH).

- Physicians must sign all applications for medical marijuana licenses.
- Physicians must hold a valid, unrestricted license to practice medicine in the State of Oklahoma, and meet the definition of “board-certified” under the rules established by either the Oklahoma Board of Medical Licensure and Supervision (“OBMLS”) or the Oklahoma Board of Osteopathic Examiners (“OBOE”).[35]
- Two physicians, within thirty (30) days of each other, must sign applications for children under eighteen (18) years of age.[36]
- Patients must submit the signed applications to the Oklahoma Medical Marijuana Authority (a division of the OSDH) which issues valid medical marijuana licenses allowing the possession and consumption of medical marijuana.
- Physician should document on the recommendation form if patients are homebound or not capable to self-administer or purchase medical marijuana due to developmental disability or physical or cognitive impairment, as the patient’s guardian or caregiver may then be eligible to apply for a caregiver’s license.

- Physicians who plan to recommend medical marijuana to patients are encouraged to register *optionally* with the OSDH on a form that is accessible at www.omma.ok.gov in order to speed up the application approval process for their patients.

Physicians do ***not*** and should not directly prescribe or dispense marijuana. They merely issue written *recommendations* that allow patients to obtain state-issued licenses to purchase marjuana from '*dispensaries*'. Consequently, licensing board actions or malpractice risks to doctors who recommend medical marijuana to patients within state guidelines should be minimal.

On the other hand, marijuana is still a Schedule I substance under the CSA.

1. It is a crime under federal law to knowingly or intentionally "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" marijuana,[37] as well as to knowingly or intentionally "possess a controlled substance."[38]
2. Federal law permits the prosecution of "principals" who commit offenses against the United States or who "aid, abet, counsel, command, induce or procure" the commission of such offenses.[39] A person may be responsible for a crime he or she has not personally carried out if he or she helps another to complete its commission.[40]
3. State regulators in some states have reprimanded or suspended physicians of their medical licenses for excessive or imprudent recommendations, such as recommending marijuana to pregnant women or individuals with admitted histories of substance abuse issues.

The OMMA requires specifically enumerated "qualifying conditions" that support a medical marijuana recommendation. Physicians should use "accepted standards a reasonable prudent physician would follow when recommending or approving any medication."[41] The physicians signatures on the recommendation forms amount to an attestation[42] to the following:

1. The physician has verified the patient/applicant's identity;

2. A bona fide physician-patient relationship has been established along with a medical record for the patient/applicant;

3. An in-person examination physical examination of the patient/applicant is conducted within the previous thirty (30) calendar days;

4. The risks and benefits (informed consent) of the use of medical marijuana with the patient/applicant and or the patient/applicant's custodial parent(s) or legal guardian(s) are discussed;

5. The physician has determined the presence of at least one medical condition for which the patient/applicant is likely to receive therapeutic or palliative benefit from the use of medical marijuana;

6. The physician is recommending a medical marijuana license to the patient/applicant in accordance with accepted standards a reasonable and prudent physician would follow for recommending or approving any medication;

7. The physician has participated in all mandatory continuing medical education as required by his or her licensing entity.[43]

Additionally, before recommending marijuana, physicians should:

1. Conduct a preliminary screening for substance abuse or mental health disorders and determine and document whether a medical marijuana recommendation presents an undue risk of abuse, addiction, or diversion;

2. Maintain accurate and complete medical records for the patient;

3. Provide follow-up care and management of the patient's medical condition, including any follow-up examination necessary to determine the efficacy of medical marijuana for the patient's condition;

4. Avoid conflicts of interest and similar fraud and abuse violations applicable to the provision of all other medical services;

5. Avoid accepting, soliciting, or offering any form of pecuniary remuneration from or to a caregiver, dispensary, processor, or commercial grower.

6. Avoid offering a discount or any other thing of value to a patient who uses or agrees to use a particular caregiver or dispensary;

7. Avoid examining a patient for the purposes of recommending medical marijuana at a location where medical marijuana is dispensed;

8. Avoid holding a medical marijuana license in his or her personal capacity or as a caregiver if actively making recommendations to other patients; and

9. Avoid holding any direct or economic interest in an enterprise that grows, transports, processes, or dispenses medical marijuana.

Finally, physicians should consult with their legal counsel to ensure that statutory and regulatory requirements are being satisfied through the physician's recommendation practices. They should also consult with their medical liability insurance carriers before issuing recommendations, as there could be civil liability risks, for example an allegation that a physician's negligence caused an overprescribed patient to injure a third party.

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[2] Sanbar, SS, Perceived "War on Doctors" Nearing 100 years: PART I (1914 - 2000), *OSMA Journal*, September 2011:303-306.

[3] Sanbar, SS, Perceived "War on Doctors" Nearing 100 years: PART II (1990s - 2011), *OSMA Journal*, October 2011:389-391.

[4] http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

[5] *"Health products containing cannabis or for use with cannabis: Guidance for the Cannabis Act, the Food and Drugs Act, and related regulations"*. Government of Canada. 11 July 2018.

[6] https://www.upi.com/Mexicos-Supreme-Court-legalizes-cannabis-for-recreational-use/9621541024238/

[7] Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, repealed by Act of June 25, 1938, ch. 675, §902(a), 52 Stat. 1059.

[8] 1913 Cal. Stats. ch. 324, §8*a;* see also Gieringer, The Origins of Cannabis Prohibition in California, Contemporary Drug Problems, 21-23 (rev. 2005).

[9] 38 Stat. 785 (repealed 1970)

[10] Pub. L. 75-238, 50 Stat. 551 (repealed 1970)

[11] 395 U. S. 6 (1969)

[12] 84 Stat. 1236

[13] 21 U. S. C. §§841(a)(1), 844(a)

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1749335/pdf/bullnyacadmed00168-0058.pdf

[15] https://caselaw.findlaw.com/us-supreme-court/545/1.html

[16] *http://www.justice.gov/opa/pr/justice-department-announcesupdate-marijuana-enforcement-policy*
[17] http://nationalacademies.org/hmd/reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx
[18] 100 conclusions about Cannabis Scientific Research-2017
[19] https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement
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[23] Wen H, Hockenberry JM. Association of medical and adult-use marijuana laws with opioid prescribing for Medicaid enrollees. *JAMA Internal Medicine* 2018; 178(5):673-678.
[24] Bradford AC, Bradford D, Abraham AJ, Bagwell Adams G. Association Between US State Medical Cannabis Laws and Opioid Prescribing in the Medicare Part D Population. *JAMA Intern Med.* April 2018. doi:10.1001/jamainternmed.2018.0266. https://www.ncbi.nlm.nih.gov/pubmed/29610897
[25] https://www.resdac.org/cms-data/files/pde
[26] Hill, KP, Saxon, AJ, The Role of Cannabis Legalization in the Opioid Crisis, *JAMA Intern Med.* 2018;178(5):679-680. doi:10.1001/jamainternmed.2018.0254
[27] 21 U.S.C. §§ 801-904
[28] *Gonzalez v. Raich*, 545 U.S. 1, 13 (2005).
[29] 21 U.S.C. § 812(b)(1)(A)-(C), (c).
[30] *Id*. § 812(b)(1)(A)-(C).
[31] Thompson Coburn LLP, *Rohrabacher-Blumenauer Amendment Included in Omnibus FY 2018 Spending Bill*, JD SUPRA (March 30, 2018).
[32] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614027.htm
[33] *http://www.huffingtonpost.com/2014/12/18/lawsuit-coloradomarijuana_n_6350162.html*
[34] State Question 788 was approved by Oklahoma voters on June 26, 2018, and codified in the Oklahoma Statutes as Sections 420A-426 of Title 63 and titled the Oklahoma Medical Marijuana Act ("OMMA").
[35] OAC 310: 681-1-4; 310: 681-1-9.
[36] 63 O.S. § 420A(L); OAC 310:681-2-2.
[37] 21 U.S.C. § 841(a)(1).
[38] Id. § 844(a).
[39] 18 U.S.C. § 2(a).
[40] *Rosemond v. United States*, 134 S. Ct. 1240, 1245 (2014).
[41] 63 O.S. § 420A(M); OAC 310: 681-1-9.1.
[42] The physician recommendation form and additional guidance from the OSDH and the Oklahoma Medical Marijuana Authority can be found at http://omma.ok.gov/guidance-for-recommending-physicians.
[43] Neither the OBMLS nor the OBOE have issued guidance or mandated any particular CME requirements related to medical marijuana; however, the June 21-22, 2018 meeting minutes of the OBMLS indicate that a discussion of medical marijuana issues was on the agenda, so physicians should continue to watch for guidance and rules from their licensing bodies.