# LEGAL LANDSCAPE

*Overview of Cannabis Laws and Regulations*

## OBJECTIVE

*This introductory chapter is intended to enable medical professionals to better understand the legal terrain of medical cannabis. It provides clinicians with an overview from a legal perspective of relevant medical cannabis regulations and what clinicians may and may not do when discussing cannabis in the context of a patient visit.*

## INTRODUCTION

This chapter provides a legal framework for the topics that will be discussed throughout this handbook as well as future interactions and conversations with patients. Further chapters will dive deeper into many of the topics touched on in this legal overview including the history of medical cannabis use, an overview of prohibition, legalization and regulation, practical information for dosing, delivery and the clinical application of cannabis, and so much more. This section will provide up to date information regarding the current regulatory landscape of medical cannabis, and the application of those regulations in a medical and legal context.

## FEDERAL LEGAL OVERVIEW

Cannabis, also commonly referred to as marijuana or hemp, is a genus of flowering plants in the family *Cannabaceae* that includes at least three species, *Cannabis sativa L., Cannabis indica*, and *Cannabis ruderalis,* as determined by plant phenotypes and secondary metabolite profiles (terpene profiles).[1] In practice, cannabis nomenclature is often used interchangeably or seemingly arbitrarily. Legally, however, hemp and marijuana are distinguished by their respective concentrations of the cannabinoid delta-9 tetrahydrocannabinol (THC) found in the flowering tops and leaves. According to federal law, cannabis with 0.3% or less concentration of THC is not marijuana; it is industrial hemp.[2,3] Industrial Hemp was included in the 2018 Farm Bill, which was signed by President Trump on December 20, 2018.

This legislature removed Industrial Hemp from the Schedule I drug classification per section 10113 of the Farm Bill.[4] With the declassification of Industrial Hemp, products that contain cannabidiol (CBD) derived from legal hemp are now federally legal. The bill removes restrictions on the sale, transport, and possession of hemp-derived products, so long as those items are produced in a manner consistent with the law.

Since 1972, cannabis has been classified as a Schedule I drug under the U.S. Controlled Substances Act because the U.S. Drug Enforcement Agency considers it to have "no accepted medical use."[5] In stark contrast to this position, 33 of the 50 U.S. states and the District of Columbia have recognized the medical benefits of cannabis and have decriminalized its medical use.[6] The approved list of conditions/diseases and the other laws/rules regarding the possession and cultivation of medical marijuana generally differ by state. In addition, 11 of the 50 U.S. states and the District of Columbia legalized recreational cannabis use for adults 21 years of age and over, with varying rules and regulations.


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In 2014, President Obama publicly commented on the recreational legalization of cannabis in Colorado and Washington, stating that "it's important for it to go forward because it's important for society not to have a situation in which a large portion of people have at one time or another broken the law and only a select few get punished." President Obama further remarked, "I don't think it's more dangerous than alcohol. In fact, it is less dangerous than alcohol in terms of its impact on the individual consumer."[7]

In line with the president's comments, the U.S. Attorney General Eric Holder announced that the federal government would allow states to create a regime that would regulate and implement the legalization of cannabis, including loosening banking restrictions for cannabis dispensaries and growers.[8]

The Cole Memo[9] and the Financial Crimes Enforcement Network (FinCEN) guidance[10] were published and provided states with some comfort in their respective legalization experiments. Unfortunately, enforcement priority decisions by the Attorney General are not in themselves changes in law and may change with each administration.

An October 2017 Gallup poll found an all-time high of 64 percent of Americans support full legalization. The same poll was also the first time Gallup recorded a majority of Republicans, 51 percent, favoring full legalization.[11]

Legal cannabis has become one of the fastest-growing industries in the United States, and state representatives have found that none of the problems predicted with legalization occurred. Sales jumped from $1.5 billion in 2013 (U.S.) to an estimated $10 billion (for North America) in 2017, according to Arcview Market Research. The industry now employs more than 150,000 Americans and has become more deeply entrenched in every quantifiable way.[12]

In addition to these recent developments, the U.S. government has set a precedent for patenting cannabis and cannabis-related inventions. For example, U.S. Pat. No. 6,630,507[13] issued on October 7, 2003, and assigned to the United States of America, is directed to methods of treating diseases caused by oxidative stress by administering therapeutically effective amounts of a CBD cannabinoid from cannabis that has substantially no binding to the N-methyl-D-aspartate (NMDA) receptor, wherein the CBD acts as an antioxidant and neuroprotectant. The U.S. Patent and Trademark Office (USPTO) confirmed that officials are now accepting and processing patent applications for individual varieties of cannabis, along with innovative medical uses for the plant and other associated inventions.

In contrast, the Office of Trademarks at USPTO often rejects cannabis trademarks when they determine there is no legal "use in commerce."[14] The Office of Trademarks further requires that the "use in commerce" be "the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark."[15] In a recent decision from the Trademark Trial and Appeal Board, the Board affirmed "the fact that the provision of a product or service may be lawful within a state is irrelevant to the question of federal registration when it is unlawful under federal law."[16]

*OTHER PATENT AND TRADEMARK CONSIDERATION*

- Federal protection is not available for cannabis trademarks, except where it does not violate the Controlled Substances Act.[17,18] Registration is refused because applicant does not have a bona fide intent to lawfully use the applied-for mark in commerce.[19,20,21]
- Plant, design, and utility patents are available for cannabis inventions.
- Copyright registrations are enforceable for cannabis creative works.

Despite the conflicting official positions within the federal government, many states have recognized that cannabis provides substantial benefits for medical and recreational uses. Cannabis is regularly used by a wide cross-section of society to treat a variety of maladies, conditions, and symptoms including, but not limited to, the following: nausea, glaucoma, lack of appetite, Crohn's disease, epilepsy, post traumatic stress disorder, intractable pain, fever, obesity, asthma, urinary tract infections, coughing, anorexia associated with weight loss in AIDS patients, pain, and multiple sclerosis. Many of these conditions will be discussed in relation to cannabis throughout this handbook, with a special focus on clinical applications.

With the number of people depending on cannabis to treat a myriad of medical conditions, and the increase in tax revenue in the states that have decriminalized both medical and recreational cannabis, it is unlikely that a reversal in policy by the federal government will take immediate effect. There will be significant legal challenges and a call for a delisting of cannabis as a Schedule I controlled substance. At this time, the legal future of cannabis is uncertain.

FEDERAL LAW OUTLINE

This outline list provides an introductory overview of relevant federal cannabis regulations. Many sections included here may not be relevant to medical application but are important for patients to consider before deciding to use medical cannabis.

*CONTROLLED SUBSTANCES Act (21 USCV 801, et seq.)*

- Marijuana is a Schedule I drug.[22] Schedule I drugs are defined as:
  - The drug or other substance has a high potential for abuse.
  - The drug or other substance has no currently accepted medical use in treatment in the United States.
  - There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- Federal preemption[23] of state laws is in "direct conflict" with the Controlled Substances Act.

*OGDEN MEMO*[24]

- First guidance from the U.S. Department of Justice (DOJ) on medical marijuana enforcement.

*COLE MEMO*[25]

- In an historic position change, the U.S. Justice Department's Deputy Attorney General James Cole announced in 2014 that the federal government would not interfere with a state's rights to manage and regulate marijuana based on eight conditions. This ruling is known as the Cole Memo and serves to remind individuals working in the legal marijuana industry that they remain under scrutiny.
- It is important to note that under the current Attorney General, the future of the Cole Memo is unknown.

- *THE COLE MEMO* states that the DOJ is not waiving "immunity" or offering "a free pass" to marijuana providers; instead, the Justice Department promises that federal prosecutors will aggressively investigate/prosecute any cannabis business that interferes/obstructs any one of the following eight federal priorities:
    - Distribution of marijuana to minors;
    - Revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
    - Diversion of marijuana from states where it is legal under state law in some form to other states;
    - State-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
    - Violence and the use of firearms in the cultivation and distribution of marijuana;
    - Drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
    - Growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
    - Marijuana possession or use on federal property.

*WILKINSON MEMO*[26]

- Extended Department of Justice enforcement priorities to tribal lands.

*THE ROHRABACHER–FARR AMENDMENT*[27]
*(recently known as the Rohrabacher–Blumenauer Amendment)*

- Legislation first introduced by U.S. Representatives Maurice Hinchey, Dana Rohrabacher, and Sam Farr in 2003, prohibiting the Justice Department from spending funds to interfere with the implementation of state medical cannabis laws. The amendment does not change the legal status of cannabis, however, and must be renewed each fiscal year in order to remain in effect.
- There is one unpublished case in California where the federal court extended the protection to recreational cannabis.[28]
- Recreational marijuana is currently legal in 11 states plus Washington, D.C., and medical marijuana is legal in 33 states.[29]

*TAXES*

- The Internal Revenue Service Section 280(e)—Calculation of taxable income:
  - May discount the cost of goods sold from gross revenues.[30]
  - May not discount ordinary business expenses.

No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of Schedule I and II of the Controlled Substances Act) which is prohibited by federal law or the law of any state in which such trade or business is conducted.[31]

*NO BANKRUPTCY PROTECTION FOR CANNABIS BUSINESSES*[32]

10th Circuit Bankruptcy Appellate Panel held:

- "Impossible for the Chapter 7 Trustee to administer the Arenases' estate because selling and distributing the proceeds of the marijuana assets would constitute federal offenses."
- "If the Trustee abandoned the Assets, the debtors would retain their business after exposing the Trustee to grave risk, provide the creditors with little or no recovery, and receive a discharge, protected all the while from their creditors' collection efforts by the automatic stay and then the discharge injunction. That is the epitome of prejudicial delay."
- Marijuana businesses are not eligible for Chapter 7, nor are they eligible for Chapter 13 bankruptcy protection.

## *Employment Law*

- Drug testing is still permitted because it is still a federal crime.
- Employees can be fired for having THC in their blood/urine, even if smoking has nothing to do with their job and had no effect on their job performance.
- Cannabis smokers are not a protected class; employers are free to discriminate.
- Rightful termination may depend on whether the employment contract contains a provision with the requirement of following all federal laws, refraining from partaking illegal drugs, and so forth.[33]

*ACCESS TO BANKING*

The Financial Crimes Enforcement Network (FinCEN) published guidance for interstate banks to allow them to accept cannabis business accounts without violating federal money laundering statutes.[34]

ADDITIONAL LEGAL CONSIDERATIONS FOR MEDICAL PROFESSIONALS

In addition to the federal legal overview, there are several other legal details medical professionals should consider when discussing cannabis with patients and caregivers. The Cole Memo provides guidelines for the regulation of medical cannabis at the state level and includes important guidelines regarding federal prosecution of cannabis businesses. The *Conant v. Walters* decision outlines how doctors can discuss and recommend cannabis for patients and is further detailed in this section. Affirmative defense is also an important topic of conversation.

*CONANT V. WALTERS—HEALTHCARE PROFESSIONALS RECOMMENDATIONS*[35]

The 9th U.S. Circuit Court of Appeals ruled that doctors may discuss medical marijuana with their patients and may issue written recommendations for its use as part of a comprehensive treatment plan—*Conant v. Walters,* 309 F.3d 629 (2002). When this ruling was appealed again, the U.S. Supreme Court refused to hear the case, allowing the decision to stand.

- After California and Arizona decriminalized medical marijuana in 1996, the Federal Department of Justice and Department of Health and Human Services sent a policy to federal, state, and local practitioner associations cautioning physicians who "intentionally provide their patients with oral or written statements in order to enable them to obtain controlled substances in violation of federal law risk revocation of their DEA prescription authority."
- In 2002, the 9th Circuit affirmed an order permanently enjoining the federal government from either:
  - Revoking a physician's license to prescribe controlled substances, or
  - Conducting an investigation of a physician that might lead to such revocation, where the basis for the government action would be solely the physician's "recommendation" of the use of medical marijuana, on First Amendment grounds.
- After 2002, a provider may discuss the pros and cons of medical marijuana with his or her patient, and issue a written or oral recommendation to use marijuana within a bona fide provider–patient relationship without fear of legal reprisal.
- And this is so, regardless of whether he or she anticipates that the patient will, in turn, use this recommendation to obtain marijuana in violation of federal law.
- On the other hand, the physician may not actually prescribe or dispense marijuana to a patient or recommend it with the specific intent that the patient will use the recommendation like a prescription to obtain marijuana.

However, despite the First Amendment protections affirmed by the 9th Circuit, most healthcare providers are reluctant to recommend medical marijuana due to a claimed lack of scientific evidence or because the organization the provider works for has a policy against such recommendations.

*AFFIRMATIVE DEFENSE*

In states that have decriminalized medical cannabis, but not recreational cannabis, individuals possessing marijuana for a medical condition may have an "affirmative defense" for such possession. Each state's specific rules are state specific, and the medical marijuana consultant should be familiar with the laws within their respective state. Generally, an affirmative defense to a criminal charge is a fact or set of facts other than those alleged by the prosecutor, which, if proven by the defendant, defeats or mitigates the legal consequences of the defendant's otherwise unlawful conduct.

# MEDICAL PROFESSIONALS

***MAY:***

- Discuss, fully and candidly, the risks and benefits of medical marijuana with patients.
- Recommend (or approve, endorse, suggest, or advise, etc.), in accordance with their medical judgment, marijuana for patient use.
- Record in their patients' charts discussions about and recommendations of medical marijuana.
- Sign government forms or inform state or local officials that they have recommended medical marijuana for particular patients.
- Testify in court or through written declaration about recommending medical marijuana for their patients.
- Educate themselves about the medical benefits of marijuana, its various clinical applications, and different routes of ingestion.

***MAY NOT:***

- Prescribe medical marijuana. This includes writing a recommendation on prescription forms.
- Assist patients in obtaining marijuana.
- Cultivate or possess marijuana for patient use.
- Physically assist patients in using marijuana.
- Recommend marijuana without a justifiable medical cause.

*Early drafts of the Declaration of Independence were written on hemp paper.*

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# NOTES