



The legal status of cannabis (marijuana) and cannabidiol (CBD) under U.S. law



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ABSTRACT

In the United States, federal and state laws regarding the medical use of cannabis and cannabinoids are in conflict and have led to confusion among patients, caregivers, and healthcare providers. Currently, cannabis is legal for medical purposes in 50% of the states, and another seventeen states allow products that are high in cannabidiol (CBD) and low in THC (tetrahydrocannabinol) for medical use. Many of these artisanal products are sold in dispensaries or over the internet. However, none of these products has been approved by the Food and Drug Administration (FDA). Understanding how federal laws apply to clinical research and practice can be challenging, and the complexity of these laws has resulted in particular confusion regarding the legal status of CBD. This paper provides an up-to-date overview (as of August 2016) of the legal aspects of cannabis and cannabidiol, including cultivation, manufacture, distribution, and use for medical purposes.

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1. Introduction

Since the 1996 enactment of the first state law allowing the medical use of cannabis, 25 states and the District of Columbia have enacted such laws; another 17 allow products that are high in cannabidiol (CBD) and low in THC (tetrahydrocannabinol). In the past several years, interest has focused on the therapeutic potential of CBD, one of the plant's major cannabinoids. Many cannabis and CBD products are available in dispensaries and over the internet. However, none of these artisanal preparations (irrespective of THC content) has been approved by the Food and Drug Administration (FDA) for safety or efficacy, and state laws requiring quality control are inconsistent and sometimes nonexistent. Controlled clinical trials are underway to investigate the use of CBD as a potential treatment for several types of seizure disorders.

Abbreviations: 8FA, 8-Factor Analysis; CBD, cannabidiol; CFR, Code of Federal Regulation; CSA, Controlled Substances Act; DEA, Drug Enforcement Administration; DHHS, Department of Health and Human Services; DOJ, Department of Justice; DSHEA, Dietary Supplement Health & Education Act; FDA, Food and Drug Administration; FD&C, Food, Drug & Cosmetic (Act); IND, Investigational New Drug; IRB, Institutional Review Board; LSD, *D*-Lysergic acid diethylamide; NDA, New Drug Application; NIDA, National Institute on Drug Abuse; THC, tetrahydrocannabinol; US, United States.

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2. The Controlled Substances Act

In the United States, the federal Controlled Substances Act (CSA) controls substances that are psychoactive or otherwise have abuse potential. The CSA controls all stages of the manufacturing and supply chain, and all handlers (including "ultimate users," such as patients). The extent or stringency of these controls is largely determined by a substance's classification in one of five schedules for controlled substances. Classification depends on a substance's medical effectiveness and abuse potential (21 USC 812). The general rule is that a substance and products derived from that substance are in the same schedule.

The criteria for substances in Schedule I are no currently accepted medical use in the United States, high potential for abuse, and lack of accepted safety for use of the drug or other substance under medical supervision. These substances include marijuana and its cannabinoid components, THCs, ibogaine, mescaline, psilocybin, peyote, heroin, and *D*-Lysergic acid diethylamide (LSD).

The criteria for substances in Schedule II are currently accepted medical use in the United States, high potential for abuse, and abuse of the drug or other substances that may lead to severe psychological or physical dependence. Schedule II substances include most opioids (e.g., oxycodone) and stimulants (e.g., methylphenidate). Opium and coca leaves also are listed in Schedule II because approved medications (e.g., morphine) were already on the market in 1970, when the CSA was enacted.

Like drugs in Schedule II, drugs in Schedules III–V have a currently accepted medical use in the United States. In addition, they have lower abuse potential when compared with drugs in the preceding schedule. The phrase “currently accepted medical use in the United States” is not defined in the CSA or in its implementing regulations. However, the Drug Enforcement Agency (DEA) has developed the following five criteria, all of which must be satisfied: (1) the drug's chemistry must be known and reproducible, (2) there must be adequate safety studies, (3) there must be adequate and well-controlled studies proving efficacy, (4) the drug must be accepted by qualified experts, and (5) the scientific evidence must be widely available.

These criteria have been upheld by federal courts (*Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C.Cir. 1994)). In addition, FDA approval of a product is sufficient to establish its “currently accepted medical use.” By contrast, state laws authorizing the use of cannabis for medical purposes and the prevalence of anecdotal reports do not satisfy this statutory standard. [DOJ, DEA, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 21 C.F.R. 40552 at p. 40567 (July 8, 2011)].

3. Research, manufacture, distribution, and possession of cannabinoids

Schedule I substances like cannabis and cannabinoids cannot be prescribed and can only be lawfully dispensed and possessed as part of a federally approved research program. Investigators seeking to conduct Schedule I research must secure a Schedule I research registration (the CSA term for license); many states also require a state Schedule I research license. These requirements, particularly for those unfamiliar with the steps involved, can be challenging. The research registration is both substance (e.g., cannabis or CBD) and protocol specific. Manufacturers, importers, and distributors also must secure Schedule I, substance-specific registrations.

Currently, investigators interested in conducting research on cannabis plant material must obtain that cannabis through the National Institute on Drug Abuse (NIDA), which has historically contracted only with the University of Mississippi to cultivate different varieties of research-grade cannabis with various THC:CBD ratios. However, the DEA has recently announced that it will register additional sources of cannabis cultivated for research or the development of FDA-approved products [1]. If an investigator is interested in conducting research on a cannabis extract or purified cannabinoid (including one synthesized in a laboratory), the preparation may be obtained through NIDA or from other sources, including importation into the United States.

Schedule II–V substances are subject to less stringent rules. For example, physicians who hold Schedule II–V prescriber registrations, as many do, may conduct research on Schedule II–V substances as a lawful “coincident activity” to their prescriber registration. They need not seek further approvals from the DEA or state controlled drug agencies. Investigators may obtain such substances from any of a number of registered manufacturers. In addition, FDA-approved products containing Schedule II–V substances may be prescribed and dispensed in clinical practice.

That Schedule I substances cannot be dispensed outside of a research program explains why physicians, in states that have authorized the medical use of cannabis, can only “certify” or “recommend” that their patients have a qualifying medical condition and may use cannabis for medical purposes, but cannot actually issue a prescription. Such state laws, which vary significantly from state to state, may permit persons other than patients and/or caregivers to manufacture and distribute cannabis preparations (often through “dispensaries”) to patients who have the recommendation of a physician or other healthcare provider. However, such activities remain illegal under federal law.

4. Distinguishing CBD products from other cannabis products

The cannabis plant contains >100 individual cannabinoids [2]. The predominant cannabinoids are THC and CBD. Tetrahydrocannabinol activates the body's endogenous cannabinoid receptors, CB1 and CB2. Activation of CB1 is responsible for THC's psychoactive properties. Cannabidiol does not directly activate those receptors at doses being studied in clinical trials [3] and is considered to be non-psychoactive [4].

There are no standardized definitions of “medical marijuana” and “high-CBD” or “low-THC” products, and media reports commonly use these terms interchangeably. “Medical marijuana” does not refer to a special variety of cannabis, mode of preparation, or dosage form. Rather, cannabis is so classified by the purpose of its use (i.e., for medical rather than recreational use). “Medical marijuana” products may contain a range of cannabinoids, although most are predominantly comprised of THC. “High-CBD” products are commonly higher in CBD content than other “medical marijuana” products, but some of these products may have levels of THC ranging from 0.3% to 5%, depending on the state law.

Similarly, there are no common descriptions of “medical marijuana” or “CBD access” state laws, which vary significantly. Some decriminalize possession by qualified patients or their caregivers, while others authorize the full panoply of manufacturing (including cultivation and manufacturing of various preparations) and distribution/retail sales, to purchase and possession by the ultimate patient users. In all cases, physicians (or in a few states also other healthcare providers) are the “gatekeepers;” that is, a patient cannot become qualified without a physician's recommendation.

5. Transporting CBD, “medical marijuana,” and investigational cannabinoid products

The media have reported cases of patients and/or family members who have obtained CBD or “medical marijuana” in another state and brought it back to their state of residence. However, transporting cannabis across states lines may not be lawful under state laws, unless a patient is participating in a clinical trial and has a letter that documents such participation. Even still, the Controlled Substances Act does not permit patients to bring cannabinoid preparations into, or take them out of, the United States, even for medical use. Of course, many patients have purchased CBD artisanal products on the internet, thus far without significant enforcement against either the patients or the vendors. However, Health Canada recently seized a shipment of CBD products being sent from the United States to patients in Canada [5].

6. Legal status of CBD

Cannabidiol is not listed separately in the Code of Federal Regulations (CFR); it is controlled in Schedule I by definition as a “derivative” or “component” of marijuana (21 USC 802). This is also true of other individual cannabinoids. Only THC is listed separately in Schedule I. According to a position statement from the DEA Office of Public Affairs, CBD from any source is a Schedule I substance (DEA, Office of Public Affairs, December 15, 2015, provided upon request to A. Mead).

6.1. Legal status of hemp

The increased interest in CBD has been accompanied by a parallel interest in the cultivation of the hemp variety of cannabis. Typically grown for its fiber or seeds, hemp is generally low in cannabinoid content. In Europe and Canada, specific hemp varieties may be cultivated, and they must have no >0.2% (Europe) [6–8] or 0.3% (Canada) THC [9], as measured in the dried flowering portion of the plant, which is the part of the plant with significant cannabinoid content.

The CSA does not define hemp; it merely exempts certain parts of the cannabis plant – stalk, fiber, and sterilized seeds (and preparations made from them) – from the definition of “marijuana.” However, if

CBD (considered “resin” under that definition) is extracted from any part of the plant, including the “exempted parts,” it is still considered marijuana and in Schedule I. Essentially, this is an “exception to the exemption.” The whole hemp plant (with roots in the ground) is defined as marijuana under the CSA.

6.2. Hemp as a source of CBD

Per above, hemp varieties are generally poor sources of cannabinoids, including CBD (2–4%); however, owing to the low level of THC, the CBD:THC ratio may still approach 10:1, or even higher. This is perhaps why hemp varieties are sometimes inaccurately referred to as “CBD rich.” Actually, true CBD-rich varieties of cannabis do exist, but for a plant to express $\geq 12\%$ CBD (in the flowering tops), it will also usually express $> 0.3\%$ THC [10]. If a pure CBD product is desired, the extract from such a plant can be put through a purification process to produce crystal-line CBD [11].

Cannabinoid expression is typically limited to flowering buds and not stalk, fiber, or sterilized seeds; this is true of all cannabis varieties. Traditional hemp is an inefficient source of CBD, requiring many acres to be cultivated to produce significant amounts of CBD extract. Moreover, hemp is considered a “bioaccumulator” or “phytoremediator.” It absorbs heavy metals and other chemical waste from the soil [12]. Accordingly, if large quantities of hemp are being cultivated to produce CBD, it is critically important that the quality of the soil is closely monitored and regulated.

The seeds of industrial hemp plants have important uses in human nutrition. They are a good source of protein, and the seed oil is rich in Omega-3 and Omega-6 fatty acids. The seed is used to make bread, cereals, and protein powder; the oil is used for margarine, salad dressing, cosmetics, and dietary supplements.

However, hemp seeds contain virtually no cannabinoids, which are in the flowers and (to a lesser extent) in the upper leaves [13]. Hemp seed oil is often used to dissolve the thick CBD extract (hence the term “CBD hemp oil”); however, as noted, olive oil, refined coconut oil, and other vehicles also can be used (hence the term “CBD oil”). In all cases, the CBD has been extracted from the flowering portion of the plant. If the entire plant is harvested, the CBD has been extracted from the total plant material, including the flowering portion.

6.3. FDA's enforcement actions relating to “CBD oils”

Under the Food, Drug, and Cosmetic (FD&C) Act, any item is considered a drug (subject to FDA's approval process) if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. The FDA determines “intended use” by reviewing a number of sources, such as advertisements and promotional statements (including websites, social media, etc.). Only products that have been FDA approved may make medical claims, and those claims must be consistent with FDA-approved labeling and give fair balance to risk information.

In February 2015 [14] and February 2016 [15], FDA issued *Warning Letters* to online CBD vendors. These letters identified specific CBD products that were misbranded because of medical claims on vendor websites. FDA's test results showed that most of the products contained little-to-no CBD; other products contained higher levels of THC than that listed on the label [14,15]. Many of these products were advertised as “nutraceuticals” or dietary supplements. In the 2016 *Warning Letters*, FDA informed the vendors that artisanal CBD products are excluded from the dietary supplement definition under the FD&C Act (21 USC 321 ff(3)(B)(ii)): if an article (e.g., CBD) is being studied as an investigational (pharmaceutical) product in “substantial clinical investigations” (i.e., Investigational New Drug [IND] exemption), and the existence of such investigations had been made public, then products containing that substance are outside the definition of a dietary supplement. The “article” being researched under an IND can be a finished product or a component of a product (e.g., CBD:THC [1:1] investigational product). As a correlate, the rule applies even if the pharmaceutical product and

the proposed dietary supplement do not have the same composition (e.g., Cholestin [red yeast rice containing lovastatin] and Mevacor [pure synthetic lovastatin]).

The Dietary Supplement Health and Education Act (DSHEA) represented a compromise between protecting the resources involved in pharmaceutical development and permitting reasonable access to dietary supplements. The provision does establish an exception if the article or substance was “marketed as” a dietary supplement or as a conventional food before the new drug clinical investigations were authorized. However, CBD was being studied as of 2006 in US-based clinical trials (involving a 1:1 CBD:THC investigational product). Based on available evidence, FDA concluded that CBD had not been previously marketed in food or as a food or dietary supplement. Moreover, the article or substance must be overtly marketed, as would be evidenced by its label. The presence of trace amounts of CBD in hemp seed oil products would not be sufficient to satisfy the “marketed as” requirement. In addition, since CBD is a Schedule I substance under the CSA, it is likely that any overt marketing of CBD would have been (and still is) in violation of federal law and for that reason would probably not have been legally “marketed as” a food or dietary supplement (even if that might be allowable under state law).

6.4. The scope of the Farm Bill

The 2014 “Farm Bill,” Section 7606 of the Agricultural Act 2014 (7 USC 5940), has contributed to further confusion in this area. The Farm Bill authorizes institutions of higher education or State Departments of Agriculture to grow “industrial hemp” for “research conducted under an agricultural pilot program or other agricultural or academic research,” so long as state law permits the growth and cultivation of the plant. For purposes of the Farm Bill, industrial hemp is defined as *Cannabis sativa* L., having a THC concentration $\leq 0.3\%$. However, “research” is not defined.

Some states interpret the Farm Bill as authorizing them to license independent, private cultivators who grow hemp, extract the CBD, and sell the resulting products on the retail market. But what really is the scope of this law? The U.S. Department of Agriculture, the Department of Health and Human Services (DHHS), and DEA recently issued a Notice concerning the Farm Bill, stating that it did not remove industrial hemp from Schedule I. If private persons are to conduct the research under a pilot program, they must be 1) licensed, registered, or otherwise authorized by the State Department of Agriculture to conduct the research or 2) employed by or under a production contract or lease to conduct research from an institution of higher education. Furthermore, industrial hemp must be cultivated exclusively for industrial purposes, which involve the fiber and seed (hence, by implication, not the flowering tops). Also, industrial hemp products may be sold in a state that has a pilot program **for purposes of marketing research**, but **not** for the purpose of general commercial activity. Finally, the Farm Bill does not change the requirements of the FD&C Act, including the fact that human therapeutic research involving CBD would have to be conducted under an IND and approved by an Institutional Review Board (IRB) [16]. Accordingly, it appears that the scope of the Farm Bill is quite narrow.

6.5. Cultivation of hemp outside the purview of the Farm Bill

In 2013, the Department of Justice (DOJ) issued a memorandum providing guidance to US attorneys regarding the exercise of investigative and prosecutorial discretion [17]. In the document, the DOJ indicated that it is not a federal priority to take enforcement action against individuals or businesses acting in accordance with state cannabis laws (medical or recreational), so long as the state has “strong and effective” regulatory and enforcement systems in place, and the cannabis-related activities in the state must not adversely affect eight listed “federal interests,” including the prevention of distribution to minors and drugged driving. The memorandum also applied to the cultivation and manufacture of industrial hemp outside the lawful purview of the Farm Bill [18]. A recent federal court ruling states that the DEA cannot expend resources to interfere

with a state's implementation of its “medical marijuana” law, including prosecuting individuals acting in compliance with that state law. *U.S. v. McIntosh*, No. 15-10117 (9th Cir. Ct. App.) (Aug. 16, 2016).

6.6. What is the likelihood that cannabis or CBD will be rescheduled?

Since 1972, several petitions to reschedule cannabis have failed. On August 11, 2016, DEA denied the two most recent marijuana rescheduling petitions because DEA and FDA found that marijuana has no currently accepted medical use and a high potential for abuse [19]. However, DEA previously noted that NIDA, FDA, and DEA have been working together to consider the potential rescheduling of pure CBD.

Scheduling or rescheduling can be initiated by an “interested person” in the form of a petition, by the DOJ/DEA, or by DHHS, usually as part of FDA's evaluation of a New Drug Application (NDA). To reschedule a Schedule I substance (or to schedule a New Chemical Entity), the NDA sponsor and DEA and FDA perform an analysis of eight statutory factors (the 8-Factor Analysis [8FA]) and use the results to identify the appropriate schedule (21 U.S.C. Sections 811, 812). Analyses include preclinical in vitro and in vivo studies (e.g., receptor binding, drug discrimination, self-administration, withdrawal/dependence, and conditioned place preference), clinical trials and any use of the specific substance outside these trials (including use outside the United States), human abuse liability studies, and laboratory manipulations to assess whether the active ingredient can be extracted for purposes of abuse. Therefore, whether the agencies independently evaluate the appropriate scheduling of CBD, or whether this assessment is conducted as part of an NDA for a CBD investigational product (several products are in ongoing clinical studies), CBD will need to undergo a full examination for abuse potential in compliance with FDA's regulatory guidance.

Upon completion of those studies (if conducted as part of a full NDA submission), the data will be analyzed by the manufacturer, and the manufacturer will propose a scheduling placement to the FDA. The FDA will review those data and at, or close to, NDA approval, will recommend a scheduling placement to the DEA. Within 90 days, the DEA will issue an “interim final rule” (IFR) scheduling the substance, under which rule the product may be marketed and dispensed. The DEA then conducts a full administrative rescheduling/scheduling process, during which time the public is given an opportunity to comment or object. After reviewing and responding to public comments, DEA issues a final rule in the Federal Register.

In general, a substance and all products containing it are in the same schedule (e.g., opium and morphine) under the CSA. However, “differential” scheduling is sometimes possible. For example, the prescription cannabinoid, Marinol, with a specific description (synthetic dronabinol/THC in sesame oil in a soft gelatin capsule in an FDA-approved product) was placed in Schedule II following its FDA approval in 1985 and, 14 years later, upon the petition of the manufacturer, was moved to Schedule III (64 Fed. Reg. 35928 (July 2, 1999); 21 CFR Section 1308.13(g)(1)), while THC in any other form remains in Schedule I (21 CFR Section 1308.11(d)(31)). Another synthetic cannabinoid, nabilone (Cesamet), was also placed in Schedule II after its FDA approval in 1985 (52 Fed. Reg. 11042 (April 7, 1987)), and no petition has yet been filed to move it to a lower schedule. If a specific cannabinoid (e.g., CBD) secures FDA approval, perhaps DEA will reschedule only that cannabinoid and retain cannabis (and other individual cannabinoids) in Schedule I.

Unless and until more rigorous and robust safety and efficacy data are produced for a number of specific, standardized cannabis preparations, it is unlikely that FDA and DEA will find that cannabis, as a substance, has a “currently accepted medical use,” a necessary prerequisite for placement in a lower schedule. Of course, 1) DEA could modify its criteria for establishing such accepted medical use or 2) Congress may schedule, reschedule, or entirely deschedule a substance through the enactment of legislation, without an analysis of abuse liability data and without a specific determination of “accepted medical use.”

7. Conclusions

The conflict between federal and state laws on the medical use of cannabis products, the lack of consistency among state laws, and the availability of artisanal cannabis and CBD products in dispensaries and online has caused significant confusion for researchers, practitioners, and patients and their caregivers, particularly with regard to CBD products. The DEA's most recent denial of two marijuana rescheduling petitions means that marijuana and its constituent cannabinoids, including CBD from any source, including hemp, will currently remain in Schedule I. However, DEA has taken some steps to facilitate future research.

Conflict of interest

Alice Mead is an employee of GW Pharmaceuticals, Inc., Carlsbad, CA.

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