Important Legislative and Regulatory Changes Impacting the Commercialization of Cannabis, Hemp, and CBD

Charles Andres

A number of important changes have occurred in the cannabis, hemp, and cannabidiol (CBD) spaces. This alert presents a snapshot of significant developments and selected future predictions.

1) The U.S. Food and Drug Administration (FDA) approved the first CBD oil drug

Recently, the FDA approved GW Pharmaceutical's oral CBD based drug, Epidiolex, to treat severe forms of epilepsy. In its press release, the FDA notes: “CBD is a chemical component of the Cannabis sativa plant, more commonly known as marijuana. However, CBD does not cause intoxication or euphoria (the “high”) that comes from tetrahydrocannabinol (THC).” Epidiolex's effectiveness was studied in three randomized, double-blind, placebo-controlled clinical trials involving 516 patients, and was shown to be effective in reducing the frequency of seizures when compared with a placebo.

The approval is significant for many reasons, including that it represents the first time the U.S. federal government has acknowledged there are medicinal benefits to be obtained from substances derived from a cannabis plant.

2) The Drug Enforcement Administration (DEA) rescheduled some, but not all, CBD derived from cannabis

Before Epidiolex's approval, CBD was classified by the DEA under the Controlled Substances Act, and subsequent amendments, as a schedule I substance—meaning that CBD had “no medically accepted use.” The FDA’s approval of Epidiolex meant that, by definition, all CBD could no longer be classified as having “no medically accepted use.”

Accordingly, the DEA rescheduled some CBD from a schedule I to a schedule V substance. Schedule V substances are considered to have the lowest abuse potential and a low potential for psychological or physical dependence. Importantly, only small amounts of cannabis derived CBD are classified as schedule V. As recited in the DEA’s Federal Register Notice: “Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V.”

3) The Farm Bill recognizes significant legal differences between CBD derived from hemp and CBD derived from cannabis

Congress and the President recently enacted the Agriculture Improvement Act of 2018, or the Farm Bill. The Farm Bill has several important provisions. For purposes of this section, the two most important provisions are as follows:

First, the Farm Bill defines hemp to mean “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” Second, the Farm Bill amends the Controlled Substances Act to state that “marihuana” [sic] does not include “hemp” and excludes from schedule I controlled substances “tetrahydrocannabinols in hemp.”

Because hemp and its extracts—which would include CBD—are not included in “marihuana” under the Controlled Substances Act, the Farm Bill provides for: the broad cultivation of hemp, the transfer of hemp-derived products in interstate commerce, and the sale of these; so long as all of the above are done in a manner consistent with all federal and state laws.

4) Commercialization of Hemp in the United States

Because of the Farm Bill’s hemp provisions, we expect the financial structure of the hemp industry to differentiate from the financial structure of the cannabis industry (e.g., all cash transactions). We expect hemp to pivot towards conventional banking and financial services. We also expect investments and capital inputs to increase in the hemp industry.

5) The FDA’s approval of the first drug containing CBD, and the hemp provisions in the Farm Bill, may open the door for more medical research on hemp derived CBD

In announcing Epidiolex's approval, FDA Commissioner Scott Gottlieb stated: “We’ll continue to support rigorous scientific research on the potential medical uses of marijuana-
derived products and work with product developers who are interested in bringing patients safe and effective, high quality products.”10 Gottlieb was explicitly signaling that the FDA is willing to work with pharmaceutical companies to bring cannabis derived products to market.

Enactment of the Farm Bill, coupled with the FDA’s willingness to consider drugs containing CBD, could open the door to an increase in FDA regulated research and approvals of drugs containing hemp derived CBD.

6) Placing CBD in foods and dietary supplements

In a recent statement, FDA Commissioner Scott Gottlieb stated in part: Additionally, it’s unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it’s illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.9

Thus, the FDA will likely continue to take enforcement actions against companies selling dietary supplements and foods that contain CBD, regardless of whether the CBD ingredient was derived from hemp or cannabis. Importantly, enforcement action will likely increase if drug claims are included in promotional messaging and labeling.

7) A tension, and uneasy truce, exists between federal and state law regarding cannabis (and CBD derived from cannabis)

The majority of states currently allow for the possession and consumption of cannabis and/or cannabis derived products (for recreational purposes), for medical uses, or in some limited capacity (e.g., for high CBD, low THC oil).9

Thus, the laws in each state can be different, and state laws often conflict with federal law (e.g., the Controlled Substances Act). A somewhat uneasy truce currently exists, after e.g., the Department of Justice, or DOJ, issued its enforcement position in an August 29, 2013, memorandum.10 This memorandum indicates, in part, that the DOJ will utilize enforcement resources based on specifically enumerated priorities, and for the most part, rely on state and local authorities to regulate “small amounts of marijuana for personal use on private property.”10

8) Physicians’ “recommendations” for cannabis and cannabis derived substances

The FDA does not regulate the practice of medicine by physicians. Nevertheless, most cannabis and cannabis derived substances—as schedule I substances—are illegal at the federal level under the Controlled Substances Act and other federal laws. Thus, any state law that allows physicians to “prescribe” cannabis could conflict with federal law. And such a conflicting state law could be found to be invalid under the Supremacy Clause of the Constitution. Therefore, many states have addressed this dilemma by implementing laws built around the Ninth Circuit’s Conant v. Walters case.11,12

In Conant, the court held that the federal government could not revoke a physician’s license to prescribe a controlled substance solely because the physician “recommended” the use of medical marijuana to a patient. The court also held that the federal government could not conduct an investigation that could lead to revocation where the basis for the government’s action is solely the physician’s professional “recommendation” of the use of medical marijuana.12 The court reasoned, in part, that the physician’s recommendation was an expression that was protected by the free speech provisions of the First Amendment, and that the dispensing of information—or a “recommendation” concerning a controlled substance—is different than the dispensing of controlled substances.12

Thus, under many state laws, physicians will, if appropriate in their professional medical opinion, “recommend” rather than “prescribe” medical marijuana.

9) A patent land grab may occur in the cannabis, hemp, and CBD spaces

Historically, many companies and individuals have been hesitant to file patents for cannabis, and cannabis derived substances, for fear that doing so would make it easier for the federal government, and specifically the DEA and DOJ, to identify and target these companies and individuals. This may change given the ground swell of favorable public opinion, the FDA’s approval of Epidiolex, the passage of the Farm Bill, and an influx of venture capital into cannabis- and hemp-related businesses.

In addition to utility patents, federal patent law13 allows for patent protection of invented or discovered and asexually reproduced plants (other than tuber propagated plants or plants found in an uncultivated state). The Farm Bill, among other things, also expands the Plant Variety Protection (PVP) Act to cover asexually reproduced varieties,14 creating the possibility of obtaining utility patents, plant patents, and PVP certificates as forms of intellectual property protection.

10) Cannabis, hemp, and CBD patents must still meet statutory requirements and, like other utility patents, can be challenged in the federal courts and the U.S. Patent and Trademark Office

Because CBD patents, including medical drug patents, may become more valuable and listed in the Orange Book,15 these patents may be challenged in federal district courts and in the U.S. Patent and Trademark Office. An example is U.S. Patent No. 9,066,920 (the ’920 patent), owned by GW Pharma Limited and Otsuka Pharmaceutical Co., Ltd. The ’920 patent contains 13 claims. Representative independent claim 1 recites:
A method of treating partial seizure comprising administering cannabidiol (CBD), to a patient wherein the CBD is present in an amount which provides a daily dose of at least 400 mg.

Claims 1-13 were challenged in an inter partes review, and claims 1 and 2 were found to be unpatentable. While it is noteworthy that claims 1-2 were shown to be unpatentable, it is equally noteworthy that claims 3-13 remained patentable.

**CONCLUSION**

Federal and state law on hemp, cannabis, and CBD continue to evolve in a fast-paced, and not-always-predictable, fashion. It is recommended that companies operating in these areas consult counsel early and often to understand and minimize the risk of running afoul of federal and state laws, and regulatory agencies.

For questions regarding hemp, CBD, and related issues, please contact Jeff Guise, Vern Norviel, David Hoffmeister, or any member of WSGR’s patents and innovation strategies or FDA/life sciences groups. (*Altern Ther Health Med.* 2019;25(S2):36-38.)

**REFERENCES**

11. *Conant v. Waters*, 309 F.3d 629 (9th Cir. 2002), cert. denied.
12. *Conant*, being a Ninth Circuit Case, does not apply to every state in the U.S. Nevertheless, many states have interpreted the U.S. Supreme Court’s denial of certiorari as an indication that the Supreme Court agrees with the Ninth Circuit’s holding.
13. 35 U.S.C. §: 161. The statute states: Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.
14. See the Farm Bill, Section 10108. The Amendment recites: (b) Right to Plant Variety Protection; Plant Varieties “Protectable.—Section 42(a) of the Plant Variety Protection Act (7 U.S.C. 2402(a)) is amended by striking ‘or tuber propagated’ and inserting, ‘tuber propagated, or asexually reproduced.’”
15. For example, Epidiolex has eight U.S. patents listed in the Orange Book, each with a listed expiration date in 2035. See https://www.accessdata.fda.gov/scripts/Cder/ob/patent_info.cfm?Product_No=001&Appl_No=210365&Appl_type=N.