LAW OFFICES OF
MICHAEL E. CINDRICH, APC

750 B STREET
SUITE 3300
SAN DIEGO, CALIFORNIA 92101

PHONE: (619) 262-2500
FAX: (619) 819-7342
MIKE@MICHAELCINDRICH.COM

October 17, 2016

Sent Via Email Only

Medical Marijuana, Inc.
Stuart W Titus, President & CEO
12255 Crosthwaite Circle
Poway, CA 92064
858-264-6400 x420
stuart@general-hemp.com

Re: LEGAL OPINION LETTER ON HEMP-BASED CBD DISTRIBUTION

Dear Mr. Titus:

This letter is addressed to you in your capacity as President and CEO of Medical Marijuana, Inc.; and its two wholly owned subsidiaries HempMeds PX, LLC, and Kannaway, LLC. You have requested that I render an opinion regarding the legality of distributing hemp-based cannabidiol ("CBD") oil throughout the United States. After thorough analysis of the applicable statutes, case law, and regulations, it is my opinion that the distribution of CBD oils derived from imported hemp is lawful in all 50 states under certain circumstances. Although CBD is a component part of cannabis, which is prohibited as a Schedule I drug under the Controlled Substances Act ("CSA"), there are several exceptions to the prohibition on cannabis that allow for the sale of hemp products in general and CBD oil in particular. With that being said, I must add the important caveat that the intended uses for which CBD oil can be sold are limited at this time.

I. Hemp Overview

Congress passed the CSA as Title II of the Comprehensive Drug Abuse Prevention and Control Act in 1970. The CSA created five categories (or "Schedules") of drug and medicine classification. Schedule I is the harshest of the five categories. Schedule I drugs are defined as having a "high potential for abuse," "no currently accepted medical use in treatment," and a "lack of medical safety for use […] under medical supervision."[1] Marijuana is a Schedule I drug.[2] Marijuana consists of the dried flowers, leaves, and stems

[1] 21 U.S.C. §812.

[2] Several bills have been proposed to move cannabis from a Schedule I to a Schedule II drug or to remove it from scheduling entirely, all of which have died in committee. See John Hudak and Grace Wallack, *How to Reschedule Marijuana, And Why It's Unlikely Anytime Soon,* Brookings Institute (Feb. 13, 2015), http://www.brookings.edu/blogs/fixgov/posts/2015/02/13-how-to-reschedule-marijuana-hudak-wallack.

of the female cannabis plant.[3] While the definition under the CSA does extend regulation to the plant's component parts, the following parts are explicitly excluded: "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, **any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks** (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."[4]

Non-psychoactive hemp is not a regulated substance under the CSA. Technically speaking, hemp is the *Cannabis sativa* plant. However, products made from hemp are typically derived from the "mature stalks" or "oil and cake made from the seeds of such plant," which fit within the plainly stated exception to the CSA definition of marijuana. The Drug Enforcement Agency ("DEA") has previously attempted to ban the sale of hemp products intended for human consumption. However, a federal court of appeals found that the agency exceeded its authority under the CSA by doing so in the case Hemp Industries Association, et al, v. Drug Enforcement Administration ("HIA v. DEA").[5]

HIA v. DEA involved a dispute between manufacturers of hemp products and the DEA over three DEA rules regarding hemp and THC. HIA argued that the DEA exceeded its statutory authority by making rules regulating non-psychoactive hemp. The DEA conversely contended that its rules were intended to clarify the regulation of tetrahydrocannabinol ("THC") under the CSA. THC is the psychoactive component contained in cannabis, which is also separately classified and regulated under the CSA. Through the challenged rules, the DEA purported to ban all products intended for human consumption containing naturally-occurring THC, including the THC found in hemp seed and oil.[6] The court has repeatedly held that the definition of "THC" in Schedule I of the CSA refers only to synthetic THC, and that any THC occurring naturally within cannabis is banned only if it falls within the Schedule I definition of "marijuana." Accordingly, the 9th Circuit Court of Appeals found that the DEA had exceeded its authority in enacting this rule, given that regulation of THC under the CSA was intended to apply only to synthetic THC, and held that "[t]he DEA's Final Rules are inconsistent with the unambiguous meaning of the CSA definitions of marijuana and THC, and the DEA did not use the appropriate scheduling procedures to add non-psychoactive hemp to the list of controlled substances."

Therefore, it is well-established that hemp and hemp-based products that contain little to no THC are legal to import and sell in the U.S.

\\

3 "Marijuana," *Merriam-Webster* (2014), http://www.merriam-webster.com/dictionary/marijuana
4 21 USC § 802(16) (emphasis added).
5 333 F.3d 1082 (9th Cir. 2003).
6 66 Fed. Reg. 51,530 (October 9, 2001).

II. CBD Overview

Cannabis is a "versatile and chemically complex plant" with many known uses.[7] It has been utilized for therapeutic purposes for millennia by civilizations all over the world.[8] Although "cannabis is one of the oldest psychotropic drugs in human history," its merits as medicine are heavily debated in contemporary society.[9] The plant contains over 400 chemical compounds, and our understanding of their impacts on the human body is ever-increasing.[10] CBD is one of many cannabinoids found in cannabis. It is a non-psychoactive component, which is often extracted with minimal THC and used for the treatment of maladies ranging from seizure disorders to PTSD.

Hemp-based oils with high concentrations of CBD likely fall under the exception to the prohibition to marijuana carved out by the court in HIA v. DEA. The hemp-based CBD oil is produced from the mature stalks of the plant, and therefore fall outside of the scope of the CSA. Unlike THC, CBD is not separately enumerated as a scheduled substance in the CSA. Also unlike THC, CBD is non-psychoactive. However, because of its recognized healing properties CBD is currently under investigation by the FDA as a potential new drug. Due to this ongoing investigation, the FDA has claimed that CBD products cannot be sold for a number of intended uses.

A. FDA Regulation of CBD

The FDA has statutorily granted authority to regulate food, drugs, medical devices, dietary supplements, cosmetics, and tobacco products.[11] The FDA has implemented standards to ensure safety and efficacy for each of these categories. Under the guidelines, hemp-based CBD oil could potentially be considered a food, dietary supplement, or drug. It should be noted here that, by the DEA's own admission, hemp-based products not intended for human consumption – such as lotions and serums – are outside the scope of FDA regulation and considered lawful.

i. CBD as a Drug

The FDA has not yet approved CBD for "the diagnosis, cure, mitigation, treatment, or prevention of disease." Therefore, CBD oils cannot be marketed and sold as drugs unless and until the FDA approves it as a safe and effective new drug. Although some studies have indicated that CBD is effective in preventing seizures, reducing inflammation, and

---

7 Gregg Bliz*, The Medical Use of Marijuana: The Politics of Medicine,* 13 Hamline J. Pub. L. & Pol'y, 118 (1992).

8 Carolynn Conron, *Canada's Marijuana Medical Access Regulations: Up In Smoke*, 6 Alb. Gov't L. Rev. 259, 261 (2013)

9 American Medical Association, *REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-09): Use of Cannabis for Medicinal Purposes* (2009), available at http://www.procon.org/sourcefiles/AMAReport_CouncilSciencePublicHealth.pdf.

10 Id.

11 21 U.S.C. Ch. 9

even inhibiting cancer growth, these claims cannot be made in the marketing of CBD products. In fact, on February 4, 2016, the FDA issued warning letters to eight CBD hemp oil retailers for making unproven medical claims about 22 different hemp-derived CBD products.

While CBD has not yet been approved as a drug, the FDA has authorized CBD for investigation as a new drug. The FDA has asserted that, while it is under investigation, CBD does not fit the definition for "a dietary supplement" or food additive.[12] The FDA has further concluded that the exception that allows products that were marketed as dietary supplements or conventional food products prior to the investigation to continue to be marketed as dietary supplements during the investigation does not apply to CBD. On its website, the FDA states that it "is not aware of any evidence that would call into question this conclusion.[13]" However, it invites interested parties to "present evidence that they think has bearing on this issue."[14]

ii. CBD as a Dietary Supplement

The FDA's contention that hemp-based CBD oils were not marketed as dietary supplements or conventional food additives before the new drug investigations were launched is unfounded. Under the FDA definition, "a dietary supplement is a product intended for ingestion that contains a 'dietary ingredient' intended to add further nutritional value to the diet."[15] Examples of dietary supplements include vitamins, minerals and other herb and botanical substances. Because hemp oil is high in nutritional value and essential fatty acids, it is often found in dietary supplements. Hemp oil is widely sold in health food stores throughout the U.S. – and has been for years. Therefore, hemp-based CBD oil clearly fits within the dietary supplements category, and meets the exception for continued sale despite being under investigation as a new drug.

iii. CBD as a Food

Under the Food, Drug & Cosmetics Act ("FDCA"), the term "food" is also loosely defined. It encompasses all products that are intended to be consumed as foods or are otherwise labeled or represented as food products.[16] Products that meet this definition must comport with the FDA's regulations for food, but do not need to undergo the "rigorous premarket approval process" pertaining to drugs.[17] Hemp-based CBD oil meets the broad definition for food if is intended for human consumption by oral ingestion, or presented in the form of foodstuffs. In general, hemp has been grown for food production for thousands of years. Because hemp oil is high in nutritional value, it is often found in food products and dietary

---

12 See 21 U.S.C. § 321(ff)(3)(B)(ii); FDA, FDA and Marijuana (last visited Oct. 10, 2016), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm

13 Id.

14 21 U.S. Code § 321(g)(1).

15 FDA, *2016 Warning Letters and Test Results for Cannabidiol-Related Products*, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm (last visited Oct. 10, 2016).

16 See 21 U.S.C. §321, Sec. 201(f)

17 Heinzerling p. 13.

supplements. Hemp oil with high CBD concentration is also widely sold in health food stores throughout the U.S. CBD may satisfy common use in food because there is a substantial history of consumption of hemp oil and thus its constituent CBD for food use.

There are several products on the market today that are treated as conventional foods, despite the fact that they clearly contain drugs. Coffee and tea, for instance, contain caffeine.[18] In contrast to the common use provisions, these substances may be added to foods when they are "Generally Recognized As Safe" (GRAS) for the intended use. Intended as a nutrient in conventional foods, hemp-based CBD oils are likely GRAS because hemp products that are imported from outside of the United States in general are GRAS.

However, a premarket determination is unnecessary. Specifically, the FDCA does not require the manufacturer to obtain the opinion of FDA about the GRAS status of hemp oil or CBD prior to using it as or in conventional foods. Thus, GRAS status is determined by the company itself. However, the FDA may disagree with a company's determination that a substance is GRAS. In that instance the FDA may pursue enforcement proceedings. Thus, although the law presents no affirmative obligation on the manufacturer, an unsupported has GRAS determination regulatory risks.

In describing when it would take enforcement actions for CBD products marketed as dietary supplements or foodstuffs containing CBD, the FDA said that it would consider "agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action."[19] Overall, hemp-based CBD oils can be sold lawfully so long as distributors avoid making medicinal claims, do not market them as intended for use as drugs, test the products for safety, and accurately label CBD percentages.

B. CBD Regulation at the State Level

Despite the fact that the federal government continues to classify marijuana as a Schedule I drug with no recognized medical use and a high potential for abuse, 25 states and the District of Columbia have enacted laws legalizing medical marijuana.[20] The medical marijuana industry has flourished because the Department of Justice (DOJ) has generally chosen not to enforce federal anti-marijuana policies in the states that have legalized the drug.[21] The states have become solely responsible for the criteria and implementation of medical marijuana laws within their borders, creating a "patchwork" that varies greatly from state-to-state.[22]

---

18 Medicines in my Home: Caffeine and Your Body, FDA (2007), http://www.fda.gov/downloads/UCM200805.pdf

19 FDA and Marijuana, supra n. 12.

20 21 U.S.C. §812.

21 James M. Cole, Memorandum for all United States Attorneys: Guidance Regarding Marijuana Enforcement. United States Department of Justice, Office of the Deputy Attorney General (August 29, 2013), available at http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf.

22 FDA and Marijuana, supra n. 12.

As a part of this medical marijuana movement, 16 states have passed versions of "CBD-only" laws to permit the production, sale and use of high CBD products.[23] Notably, none of the CBD-only states, except for Kentucky, require compliance with federal law regarding industrial hemp.[24] Each state sets its own limits on who can obtain CBD products and under what conditions they can be sold. Therefore, it is important to keep in mind that certain state limitations may apply. A federal court in US v. McIntosh found that § 542 prohibits DOJ from spending funds from relevant appropriations acts for the prosecution of individuals who engaged in conduct permitted by state medical marijuana laws and who fully complied with such laws. However, individuals who do not strictly comply with all state-law conditions regarding the use, distribution, possession, and cultivation of medical marijuana have engaged in conduct that is unauthorized, and prosecuting such individuals does not violate § 542. If hemp-based CBD oil were to be marketed as medicine in accordance with applicable state law, it would likely fit within the exception carved out in US v. McIntosh.

The Omnibus Appropriations Act of 2016 (P.L. 114-113), passed on December 18, 2015, contains a similar provision at section 763 that reads: "None of the funds made available by this act or any other act may be used… to prohibit the **transportation**, processing, **sale** or use of industrial hemp that is grown or cultivated in accordance with section 7606 of the Farm Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated."

Based on the Omnibus Appropriations Act of 2016 and the decision in US v. McIntosh, imported hemp-based CBD oils may be sold in all 50 states without fear of prosecution. While neither Omnibus Act nor the federal court case mention CBD specifically, CBD is a naturally occurring component part of hemp and it is reasonable to assume that CBD is covered by these laws.

\\

\\

[23] Alabama, Florida, Georgia, Idaho, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, Wyoming.

[24] In the 2014 Farm Bill, Congress carved out an exception to the CSA's definition of cannabis for "industrial hemp," defined as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 USC § 7606(b)(2).

III. Conclusion

Overall, the laws applying to CBD are complex, nuanced, and in flux. At the federal level, hemp-based CBD oil does not fall under the definition of marijuana provided under the CSA. The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule CBD as a separate substance. Therefore, CBD derived solely from mature hemp stalks, whether from a state which has legalized hemp growth and cultivation or from overseas, is legal throughout the US. However, the marketing of CBD must be done in accordance with the FDA rules. CBD-specific state laws further complicate matters, but provide more of a shield than a sword in that compliance with state law will certainly protect against prosecution.

Sincerely,
LAW OFFICES OF MICHAEL E. CINDRICH, APC

Michael E. Cindrich