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July 8, 2013

RE: Concerning the Legality of Cannabidiol (CBD) Oil under Federal Law

This law firm represents the CannaVest Corporation. I am providing this letter on behalf of my client in response to your request for a legal opinion as to the federal legality of ******* industrial hemp-derived CBD products. Based upon my professional judgment, the following analysis applies to the sale of CBD products. Please note that this Letter does not constitute a guaranty of a potential outcome in a court of law, but rather, is a comprehensive analysis of the CSA and its related judicial interpretation in this context.

QUESTION PRESENTED

Is industrial hemp-derived CBD oil produced and sold in the United States a violation of the Controlled Substances Act (CSA)?

SCOPE/ASSUMPTIONS

The legal analysis contained herein addresses the federal statutory and regulatory provisions of the United States Controlled Substances Act, Title 21, Chapter 13, U.S.C.S., pertaining to the sales and distribution of cannabidiol oils and products. This question is specifically targeted to cannabidiol (CBD). Importantly, this analysis is based on the assumption that the raw product industrial hemp material are lawfully imported[1] from international markets, and the CBD oil/products are produced and manufactured within the United States from said import materials.

This letter is limited to the analysis of the CSA, and does not address, nor does it consider, the rules or regulations governing the Food and Drug Administration, the Federal Food, Drug, and Cosmetic Act (often abbreviated as FFDCA, FDCA, or FD&C), or Investigational New Drug (IND) rules, as they may or may not be applicable.

[1] Lawfully imported under approved tariff codes to its FDA registered and certified facility in the United States.

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SHORT ANSWER

No. The sale, production and distribution of CBD oils/products derived from imported raw material industrial hemp is not in violation of the CSA.

ILLUSTRATIVE CHART

See attached summary flow chart.

BACKGROUND

Industrial hemp is a commonly used term for non-psychoactive, non-drug varieties of the species Cannabis sativa L. that are cultivated for industrial rather than drug purposes. Industrial hemp plants grown in Canada, China, and Europe are bred to contain less than 0.3% and 0.2% by weight of tetrahydrocannabinol (THC), the psychoactive element, in the upper portion of the flowering plant, respectively, versus the drug marijuana varieties, which typically contain 3 to 25% THC in their flowers.

Cannabidiol is naturally occurring in industrial hemp and is devoid of psychoactive effect. As set forth herein, natural cannabinoids from industrial hemp are specifically exempt from the CSA. Since natural cannabinoids are found in all industrial hemp products, and industrial hemp products are found in many grocery store shelves nationwide, industrial hemp oils are the easiest legal manner in which to obtain CBD. Products made from industrial hemp are found in retail stores nationwide, thanks to a federal exemption to the definition of "marijuana," as explained below.

Since 1937, federal law has specifically provided that industrial hemp fiber, sterilized seed and seed oil are *exempt* from the definition of "marihuana" and are thus *not* controlled substances under that law. Under the CSA, illegal marijuana does *not* include industrial hemp fiber, seed or oil. The definition of "marihuana" specifically *excludes* "the mature stalks of such [cannabis] 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…." 21 U.S.C. § 802(16).

The CSA's predecessor statute with respect to regulation of marijuana was the Marihuana Tax Act of 1937, which set forth a definition of marijuana that the CSA adopted without change. The Marihuana Tax Act specifically differentiated between drug marijuana and industrial hemp through a system under which drug marijuana varieties of cannabis were taxed at a level so high

as to effectively prohibit their production, while non-drug industrial hemp cultivation was assessed a minimal tax in order to permit and encourage its production.

In general, the drug is derived from the flowers or leaves of the plant while the fibers used for rope and other industrial products are taken from the stalk. Cannabis sativa plants grown for industrial hemp products generally are cultivated and mature differently from those intended for the marijuana drug. All contain THC, the ingredient that gives marijuana its psychoactive/euphoric properties; but those plants grown for drug use contain a significantly higher concentration of THC than those grown for most industrial products. Industrial hemp seeds and oil typically contain minuscule trace amounts of naturally occurring THC.

Industrial hemp can be grown as a fiber and/or seed crop. The statutory exclusion of industrial hemp stalk, fiber, sterilized seed, and seed oil from the scope of the CSA has enabled U.S. individuals and businesses to legally import, purchase, use, and trade in sterilized industrial hemp seeds, oil, stalk and fiber, and products made from those exempt parts of the plant. Industrial hemp food, oil and fiber products are available throughout the world. Industrial hemp is currently cultivated by farmers in more than 30 countries including Canada, England, France, Germany, Hungary, Russia and China. Like CannaVest, companies currently selling industrial hemp fiber, seed and oil products in the U.S. generally either import industrial hemp fiber, seed and oil from Canada, Asia or Europe, for use in manufacturing these products in the U.S., or import already finished products from Canada or Europe.

In *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012 (9th Cir. 2004), the Ninth Circuit ruled that naturally occurring cannabanoids in industrial hemp foods, including oil, were never scheduled under the CSA; therefore, the DEA has no jurisdiction. This means that CBD, and even THC, when in industrial hemp oil, are legal.

When the Hemp Industries Association defended industrial hemp's exempt status in Federal Court in 2004, the DEA declined to challenge this ruling, which is why there continues to be a wide variety of industrial hemp products on the market today. *See Hemp Industries Association v. DEA,* 357 F.3d 1012 (9th Cir. 2004). If the DEA really was trying to ban industrial hemp foods, it would have appealed; that did not occur. CBD producers and distributors can rely on this case, accordingly.

In this case, the Court concluded: "[a]s in the case of poppy seeds commonly consumed on bagels and expressly exempted from the CSA, that come from a non-drug variety of, but the same species as, the opium poppy…non-psychoactive hemp seed products do *not* contain any controlled substance as defined by the CSA..." 357 F.2d at 1017. The Court further found that

"[t]he non-psychoactive hemp in…products is derived from the 'mature stalks' or is 'oil and cake made from the seeds' of the Cannabis plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana. … Congress knew what it was doing and its intent to exclude nonpsychoactive hemp from regulation is entirely clear." *Id*. at 1018.

Thus, it is clear that industrial hemp stalk, fiber, non-viable seed and oil, and products of any and all kinds made from those plant parts, have always been, and remain, lawful under the CSA.

The DEA's present position is that CBD is a schedule I controlled substance under the CSA. However, I am an attorney who has thoroughly researched this issue. And I believe the DEA is mistaken when its states that industrial hemp-derived CBD is illegal. Regardless of what the DEA may say, I know of no prosecution or seizure of these products ever occurring. There are extensive procedures that must be followed in order to place a substance within any of the Schedules listed in the Controlled Substances Act, and that process has never been initiated with respect to CBD. That process would likely fail anyway because of the Ninth Circuit's opinions in the Hemp Industries Association's cases. *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012 (9th Cir. 2004); *Hemp Indus. Ass'n v. DEA,* 333 F.3d 1082 (9th Cir. 2003). These cases expressly exempt all naturally occurring cannabinoids from the CSA's definition of marijuana; and this ruling even protects patients in non-legal states, since it is a federal decision. I seriously doubt that any prosecution under the CSA for industrial hemp derived CBD would survive a motion to dismiss. Thus, the DEA's position is devoid of logic, and is unsupported by the law, as set forth herein.

DISCUSSION

1. IMPORTATION OF RAW INDUSTRIAL HEMP/INDUSTRIAL HEMP OIL

The importation of industrial hemp is lawful under U.S. Law, as set forth herein.

A number of United States District Court cases have examined the issue of cultivating industrial hemp in the United States and have found that the domestic ***cultivation*** of such may be a violation of the CSA. *See New Hampshire Hemp Council, Inc. and Derek Owen v. Donnie R. Marshall, Acting Administrator, United States Drug Enforcement Administration*, 203 F.3d 1 (1st Cir. 2000); *United States of America v. Alexander "Alex" White Plume*, 447 F.3d 1067 (8th Cir. 2006); *Monson, et al v. DEA, et al*, 589 F.3d 952 (8th Cir. 2009). But these rulings

concerning ***cultivation*** of industrial hemp have recently been statutorily relaxed by the passage of the Farm Bill.[2]

However, the foregoing cases are all distinguishable, as they focus on the domestic ***cultivation*** of industrial hemp, and do not examine the lawful possession and processing of imported industrial hemp into a variety of CBD products. Federal Courts have concluded that it is indeed lawful to import the stalks, fibers, and oils of industrial hemp, as follows. *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012, 1014 (9th Cir. 2004); *Hemp Indus. Ass'n v.DEA,* 333 F.3d 1082, 1089 (9th Cir. 2003). These 9th Circuit cases, and the operations of the plaintiffs in those cases, are directly analogous to that of CannaVest, who produces CBD products derived from imported industrial hemp. There has been no negative treatment by any court in the U.S. regarding these 9th Circuit cases; and, as set forth above, these decisions were not appealed by DEA.

The express language of the CSA has, since 1937, specifically provided that industrial hemp fiber, sterilized seed and seed oil are *exempt* from the definition of "marihuana" and are thus *not* controlled substances under that law. By virtue of this exclusion, it is currently lawful under federal law—and has been for almost 70 years—to import into the U.S., sell within the U.S., and make and sell products made from, the excluded parts of the Cannabis plant—*i.e.*, industrial hemp fiber, stalk, seed and oil.

This statutory exclusion has allowed U.S. individuals and businesses to legally purchase, use and trade in sterilized hempseeds, hempseed oil, hempseed cake, hemp fiber and products made therefrom. Due to minimal THC content, leaves and flowers from industrial hemp have no potential for drug use. Article 28 of the *UN Single Convention Treaty on Narcotic Drugs*, 1961, signed by the USA in 1968, explicitly states that: "This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes."

As succinctly stated by the Federal Court, "[t]he industrial hemp plant itself, which falls under the definition of marijuana, may not be grown in the United States. Therefore, the seeds and oil must be *imported*." 333 F.3d at 1085 n.2 (emphasis added). Relying on this statutory exemption, U.S. individuals and businesses have purchased and sold consumable products containing

[2] *See* Section 7606 of the Agricultural Act of 2014, concerning the Legitimacy Of Industrial Hemp Research, which states that: "[n]otwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), the Safe and Drug-Free Schools and Communities Act (20 U.S.C. 7101 et seq.), chapter 81 of title 41, United States Code, or any other Federal law, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)) or a State department of agriculture may grow or cultivate industrial hemp…"

sterilized industrial hemp seeds and oil, which generally are imported from Canada or Europe. *Id.* It has been further noted by our Supreme Court that these fibers -- industrial hemp, sisal, jute, manila, and the like -- could not be grown in the United States,[3] and must be imported. *Limbach v. Hoover & Allison Co*., 466 U.S. 353 (1984)(noting that industrial hemp fibers are not grown in the United States but can be imported).

Thus, imported product falling within the exception to the CSA can be lawfully imported.

2. Legal Definition of Marihuana[4]/Marijuana

The present definition of "marijuana" was first employed in the Marihuana Tax Act of 1937, 50 Stat. 551. There, the basic definition covered all cannabis sativa plants whether intended for industrial use or drug production, but the statute effectively distinguished between these two distinct uses by taxing them differently. All producers of cannabis sativa and certain legitimate users (e.g., doctors) were subject to a small tax, ($1 per year), Marihuana Tax Act § 2(a), 50 Stat. at 552; see also S. Rep. No. 75-900, at 4, but no tax was applied to transfers of the mature stalk of the plant, which is useful only for industrial use, S. Rep. No. 75-900, at 4, and which was specifically excluded from the definition of "marijuana." Marihuana Tax Act § 1(b), 50 Stat. at 551.

In 1970 Congress adopted the Controlled Substances Act (codified at 21 U.S.C. § 801 et seq.) repealing the 1937 tax statute, but carrying forward its definition of marijuana into the present criminal ban on production, sale and possession. *United States v. Walton*, 514 F.2d 201, 203 (D.C. Cir. 1975). In 1937 Congress had indicated in legislative history that production for industrial uses would be protected (primarily by a relatively low tax), see S. Rep. No. 75-900, at 4; Smith, 269 F.2d at 218-20. Congress' main vehicle for protecting industrial use plant production in 1937 was not its basic definition of "marijuana," which included plants ultimately destined for industrial use; it was the complex scheme of differential tax rates and other requirements for transfers.

The CSA makes it illegal to manufacture, distribute, dispense, or possess any controlled substance except as authorized by the CSA. 21 U.S.C. §§ 841(a)(1), 844(a). A controlled substance is anything listed in a schedule under the CSA. *Id.* at § 802(6). The CSA establishes five "schedules" of controlled substances differentiated by the scheduled drugs' potential for abuse, usefulness in medical treatment, and potential consequences if abused. To be placed on

[3] *See* Note 2 re recent legislative exception.
[4] Federal statutes use the spelling "marihuana," but for uniformity I substitute the more popular spelling.

Schedule I, a drug or substance must have a "high potential for abuse," must have "no currently accepted medical use in treatment in the United States," and there must exist "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1).

"Marihuana" (marijuana) and "tetrahydrocannabinols" (THC) are both listed on Schedule I. *Id.* at § 812(c)(Schedule I)(c)(10), (17)). Given the 1937 intent to protect industrial uses and the carrying forward of the definition, the 1970 statute should also be read to protect production for industrial uses by interpolating this distinction between psychoactive and non-psychoactive strains of cannabis sativa.

Under the CSA, "marijuana" is defined--not by the DEA but by Congress--as follows:

> [A]ll parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. ***Such term does not include 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.
>
> 21 U.S.C. § 802(16)(emphasis added).

By definition, the listing of "marijuana" in Schedule I ***excludes*** 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. *Id.* (quoting 21 U.S.C. § 802(16)).

The above analysis was expressly noted, as the Court interpreted the foregoing definition, and held that "the listing of 'marijuana' in Schedule I excludes 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." (quoting 21 U.S.C. § 802(16)).

Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin, stalks, oil or cake of non-psychoactive industrial hemp when it passed the

1937 "Marihuana Tax Act," and when it adopted the Tax Act marijuana definition in the CSA. As a result, when Congress excluded from the definition of marijuana such portions of a cannabis plant.

Thus, imported industrial hemp stalks, fibers, oils, or cakes derived from a hemp plant imported internationally are not legally defined as marijuana and are, thus, not unlawful to possess. Such is not "marijuana." Here, CBD products produced and sold by CannaVest, made from the non-psychoactive hemp, is derived from the "mature stalks" or is "oil and cake made from the seeds" of the cannabis plant and, therefore, these products fit within the plainly stated exception to the CSA definition of "marijuana."

3. Definition of THC

Thus far, it is clear that CBD products produced from the stalks and fibers of a lawfully imported industrial hemp plant is lawful, as it falls outside of the definition of "marijuana." But what about THC? Industrial hemp plants do contain trace amounts (not to exceed .3%) THC.

The definition of "THC" under the CSA includes ***only*** synthetic THC. 21 C.F.R. § 1308.11(d)(27). THC is defined there as "[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers...." The lawful definition of THC expressly ***excludes*** THC that is naturally occurring in the stalks and fibers of a lawfully imported industrial hemp plant. And the controlled substances listing of THC is different from the listings for DMT, mescaline, psilocybin, and psilocyn, the definitions for which are not limited to synthetic forms of the drugs. *See* 21 C.F.R. § 1308.11(d).

In *Hemp Indus. Ass'n. v. DEA, supra,* the court held that the DEA could regulate products containing natural THC if it is contained within marijuana, and can regulate synthetic THC of any kind. But they cannot regulate *naturally-occurring* THC *not* contained within or derived from marijuana, i.e., non-psychoactive hemp products, because non-psychoactive hemp from the stalks and fibers of such a plant is not included in Schedule I. The Court concluded that the "DEA has no authority to regulate drugs that are not schedule…." *Id.* at 1018.

Furthermore, the Court concluded, "[I]f naturally-occurring THC were covered under THC, there would be no need to have a separate category for marijuana, which obviously contains naturally-occurring THC. Yet Congress maintained marijuana as a separate category." *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012, 1014 (9th Cir. 2004)(quoting *Hemp Indus. Ass'n v. DEA,* 333 F.3d 1082, 1089 (9th Cir. 2003).

In summary, under the CSA, the DEA can regulate foodstuffs and related products containing natural THC if it is contained within "marijuana," and can regulate synthetic THC of any kind. But they cannot regulate *naturally-occurring* THC *not* contained within or derived from marijuana--i.e., non-psychoactive industrial hemp products--because nonpsychoactive industrial hemp is not included in Schedule I, as set forth above. This is because statutes must be interpreted strictly and pursuant to their specific terms, and because the DEA has no authority to regulate drugs that are not scheduled. CannaVest's products do not contain the "synthetic" "substances or derivatives" that are covered by the definition of THC, and nonpsychoactive industrial hemp is explicitly excluded from the definition of marijuana.

4. Preemption Argument

In addition to the foregoing, even "marijuana" utilized for medical purposes may not fall under the CSA in any event. Surprisingly, no court as yet, state or federal and including this Court and the United States Supreme Court, has made a full analysis of the history of the federal Controlled Substances Act to determine whether the medical use of marijuana under a state program was intended by Congress when the Act was promulgated in 1970 to even be covered by the Act. *See*, Garvey, Todd, "Medical Marijuana: The Supremacy Clause, Federalism, and the Interplay Between State and Federal Laws," Congressional Research Service Report for Congress, No. R42398 (November 9, 2012) ("CRS Report), 4 at 12.

Although the U.S. Supreme Court in *Raich*, did hold that the production and consumption of medical marijuana under state programs are within Congress's power to regulate the activity under the Commerce Clause, it did not reach the issue of whether Congress had in fact done so through the federal Controlled Substances Act ("CSA"). *City of Garden Grove v. Superior Court*, 157 Cal.App.4th 355, 382 (Cal. App. 2008); *see also, discussion*, Mikos, 62 Vand. L. Rev. at 1441-2 (2009).

If the activities of acquisition, possession, growing, manufacture, and distribution of marijuana, and the implementing legislation setting up a medical marijuana state's program of registration and licensing are authorized by state law, such would appear to come into direct conflict with the prohibitions of the CSA expressly prohibiting such activities unless one of the following were to occur or exist: (1) marijuana was removed by an act of Congress as a listed substance under Schedule I of the CSA; (2) marijuana was delisted as a Schedule I substance by the DEA/FDA through the administrative procedure set forth in the CSA; or (3) a court interpreting the CSA ruled that Congress only intended the Schedule I listing in 1970 to include "non-medical" uses of

marijuana and that, therefore, recognized "medical uses of marijuana" under a state program and regulation do not fall within the Schedule I listing.

The first two do not appear likely to occur anytime soon, leaving in jeopardy the status of medical marijuana programs in various states. Neither the United States Supreme Court, nor any other high court has as yet engaged in a proper and full Preemption Doctrine analysis to determine whether the Congress, the drafters of the CSA, ever intended to include state recognized medical uses of marijuana in the CSA's Schedule 1 listing of marijuana, or whether the listing was intended to be limited to non-medical uses such as recreational uses of marijuana. A proper analysis requires an in-depth examination of the legislative history of the federal CSA to determine the actual intent of Congress. It remains an issue of first impression within the United States.

If it can be demonstrated that when Congress promulgated the federal CSA in 1970 that it intended to cover *only* non-medical uses of marijuana, then subsequently enacted state recognized medical uses of marijuana would not fall within the scope of the federal CSA, there would be no conflict between the medical marijuana states and the federal scheme and purpose of the CSA, and medical marijuana would not be in violation of federal law.

The relevant portion of the CSA, 21 U.S.C. § 812, states:

> **Schedules of controlled substances.**
> **…**
> **(b)** ***Placement on schedules*****;** ***findings required***
> Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, *a drug or other substance* ***may not be placed in any schedule unless the findings required for such schedule are made*** *with respect to such drug or other substance*.
> The *findings required* for each of the schedules are as follows:
> **(1) Schedule I.** –
>
> (A) The drug or other substance has a high potential for abuse.
> (B) The drug or other substance has ***no currently accepted medical use in treatment in the United States***.
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

> By the plain language of the Act, in order to place a substance such as marijuana under Schedule I of the CSA, there has to be a specific "finding, among other findings, that: "The drug or other substance has ***no currently accepted medical use in treatment in the United States***." 21 U.S.C. §812(b)(1)(B).

Bu there is extensive evidence and state adopted legislation expressly indicating that medical marijuana does indeed have accepted medical uses in the U.S.

In the late 1980s, DEA Chief Administrative Law Judge Francis L. Young heard testimony over two years from a number of physicians and other experts and patients on the medicinal value of marijuana, found that a "respectable minority" of American physicians accept those uses, and ruled that was sufficient to demonstrate that marijuana had a currently accepted medical use supporting the rescheduling of marijuana from Schedule I.19.

The U.S. government has also formally acknowledged the medical benefits of marijuana. On April 1999, the United States filed a patent application for the use of cannabinoids, defined broadly to include all cannabinoids including THC and cannabidiol (CBD), to "provide a new class of antioxidant drugs that have particular application as neuroprotectants …"

Furthermore, over one-third of the US, states, population, and territory, have legalized marijuana for medical use through state programs.

The plain, common, meaning of the word "currently" is "occurring or belonging to present." *Brigham Young Univ. v. Pfizer*, 2010 WL 3855347, *3 n. 19 (D.Utah 2010) (citing, Merriam-Webster Dictionary 445 (1998)). When read with the Section 812(b) requirement that there be explicit "findings" *at the time of scheduling*, the term "currently" refers to the time of scheduling. *See, e.g., Owens v. U.S. Dept. of Ag.*, 45 F.Supp.2d 509, 511 n. 3 (W.D.Va. 1998). Thus, by the clear language of the statutory provision itself, there was no accepted medical use of marijuana *at the time* Congress temporarily placed it under Schedule I *in 1970.*

"The statutory findings required for agency scheduling decisions clearly state that the agency may not, in the presence of Congressional action, subject drugs with a currently accepted medical use in the United States to Schedule I controls." *Grinspoon*, 828 F.2d at 890.

That said, it is likely that a Court would determine that the CSA is preempted by these state programs, laws, and science.

CONCLUSION

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In conclusion, *********'s CBD products, as set forth herein, are not unlawful under the CSA.

Sincerely,

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