Alcohol & Marijuana Control Office
550 W. 7th Ave, Suite 1600
Anchorage, AK 99501

Date: 2/10/17
Case Number:AB17-070

Notice of Violation

(3AAC 306.805)

Licensee	License Number	Type of License
Silverthorn Investment Group LLC	**10316**	**Retail**
D.B.A.	**How Delivered**	**Law Enforcement Agency**
Denali 420 Recreationals	**Electronic/Certified Mail**	**AMCO**
Street or P.O. Box	**City, State**	**Zip**
2876 N Rex Road	**Houston, AK**	**99694**

This is a notice to you as licensee that an alleged violation has occurred. If the Marijuana Control Board decides to act against your license, under the provisions of AS 44.62.330 - AS 44.62.630 (Administrative Procedures Act) you will receive an Accusation and Notice of your right to an Administrative

On 2/9/17 It was observed by AMCO investigators that your location had marijuana oil (CBD Oil) manufactured from a source outside the State of Alaska for sale. This action is in violation of the following:

3AAC306.305-Retail Marijuana Store Privileges
3AAC306.310-Acts Prohibited at Retail Marijuana Store
3AAC306.330-Marijuana Inventory Tracking System
3AAC306.340-Testing Required for Marijuana and Marijuana Products
3AAC306.345-Packaging and Labelling

Reference:
AS17.38.010(b)(2),(3)
AS17.38.131-Enforcement Powers
AS17.38.900(10),(15)-Definitions
3AAC306.830-Seizure of Marijuana Product
3AAC306.830(b)-Seizure of Marijuana Product (Hearing within 10 Days)

Hearing Note: This is not an accusation or a criminal complaint.

You are directed to respond to the Director of the Marijuana Control Board in writing to this Notice of Violation within 10 days of receipt to explain what action you have taken to prevent a reoccurrence of this violation. FAILURE TO RESPOND TO THIS NOTICE OF VIOLATION WITHIN 10 DAYS WILL RESULT IN YOUR APPEARANCE, EITHER IN PERSON OR TELEPHONICALLY, BEFORE THE MARIJUANA CONTROL BOARD AT THEIR NEXT REGULARLY SCHEDULED BOARD MEETING.

***Please include your Marijuana Establishment License Number in your response.**

Alcohol & Marijuana Control Office
ATTN: Enforcement Unit
550 W. 7th Ave, Suite 1600
Anchorage, Alaska 99501

A Response is Required

3 AAC 306.805 provides that upon receipt of a Notice of Violation, a licensee may request to appear before the board and be heard regarding the Notice of Violation. The request must be made within ten days after receipt of the Notice. A Licensee shall respond, either orally or in writing, to the Notice.

Receipt:	Violation Observed By: Rukes
Filed By: Jeff Rukes	Title: Investigator III

THE STATE of ALASKA
GOVERNOR BILL WALKER

Department of Commerce, Community, and Economic Development

ALCOHOL AND MARIJUANA CONTROL OFFICE

550 West 7th Ave, Suite 1600
Anchorage, AK 99501
Main: 907.269.0350
Fax: 907.272.9412

February 10, 2017

Denali 420
2876 N. Rex Road
Houston, AK 99694
Via Certified and Electronic Mail

NOTICE OF HEARING

Re: Alaska Retail Marijuana Store License #10316

You are hereby notified that, on February 9, 2017, the following marijuana product was seized from your licensed place of business in accordance with 3 AAC 306.830. Seizure of marijuana or marijuana product :

Description of Item	Estimated Weight/Volume/Amount
*Please see attached Written Inventory Receipt	

The marijuana product listed above was found to be in violation of regulations pertaining to licensure as a Marijuana Retail Establishment:

3 AAC 306.305. Retail marijuana store privileges

3 AAC 306.310. Acts prohibited at retail marijuana store

3 AAC 306.330. Marijuana inventory tracking system

3 AAC 306.340. Testing required for marijuana and marijuana products

A hearing before the board has been scheduled to discuss the disposition of the items listed above.

Time: 1:00 pm
Date: 2-17-17
Location: 550 West 7th Avenue Suite 1600 Conference room, Anchorage, AK 99501

To participate telephonically, you must provide the following investigator the telephone number at which a registered representative of the licensed business may be reached. Your representative will be contacted at this number at the appointed time of hearing.

Investigator: Joe Bankowski
Email address: joe.bankowski@alaska.gov
Phone number: 907-269-0355

If a registered representative of the licensed business does not appear in person or participate telephonically at this hearing, or if after a hearing the board finds that seizure of the marijuana product was justified, the marijuana product may be destroyed.

A registered representative of the licensed business may request a reasonable delay by notifying the investigator listed above no later than 48 hours prior to the hearing. The seized items will remain in the possession of the state until the board has rendered a decision.

Please contact the investigator listed above with any additional questions you may have.

Denali 4/20

9DL
- Charlotte's web Disp vape pen
9DL - mint Chocholate - 19
9DL Strawberry - 16
9DL Natural - 11
9DL Charlotte's web
9DL Everyday mint chocholate 1
1 oz olive oil 1
9DL Everyday plus Olive oil 1
1 oz
9DL Everyday mint chocholate 1
3.38 oz Olive oil 1
9DL - Everyday plus mint chocholate 1
3.38 oz Olive oil 2
9DL - Everyday Advanced olive oil 2
1 oz
9DL - Gel pen 2
2 mg
9DL - Hemp extra 5
30 capsules

9DL Mary's Nutritionals
- Transdermal patch - 9
.92 g
9DL muscle freeze 2
75 mg, 1.5 oz

9DL muscle freeze 2
200mg 4 oz

JDZ Marijs Nutritionals -2
30 - 5 mg Capsules

JDZ Compound -2
100mg 1oz

JDZ Gel Pen -2
50 - 2mg Doses
.3oz

21/9/17

LANCE CHRISTIAN WELLS
ALASKA CANNABIS LAW GROUP, LLC.
733 West 4th Avenue, Suite 308
Anchorage, AK. 99501
www.LanceCWells.com
lwells@gci.net

Phone 907-274-9696 **Fax 907-277-9859**

February 16, 2017 Hand Courier Delivery

Ms. Sara Chambers, Acting Director
AMCO
550 W. 7th Avenue, Suite 1600
Anchorage, AK. 99501

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ALCOHOL MARIJUANA CONTROL OFFICE
STATE OF ALASKA

RE: My Client Silverthorn Investment Group, LLC
d/b/a Denali 420 Recreationals
License Number 10316
Response to Notice of Violation
Your Case Number AB17-070

Dear Ms. Chambers:

I am in receipt of the Notice of Violation dated 2/10/2017, reference the CBD's seized and removed from Denali 420 Recreationals, LLC as well as other retail stores throughout Alaska. In response to the notice of violation and the email you subsequently circulated, please rest assured that no CBD's or other marijuana products will be placed upon the shelves or made for sale unless made in Alaska, tested and passed certification and sold through licensed AMCO purveyors. Your email was clear. You have our full support and attention on this. Furthermore, all persons employed and working with Denali 420 have been advised of this as well.

While not meaning any disrespect, it was and is still believed by me as well as others within the marijuana legal community that since these products are sold nationally and carried by major chain stores throughout the United States including Alaska (and still are) they were not subject to AMCO regulations as they contain no THC and that their sale is not in violation of any federal law or DEA claimed reclassification of which their authority to do so is once again questionable. See attached.

However, we will comply with all your requirements and no longer will they be made available at the store nor have they been since their seizure occurred. This matter is going through the court process at this time and I suspect we will again receive a favorable ruling as there is already 9th Circuit precedent favorable to this particular issue. I have

included several opinions for your review. We will just have to see where it goes with the 9th Circuit and perhaps then AMCO will reevaluate its position on this subject.

I would like to schedule a time to speak before the board as to this matter pursuant to 3 AAC 306.805 at a time that is convenient. I will be present in person for the hearing on 2/17 @ 1:00 p.m. and Mr. Jared Lamb will be available by phone at 907-342-2454. Investigator Bankowski has also been made aware of this on 2/15/2017 via phone message.

In closing, Denali 420 Recreationals is dedicated to working with AMCO, seeing this through and doing it right. I am requesting the violation be dismissed as this particular area was unclear under the state regulations, no clear guidelines in place and appears still under investigation by AMCO. Lastly, 9th circuit authority seemed clear as to this issue.

Thank you for taking the time to consider this letter and its attachments.

Sincerely yours,
Alaska Cannabis Law Group, LLC.

Lance C. Wells, Esq.

cc: Client Jared Lamb: Denali 420 Recreationals

Enclosure

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357 F.3d 1012 (9th Cir. 2004), 03-71366, Hemp Industries Ass'n. v. Drug Enforcement Admin. /**/ div.c1 {text-align: center} /**/

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357 F.3d 1012 (9th Cir. 2004)

HEMP INDUSTRIES ASSOCIATION; All-One-God-Faith, Inc., dba Dr. Bronner's Magic Soaps; Atlas Corporation; Nature's Path Foods USA Inc.; Hemp Oil Canada, Inc.; Hempzels, Inc.; Kenex Ltd.; Tierra Madre, LLC; Ruth's Hemp Foods, Inc.; Organic Consumers Association, Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION, Respondent.

Hemp Industries Association; All-One-God-Faith, Inc., dba Dr. Bronner's Magic Soaps; Atlas Corporation; Nature's Path Foods USA Inc.; Hemp Oil Canada, Inc.; Hempzels, Inc.; Kenex Ltd.; Tierra Madre, LLC; Ruth's Hemp Foods, Inc.; Organic Consumers Association, Petitioners,

v.

Drug Enforcement Administration, Respondent.

Nos. 03-71366, 03-71693.

United States Court of Appeals, Ninth Circuit

February 6, 2004

Argued and Submitted Sept. 17, 2003.

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Joseph E. Sandler, Sandler Reiff & Young, Washington, D.C. and Patrick Goggin, San Francisco, CA, for the petitioners-appellants.

Daniel Dormont, Senior Attorney, Drug Enforcement Administration, Washington, D.C., for the respondent-appellee.

On Petition for Review of an Order of the Drug Enforcement Agency. DEA Nos. Fed.Reg. DEA-205F, DEA-206F.

Before SCHROEDER, Chief Judge, B. FLETCHER, and KOZINSKI, Circuit Judges.

OPINION

BETTY B. FLETCHER, Circuit Judge.

Appellants manufacture, distribute, or sell comestible items containing oil or sterilized seeds from "hemp"--a species of plant within the genus *Cannabis.* They challenge two Drug Enforcement Administration ("DEA") regulations that, taken together, would ban the sale or possession of such items even if they contain only non-psychoactive trace amounts of tetrahydrocannabinols ("THC"). The DEA asserts that natural, as well as synthetic, THC is included in Schedule I of the Controlled Substances Act ("CSA"). We have previously held that the definition of "THC" in Schedule I 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."[1] We reiterate that ruling here: in accordance with Schedule I, the DEA's relevant rules and regulations may be enforced only insofar as they ban the presence of marijuana or synthetic THC.

I. BACKGROUND

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Appellants' business activities include importing and distributing sterilized hemp seed and oil and cake derived from hemp seed, and manufacturing and selling food and cosmetic products made from hemp seed and oil.[2] On October 9, 2001, the

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DEA published what it labeled an "Interpretive Rule" stating that "any product that contains any amount of THC is a schedule I controlled substance...." Interpretation of Listing of THC in Schedule I, 66 Fed.Reg. 51530, 51533 (Oct. 9, 2001). This rule would have banned the possession and sale of Appellants' products. On the same day, the DEA proposed two rules that subsequently became final on publication in the Federal Register on March 21, 2003. Clarification of Listing of THC in Schedule I, 68 Fed.Reg. 14114 (March 21, 2003). These rules ("Final Rules") are the subject of the instant appeal. DEA-205F amends the DEA's regulations at 21 C.F.R. § 1308.11(d)(27) so that the listing of THC in Schedule I includes natural as well as synthetic THC. DEA-206F exempts from control non-psychoactive hemp products that contain trace amounts of THC not intended to enter the human body. We stayed enforcement of the Final Rules pending disposition of this appeal.

Appellants challenged the putative Interpretive Rule in *Hemp Industries Assoc. v. DEA,* 333 F.3d 1082 (9th Cir. 2003) (" *Hemp I* "). During our consideration of that case, the DEA notified us that it would soon issue the Final Rules. We set aside considering the merits of *Hemp I* to await them. After their publication, we solicited briefing from both parties as to whether *Hemp I* was rendered moot by the publication of the Final Rules. Appellants in *Hemp I* argued that the case was not moot. A majority of the panel agreed. *Hemp I* was filed on June 30, 2003.

Hemp I addressed whether the putative Interpretive Rule was an interpretive rule or a legislative rule under the Administrative Procedure Act. That question turned primarily on whether the putative Interpretive Rule would "amend the DEA's own regulation on the coverage of naturally-occurring THC in Schedule I." *Hemp I,* 333 F.3d at 1088. In that context, we 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.

Id. (quoting 21 U.S.C. § 802(16)). We held further that the listing of THC in Schedule I, as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970, applied only to synthetically-created THC. We reasoned that "if 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 I,* 333 F.3d at 1089. We concluded that THC naturally-occurring within non-psychoactive hemp products did not fall under the DEA's regulation, which provided:

The Director has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having a potential for abuse because of their:

..

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(3) Hallucinogenic effect:

..

Synthetic equivalents of the substances contained in the plant, or in the resinous

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extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity....

21 C.F.R. § 320.3(c) (1970).[3] We held that the imposition of a ban on THC occurring naturally within non-psychoactive hemp products amended the DEA's own regulations, and that doing so could be accomplished, if at all, only by a legislative rule. *Hemp I,* 333 F.3d at 1091. We explicitly reserved the question of the validity of the DEA's proposed legislative rules, which have become the Final Rules, until the instant case was before us. *Id.*

II. JURISDICTION

We have jurisdiction to review Appellants' claims that the DEA's Final Rules are invalid under 21 U.S.C. § 877, and the claim of a violation of the Regulatory Flexibility Act under 5 U.S.C. § 611.

III. ANALYSIS

Appellants offer three arguments why the Final Rules may not be enforced with respect to THC naturally-occurring in non-psychoactive hemp products. First, they argue that DEA-205F is a scheduling action--placing non-psychoactive hemp in Schedule I for the first time--that fails to follow the procedures for such actions required by the Controlled Substances Act ("CSA"). Second, they argue that the adoption of DEA 206F is arbitrary and capricious in exempting non-psychoactive hemp products intended to be eaten by animals but not those intended to be eaten by humans, when humans seeking (in vain) any psychoactive effect from these substances could easily eat either. Third, they argue that in issuing DEA-205F, the DEA violated the Regulatory Flexibility Act ("RFA"). We need not reach the latter two arguments because we agree with appellants that the DEA scheduled non-psychoactive hemp without following the required procedures.

We review federal rules and regulations under *Chevron U.S.A, Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). Under *Chevron's* two-part test, "we must decide (1) whether the statute unambiguously forbids the Agency's interpretation, and, if not, (2) whether the interpretation, for other reasons, exceeds the bounds of the permissible." *Barnhart v. Walton,* 535 U.S. 212, 218, 122 S.Ct. 1265, 152 L.Ed.2d 330 (2002) (citing *Chevron,* 467 U.S. at 843, 104 S.Ct. 2778). While at step one we "must give effect to the unambiguously expressed intent of Congress," if "the statute is silent or ambiguous with respect to the specific issue," at step two we will "sustain the Agency's interpretation if it is based on a permissible construction" of a statute. *Id.* at 217-18, 122 S.Ct. 1265 (internal quotation marks omitted).

A. Procedures for Scheduling a Controlled Substance

Since under the *Chevron* standard we conclude that Congress did not regulate non-psychoactive hemp in Schedule I, we must consider whether the DEA followed the appropriate procedures to schedule it as a controlled substance. The DEA concedes

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that it did not use the following procedures spelled out in the CSA to adopt the Final Rules.

Under 21 U.S.C. § 811(a):

the Attorney General may by rule--

(1) add to such a schedule or transfer between such schedules any drug or other substance if he--

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed.

... Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5[5 U.S.C. §§ 551 et seq.].

21 U.S.C. § 811(a) calls for formal rulemaking procedures, as described in 5 U.S.C. §§ 556 and 557. Formal rulemaking requires hearings on the record, and section 557(c) invites parties to submit proposed findings and oppose the stated bases of tentative agency decisions, and requires the agency to issue formal rulings on each finding, conclusion, or exception on the record. We will not reproduce the entirety of the Administrative Procedure Act here; it suffices to say that the DEA did not and does not claim to have followed formal rulemaking procedures.

In addition, the DEA did not comply with § 811(a)(1)(B), because the findings required by § 812(b) were not made. Section 812(b) states:

(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.

The DEA does not purport to have met the requirements for placement of non-psychoactive hemp on Schedule I, and indeed disclaims any need to show that non-psychoactive hemp "has a high potential for abuse." Instead, the DEA argues that naturally-occurring THC in those parts of the hemp plant excluded from the definition of "marijuana" have always been included under the listing for "THC," and that it had no previous need to clarify this because the intentional use of such products in foodstuffs is relatively new within the United States. The DEA urges that under *Chevron* its definition of the meaning of "THC" in the CSA should be given deference. However, no deference is required because this issue is resolved at *Chevron* step one: the statutory language on point unambiguously precludes an interpretation of the THC definition that includes non-psychoactive hemp.

B. CSA Definitions of THC and Marijuana

Two CSA provisions are relevant to determining whether Appellants' hemp products

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were banned before the passage of the Final Rules: the definition of THC and the definition of marijuana. Both are unambiguous under *Chevron* step one: Appellants' products do not contain the "synthetic" "substances or derivatives" that are covered by the definition of THC, and non-psychoactive hemp is explicitly excluded from the definition of marijuana.

1. Statutory Definition of THC

The DEA contends that Appellants' food products may be banned as "any material compound, mixture or preparation" that "contains any quantity of" THC. *See* 21 C.F.R. § 1308.11(d). However, the definition of THC under the CSA includes only synthetic THC. 21 C.F.R. § 1308.11(d)(27) (defining banned THC 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....").[4] As we noted in *Hemp I,* with a more elaborate explanation than we will provide here:

Notably, if 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 I, 333 F.3d at 1089. 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).

Therefore, DEA-205F may ban products that "contain[ ] any quantity" of THC only insofar as it does not improperly expand the definition of THC as it is used in the CSA. For the same reason, 21 U.S.C. §§ 823(f) and 841(a)(1), which disallow human consumption of Schedule I controlled substances outside of FDA-approved, DEA-registered research, do not apply to non-psychoactive hemp products: such products do not contain a "Schedule I controlled substance" as the CSA defines it.

As we did in *Hemp I,* we reject the DEA's contention that the Final Rules merely "clarify that the longstanding placement of THC in schedule I includes both natural and synthetic THC." 68 Fed.Reg. 14116 (Mar. 21, 2003). The DEA's action is not a mere clarification of its THC regulations; it improperly renders naturally-occurring non-psychoactive hemp illegal for the first time.

2. Statutory Definition of Marijuana

Under 21 U.S.C. § 802(16):

The term "marihuana" means all 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.

The non-psychoactive hemp in Appellants' 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

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stated exception to the CSA definition of marijuana.

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Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) in the resin of non-psychoactive 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 "mature stalks of such plant, fiber ..., [and] oil or cake made from the seeds," it also made an exception to the exception, and included "resin extracted from" the excepted parts of the plant in the definition of marijuana, despite the stalks and seeds exception.[5] 21 U.S.C. § 802(16). Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from regulation is entirely clear. The 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.

Although we have determined that non-psychoactive hemp is not banned under Schedule I, we need not determine in this proceeding whether under the current statute it could be listed if the agency were to undertake appropriate rulemaking. We hold only that the DEA did not follow the requisite proceedings for scheduling under 21 U.S.C. §§ 811(a) and 812(b). The Final Rules therefore may not be enforced with respect to THC that is found within the parts of *Cannabis* plants that are excluded from the CSA's definition of "marijuana" or that is not synthetic.

We find unambiguous Congress' intent with regard to the regulation of non-psychoactive hemp. Therefore, we reject the Final Rules at step one of the *Chevron* test and need not reach *Chevron* step two.[6]

IV. CONCLUSION

The DEA's Final Rules purport to regulate foodstuffs containing "natural and synthetic THC." And so they can: in keeping with the definitions of drugs controlled under Schedule I of the CSA, the Final Rules can regulate foodstuffs 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 is not included in Schedule I. The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance.

The DEA's definition of "THC" contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld. DEA-205F and DEA-206F are thus scheduling actions that would place non-psychoactive hemp in Schedule I for the first time. In promulgating the Final Rules, the DEA did not follow the

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procedures in §§ 811(a) and 812(b) of the CSA required for scheduling. The amendments to 21 C.F.R. § 1308.11(d)(27) that make THC applicable to all parts of the *Cannabis* plant are therefore void. We grant Appellants' petition and permanently enjoin enforcement of the Final Rules with respect to non-psychoactive hemp or products containing it.

PETITION GRANTED.

·Yogendra PRASAD, Petitioner, v. John ASHCROFT, United States Attorney General,

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Respondent., 2004 WL 583669 (Appellate Brief) (C.A.9 February 9, 2004), Brief for Respondent Briefs and Other Related Documents

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Notes:

[1] The Act spells this as "marihuana." We employ the modern spelling here.

[2] We refer to hemp stalks, fiber, oil and cake made from hemp seed, and sterilized hemp seed itself-- *i.e.,* those substances excluded from the definition of marijuana under 21 U.S.C. § 802(16)--as "non-psychoactive hemp." A "psychoactive" substance is one "affecting the mind or behavior." *Merriam-Webster Dictionary.*

The non-psychoactive hemp used in Appellants' products is derived from industrial hemp plants grown in Canada and in Europe, the flowers of which contain only a trace amount of the THC contained in marijuana varieties grown for psychoactive use. The hemp seed used in food products is an "achene," or small nut, that is either hulled for direct consumption or crushed for oil. It "contains 20 percent high-quality, digestible protein, which can be consumed by humans." U.S. Dept. of Agriculture, *Industrial Hemp in the United States: Status and Market Potential* 15 (Jan.2000), *available at* http://ers.usda.gov/publications/ages001e/ages001e.pdf. Hemp seed oil "has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils ... and a similar profile of other nutrients, such as sterols and tocopherols." Thompson, Berger & Allen, Univ. of Kentucky Center for Business and Economic Research, *Economic Impact of Industrial Hemp in Kentucky* 7-8 (July 1998), *available at* www.industrialhemp.net/pdf/hempstudy.pdf. Appellants list a wide range of current and planned commercial products that use hemp oil or seed, including roasted hulled seed, nutrition bars, tortilla chips, pretzels, beer, candy bars, margarine, sauces, dressings, and non-dairy versions of milk and cheese.

[3] In 1971 the title "Tetrahydrocannabinols" and a code number were added. The regulations were later transferred from 21 C.F.R. § 320.3(c) to 21 C.F.R. § 1308.11(d)(27). The Final Rules amended 21 C.F.R. § 1308.11(d)(27) to insert the words "Meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), as well as" immediately before "[s]ynthetic equivalents of the substances contained in the cannabis plant" in the section quoted above. In considering the propriety of the Final Rules, we necessarily consider the propriety of this amendment to § 1308.11(d)(27).

[4] The Final Rules at issue here amend the definition of THC to include naturally-occurring THC. Because we consider here the propriety of those amendments, we quote the previous definition, which had been in effect since 1970. *See supra* note 3.

[5] The DEA argues that because hemp seeds contain some THC, we should allow it to include hemp seeds and its derivatives as within the "exception to the exception" for the extraction of resin. Neither we nor the DEA are in any position to ignore the express exception for hemp seeds in the CSA, nor can we construe "resin" broadly to mean "seeds" as well. As the DEA informs us, the "exception to the exception" for resin was apparently included out of concern that the "active principle" in marijuana, later understood to be THC, might be derived from nonpsychoactive hemp and so be used for psychoactive purposes. We note that Congress' policy decision is still effective

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in prohibiting psychoactive drugs: the DEA makes no showing that extracts from parts of hemp seeds or stalks other than resin are used or could be used for psychoactive purposes.
[6] Because our conclusion with respect to *Chevron* deference suffices to invalidate DEA-205F as applied to non-psychoactive hemp products, we need not address Appellants' Regulatory Flexibility Act arguments.

Citing References :

447 F.3d 1067 (8th Cir. 2006), 05-1654, United States v. White Plume

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United States Court of Appeals, Eighth Circuit.05/17/2006 447 F.3d 1067

419 F.3d 949 (9th Cir. 2005), 03-16194, Wells Fargo Bank N.A. v. Boutris

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Teva Pharmaceuticals, Industries, Ltd. v. Food and Drug Administration, 122304 DCDC, 04-1416 (RBW)

United States District Court, District of Columbia12/23/2004

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HOBAN LAW GROUP

THE NATION'S PREMIER CANNABUSINESS FIRM

December 14, 2016

DÉJÀ VU? IS THE DEA UNLAWFULLY ATTEMPTING TO OUTLAW ALL CANNABINOIDS…AGAIN?

I. INTRODUCTION

The Drug Enforcement Administration (DEA) has, yet again, demonstrated its lawless recalcitrance for the prevailing law. A new Rule published in the *Federal Register*, and currently set to become effective on January 13, 2017, seeks to control all naturally occurring cannabinoids from the *Cannabis sativa L* plant. The DEA attempted something very similar in 2003, and the Ninth Circuit Court of Appeals rejected its efforts as unlawful and beyond the scope of the DEA's delegated Congressional authorization. But, here we go again.

Within the framework of existing laws, a robust cannabis industry, including consumer, textile and manufacturing industries based around non-psychoactive varieties of the *Cannabis sativa L.* plant and derivatives and cannabinoids derived therefrom, has evolved from the efforts of thousands of companies across the United States and globally. These industries, which already exist in the European Union, Latin America, Canada and China, among other countries, are rapidly growing, creating vast economic opportunities along with job creation. Absent a reversal or the striking of the DEA's Rule, these businesses and industries stand to suffer a devastating impact from this Rule. To protect these individuals, businesses and this industry, the DEA's actions cannot be overlooked.

More specifically, on Tuesday, December 14, the *Federal Register* published information concerning a Final Rule enacted by the DEA pertaining to a change to 21 CFR 1308. In sum, the DEA has created a new Administration Controlled Substances Code Number for "Marihuana Extract." According to the *Federal Register*, "[t]his code number will allow DEA and DEA-registered entities to track quantities of this material separately from quantities of marihuana" in order to comply with "relevant treaty provisions." There are a number of unusual things about this DEA action; not the least of which is that it appears to be, yet again, outside of the scope of the DEA's power and authority as it pertains to the legality and regulation of the *Cannabis sativa L* plant.

The fact that the DEA, an unelected government body with no legislative authority, is attempting to outlaw all cannabinoids is concerning and problematic as it pertains to portions of the plant not legally defined as "marihuana," and as it pertains to lawfully cultivated and processed Farm Bill-compliant industrial hemp. The discussion below addresses many of the salient reasons why the DEA's most recent action cannot stand, and outlines an action plan accordingly.

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II. DISCUSSION

A. The DEA/*Federal Register* Issue

The DEA's new definition for "Marihuana Extract" includes: "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." The primary problem with this new definition is that it purports to broadly outlaw all 80-plus cannabinoids [such as cannabidiol (CBD), cannabinol (CBN), cannabigerol (CBG), etc.] contained within this genus. And cannabinoids are not unlawful controlled substances. The only cannabinoid that has been specifically identified in the Controlled Substances Act (CSA) is tetrahydrocannabinol (THC), as set forth below.

Per the *Federal Register*, the DEA previously established separate code numbers for marijuana and for tetrahydrocannabinols (THC), but not for "Marihuana Extract." This is true, and directly related to the DEA's Congressionally-delegated authority under the Controlled Substances Act (CSA) because "marihuana" (marijuana) and "tetrahydrocannabinols" (THC) are both listed on Schedule I. 21 U.S.C. §812(c)(Schedule I)(c)(10), (17)).

B. CSA INCLUSION OF THC

But even the CSA definition of THC, as an individually identified cannabinoid, does not appear to prohibit inclusion of THC in these extracts, as the Ninth Circuit determined when it stated that 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.*

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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 non-psychoactive 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.

C. FEDERAL DEFINITION OF "MARIHUANA"

It is clear that marijuana, or "marihuana," is a controlled substance. But not all parts of the *Cannabis sativa L* plant are considered "marihuana" under the federal definition. Moreover, when it comes to industrial hemp, as set forth in the Agriculture Act of 2014 (commonly known as the Farm Bill), the entire industrial hemp plant is lawful, as set forth more fully below.

To be clear, the federal definition of marihuana expressly excludes various portions of this plant. Yet, the DEA fails to recognize this express caveat. Under the CSA, "marihuana" 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 "marihuana" 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. *Hemp Indus. Ass'n.*, 357 F.3d at 1014 (quoting 21 U.S.C. § 802(16)). Thus, any extracts derived from the foregoing portions of a *Cannabis sativa L* plant lawfully cultivated outside of the United States remain lawful.

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D. FARM BILL'S EXPRESS AUTHORIZATION OF INDUSTRIAL HEMP, INCLUDING CANNABINOIDS DERIVED THEREFROM

The Farm Bill renders the entire industrial plant, including extracts, as lawful. On February 7, 2014, President Obama signed the Agricultural Act of 2014 into law. See P.L. 113-79 (§7606). Section 7606 of the act, Legitimacy of Industrial Hemp Research, defines industrial hemp as distinct from marijuana and authorizes institutions of higher education or state departments of agriculture in states that legalized hemp cultivation to conduct research and pilot programs across the country. *Id.*

Importantly, the Farm Bill specifies that the entire "industrial hemp" plant is made lawful, *in spite of, or notwithstanding, the CSA*. As such, it expressly carves out an exception to the CSA for the entire industrial hemp plant and products/extracts therefrom. *Id.* Specifically, it 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 (with certain regulatory limitations)." *Id.* And industrial hemp has been defined, accordingly, as an exclusion/exception to the CSA, 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." *Id.* There it is expressly clear that all parts of said plant, within this definition, are lawful, including but not limited to the extracts therefrom.

E. CANNABINOIDS ARE NOT ILLEGAL CONTROLLED SUBSTANCES

Cannabinoids are not illegal if they are derived from certain parts of the plant, and the Farm Bill expressly indicates that the entire plant is lawful, as set forth above.

Moreover, naturally occurring cannabinoids are not unlawful substances *per se*. In *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012 (9th Cir. 2004), the Ninth Circuit ruled that naturally occurring cannabinoids in industrial hemp foods, including oil, were never scheduled under the CSA; therefore, the DEA has no jurisdiction. This means that naturally occurring industrial hemp cannabinoids are federally legal in the view of the Ninth Circuit.

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.

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F. DEA CITATION OF INTERNATIONAL TREATIES

By citing reconciliation with international treaties as the premise for this Rule, the DEA appears to be seeking to invoke 21 CFR 1308.46, which, in theory, allows the DEA to bypass normal rulemaking procedures, effectively eliminating due process from the procedures set forth by Congress and through the *Federal Register*. This use of such procedure by the DEA is akin to emergency rulemaking and not only undermines the premise of due process afforded to adversely affected interested persons, but is essentially is an abuse of process and appears to be an attempt to circumvent Congressional restrictions upon the DEA's authority.

G. *HEMP INDUS. ASS'N v. DEA* CASE PRECEDENT

Fundamentally, cannabinoids are not specifically or generally defined under the Federal Controlled Substances Act (the "CSA"). However, through its ruling, the DEA has improperly taken the position that all cannabinoids, even isolated and pure cannabinoids such as CBD, are unlawful under the CSA. Without an express provision under the CSA, it is questionable whether the DEA has any sort of authority to take this position. But more importantly, in the case of *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082 (9th Cir. 2003), the DEA attempted to initiate rules and interpretations concerning certain cannabinoid constituents of a *Cannabis sativa L* plant that were not expressly set forth under the CSA or the DEA's own regulations (at the time), and the Ninth Circuit Federal Court of Appeals struck down its efforts, stating that: "[t]he petition requesting that we declare the rule to be invalid and unenforceable is GRANTED." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082 (9th Cir. 2003). In short, an agency – such as the DEA – is not permitted to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning. Yet, here they go again, and, again this needs to be stopped.

H. CONGRESSIONAL BUDGETARY APPROPRIATIONS ACTS DE-FUNDING DEPARTMENT OF JUSTICE PURSUANT TO FARM BILL

To further confirm Congressional intent pursuant to the Farm Bill, Congress enacted the Consolidated and Further Continuing Appropriations Act of 2015 (Pub. L. 113-235, 128 Stat. 2130, §538 (2014)), and re-authorized such regulations in the Consolidated Appropriations Act, 2016, (Pub. L. No. 114-113, 129 Stat. 1175 (§763)), and most recently, this week extended the same through April 28, 2017 (collectively, the "Spending Bill") (Pub. L. No. 114-254)
. The Spending Bill effectively precludes block federal law enforcement authorities from interfering with conduct authorized by the Farm Bill, such state agencies and hemp growers, as well as to counter efforts to obstruct agricultural research. Accordingly, the Spending Bill sets forth:

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None of the funds made available by this Act or any other Act may be used—

(1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or
(2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.

See Pub. L. No. 114-113, 129 Stat. 1175 (§763). The enforceable effect of the Spending Bill's de-funding mechanisms have since been affirmed in multiple cases. *See U.S. v. Marin Alliance for Medical Marijuana (MAMM)*, Case No. 98-00086; *see also U.S. v. McIntosh,* Case No. 15-10122 (2016).

Therefore, the DEA's final rule regarding "Marihuana Extract" not only contradicts its own rule-making authority, as otherwise discussed herein, but also explicitly conflicts with the Spending Bill provisions enacted by Congress, which disallows the DEA from expending resources that conflict with the Farm Bill.

I. DEA FINAL RULE DISTINCTION BETWEEN "CANNABIS RESIN" AND "MARIHUANA EXTRACT"

There is a positive aspect to this publication and the DEA's position accordingly. Specifically, the new Rule defines "marihuana extracts" as distinct from its resins – "Marihuana Extract" is a new category and is "other than the separated resin (whether crude or purified) obtained from the plant." It finds that the "use of the term 'cannabinoid' necessitates that the DEA clarify that the new marihuana extract category (drug code 7350) is **not** intended to include 'cannabis resin' as defined in the U.N. Single Convention (and under the CSA)." 21 CFR Part 1308, 81 FR 90194 This is an important distinction because it effectively acknowledges that cannabis extracts are not resins, but are something else altogether. This is a good sign because the CSA definition of marijuana makes any resins extracted from any part of the plant unlawful. 21 U.S.C. 802(16). And we have always known that resins are distinct from extracted oils; this Rule expressly makes that distinction and furthers the argument that the DEA has exceeded its jurisdiction here.

J. CANNABINOIDS ARE NOT EXCLUSIVELY NATURALLY OCCURRING IN CANNABIS PLANTS

The genus *Cannabis sativa L.* possesses over eighty distinct and naturally occurring cannabinoids. For example, research indicates cannabinoids also naturally occur in coneflower (*Echinacea*), oxeye (*Heliopsis helianthoides*), electric daisy (*Acmella oleracea*), *Helichrysum umbraculigerum*, liverwort (*Radula marginata*), black pepper (*Piper nigrum*) and even chocolate (*Theobrama cacao*) plants.

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Importantly, the DEA has even admitted that cannabinoids naturally occur in other plants and/or can be derived from sources other than marijuana. *See 21 CFR Chapter II*, Docket No. DEA-426, p. 53698 Further, the DEA also admits the tetrahydrocannabinol is the main psychoactive cannabinoid in marijuana – psychoactivity being the main impetus behind scheduling (synthetic) tetrahydrocannabinol – while also acknowledging that many of the other cannabinoids, specifically including CBD, do not possess psychoactive effects. *See 21 CFR Chapter II*, Docket No. DEA-426, p. 53698; Docket No. DEA-427 53778.

K. ACTION PLAN

There are administrative procedures, including requests for hearing, and/or the commencement of litigation seeking injunctive and declaratory relief that can be taken in response to the DEA's Rule. Examples of such prior challenges include the *HIA v. DEA* case itself, along with recent challenges regarding the DEA's ruling with regard to banning Kratom. Our team is diligently and expediently working to prepare a recommended strategy in response to the DEA's Rule and looks forward to working on behalf of the continued success of the effected industries.

/s/ Robert T. Hoban, Esq.
Managing Partner, Hoban Law Group

/s/ C. Adam Foster, Esq.
Partner, Hoban Law Group

/s/ Garrett Graff, Esq.
Associate Attorney, Hoban Law Group, Hemp Attorney

/s/ Dennis Brovarone, Esq.
Senior Attorney, Hoban Law Group, Hemp Attorney

/s/ Patrick Goggin, Esq.
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/s/ Lisa Sweeney, Esq.
Counsel, Hoban Law Group, Hemp Attorney

/s/ Matthew Smith, Esq.
Counsel, Hoban Law Group, Hemp Attorney

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CV Sciences, Inc. Comments on DEA Ruling Re: Cannabis Extracts Amid Media Confusion

On December 14, 2016, the Drug Enforcement Agency (DEA) issued a ruling regarding a new Administration Controlled Substances Code Number for "Marijuana Extract." This new code was established to allow regulatory agencies to track quantities of material separate from marijuana and THC (which codes currently exist), and further stated that any cannabinoids from the cannabis plant fall under this newly defined code. After the agency's release, media outlets have treated this as an official ruling that cannabidiol derived from either marijuana or hemp falls under Schedule 1 of the Controlled Substances Act.

Hemp Is Exempt from the Definition of Marijuana

"CV Sciences stands by the 2004 Hemp Industries Association (HIA) v. DEA Ninth Circuit Court ruling that defines industrial hemp as *Cannabis Sativa L.* under 0.3% THC by dry weight, thus making hemp exempt from the Controlled Substances Act's (CSA) definition of marijuana. That said, our hemp-derived consumer products continue to be sold in hundreds of retail outlets across the country," stated Michael Mona, Jr., chief executive officer and president at CV Sciences.

As active members of the HIA and other major hemp organizations, we have reviewed the ruling with our legal advisors and discussed it with industry experts. The general consensus is that this ruling did not change the status of CBD.

DEA Has No Legislative Authority to Outlaw Cannabinoids

Amid the media frenzy inaccurately interpreting this agency action, it is important to note the following points:

- For decades, federal law has permitted the import and US sale of foreign-grown hemp products. CV Sciences has been importing foreign-grown hemp since 2012.
- Sec. 7606 of the Farm Bill defines hemp as distinct from marijuana.
- DEA is an unelected body with no legislative authority - their attempt to outlaw all cannabinoids is outside of their scope of power and authority as it pertains to the legality of the *Cannabis Sativa L* plant. Adding CBD products to the federal schedule of controlled substances would require new legislation to pass in Congress or action taken by the Attorney General, amending the CSA. It is likely that the DEA will face litigation from industry leading organizations determined to bring clarity to this nuanced situation.
- CBD is not listed on the federal schedule of controlled substances.

DEA's Rule Was Administrative

- The Final Rule published on December 14th was not a scheduling action but rather an administrative action related to record keeping. DEA Headquarters Public Affairs Officer Barbara Carreno stated, "This Federal Register Notice does not change control status of anything having to do with marijuana. No provisions of the Controlled Substances Act protocols have changed. This is a record-keeping matter."

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- The code assigned to "marihuana extract" in the rule is "Administration Controlled Substances Code Number" for the purposes of identification of substances on registration forms.
- The rule was originally published as a proposed rule in 2011 BEFORE the Farm Bill and did not mention CBD or hemp.

We mirror the sentiments of the fellow industry leaders who believe that the DEA rule on "marihuana extracts" was not directed at hemp-derived CBD products. We also believe there is no imminent change in DEA policy regarding hemp-derived CBD products.

The Demand for Hemp-Derived CBD Products Will Continue to Grow

CV Sciences continues to be committed to providing quality CBD oil derived from non-psychotoxic industrial hemp, which is legal to import and sell in the United States. "The demand for hemp-derived CBD has been growing with ferocity over the last few years. *The Hemp Business Journal* estimated that the CBD market will grow to a $2.1 billion market in consumer sales by 2020 with $450 million of those sales coming from hemp-based sources," Mona explained. "The hemp-derived CBD product category will continue to grow as demand continues to rise."

CV Sciences is happy to schedule appointments to discuss this further with their Retailer partners. If you are interested, please contact education@pluscbdoil.com to set up a call with CV Sciences management.

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December 22, 2016

Michael Mona III
Chief Operating Officer, Co-Founder
CV Sciences, Inc.
591 Camino de la Reina
Suite 1200
San Diego, CA 92108

Re: The Drug Enforcement Administration's rule regarding "marihuana extracts"

Mr. Mona:

On December 14, 2016, the Drug Enforcement Administration (the "DEA") published a final rule for the establishment of a new drug code for "marihuana extracts" (the "Rule" – attached hereto as Appendix A). Some breathless media reports – consistent with the new media paradigm's controversy-selling "clickbait" culture – have suggested that the Rule threatens retail hemp products, particularly cannabidiol (CBD). Some of the more irresponsible articles have even suggested that the Rule changes federal law, posing imminent exposure to criminal liability to those who sell or possess hemp products.

After careful study of the rule, however, we join the opinion of hemp industry legal experts, congressional hemp champions -- and even DEA spokesmen themselves -- in concluding that the Rule is simply administrative, procedural and ministerial in nature. Only Congress can change federal law, and that simply has not happened here.

Federal law – established by the 2014 Farm Bill and 2016 Omnibus Law – emphatically mandates that industrial hemp grown as part of state-sanctioned pilot programs is exempted from the Controlled Substances Act, and that federal agencies (such as the DEA) are prohibited from interfering with pilot programs and/or the interstate sale or transport of hemp products that are produced in pilot programs. Previously, for decades, federal law (as confirmed by the 9th Circuit Court of Appeals) permitted the import and U.S. sale of foreign-grown hemp products.

No federal agency can rewrite federal law. Indeed, the Rule merely assigns an administrative scheduling code to marihuana extracts for identifying and cataloguing substances on registration forms. This was not an action to "reschedule" hemp or CBD as a controlled, or otherwise illegal substance, but rather an administrative action related to record keeping. Indeed,

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the Rule that was finalized this month was originally published as a proposed rule in 2011, three years BEFORE the Farm Bill and didn't mention CBD or hemp.

Perhaps most comforting, the DEA has confirmed that the Rule does not fundamentally change the legal landscape for CBD. I have spoken to aides to top U.S. Congressmen who have been reassured by DEA officials that introducing a scheduling code for marihuana extracts was merely intended better catalogue and track substances in accordance with United Nations-tracking standards. Further, DEA spokesman Russ Bauer told the *Denver Post* (see article, attached hereto Appendix B), "[The Rule] is primarily an administrative move and does not reflect a change in any control status." According to Bauer, the Rule, at its core, "would allow the DEA's internal accounting mechanisms to be more accurate to track elements such as scientific and medical research. Researchers use the codes to identify which substance is subject to the project."

The article also reports that "[a]lthough those who ship CBD oil would be in violation of federal law . . . [the Rule] does not change the DEA's enforcement priorities." We certainly disagree with DEA's interpretation of federal law in this regard – again this flies in the face of clear precedent and statutory language – but are comforted by the signal that this does not signal a change in enforcement priority.

As for the concern raised by some of your hemp product retailers that they may be subject to DEA raids and confiscation; such action would be unprecedented. In recent months, we have only been made aware of only one coordinated law enforcement response to the sale of retail hemp products—by state regulators in Texas. This year, the Texas Department of Public Safety ("DPS") raided four People's Pharmacy retail locations and confiscated hemp products, including CBD hemp oil. DPS tested the products and found no detectable THC. DPS returned the confiscated products and did not pursue enforcement action against the retailers. DPS legal counsel issued this statement:

> Attached is the lab report regarding the 'CBD hemp oil' from People's Pharmacy. The report indicates the presence of cannabidiol (CBD). The report does not indicate any detectable tetrahydrocannabinol (THC). Given certain ambiguities regarding the status of CBD under the Texas Controlled Substances Act (CSA), the department, after consulting with prosecutors, does not intend to pursue enforcement action based on the tested substance. This discretionary enforcement decision does not constitute a general opinion about the legality of any product.

We are of the opinion that the Rule is an administrative and ministerial action and without the force of law. In operation, the Rule assigns a scheduling code to marihuana extracts for purposes of internally identifying and cataloguing substances in accordance with United Nations standards. As the DEA confirmed, the Rule does not target or alter the legal status of CBD. Most encouraging, though, is the supremacy of federal law, which distinguishes hemp from marijuana and under Farm Bill programs, exempts industrial hemp from the Controlled Substances Act.

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The legal advice and opinions set forth herein are an expression of our professional judgment and not a guaranty of a result. The federal agencies mentioned above may contest the interpretations we have provided.

Respectfully yours,

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HOBAN & FEOLA, LLC
ATTORNEYS AT LAW

Robert Hoban, Managing Partner
303-674-7000 Phone

July 8, 2013

[INSERT RECIPIENT ADDRESS]

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 CannaVest's 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

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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

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"[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

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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

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[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…"

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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.

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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

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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).

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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

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

Sincerely,

Robert T. Hoban

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