



January 14, 2019

CBD from Industrial Hemp

Executive Summary

Over the past couple of years, there has been a rapid proliferation in the sale of products containing cannabidiol (CBD) derived from industrial hemp. (A smaller number of products contain cannabigerol (CBG)). Many of the products are being marketed for human or animal consumption for either: 1). use in preventing, treating or curing diseases; or 2). use in altering the structure or function of human and animal bodies. With the exception of a single drug that was recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of certain pediatric seizures, none of these products have been approved for use by that agency. None of the manufacturers of these products appear to be registered by the FDA or licensed by the Minnesota Board of Pharmacy (Board) as drug manufacturers. It is probable that many of the companies are not following current good manufacturing procedures for drug products. Consequently, the Board cannot offer even minimal assurances to the public that these products are both effective and safe.

Contrary to the claims of some who are involved in the burgeoning industrial hemp industry, it is not legal to extract CBD, CBG, or any other cannabinoid, from industrial hemp, place it into a product intended for human or animal consumption, and sell those products. The sale of such products is illegal under both federal law and Minnesota law. At this time, the primary issue does not involve the status of hemp as a controlled substance. Instead, such products are considered to be misbranded and adulterated under both the federal Food, Drug & Cosmetic Act (FD&C Act) and under certain sections of Minnesota Statutes Chapter 151.

When the Legislature enacted the Industrial Hemp Development Act (Minn. Stats Chapter 18K), it defined “industrial hemp” to mean (emphasis added):

“the plant *Cannabis sativa* L. and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. ***Industrial hemp is not marijuana as defined in section 152.01, subdivision 9.***”

The emphasized sentence is important because Minn. Stats. §152.02 does not specifically list CBD, by name, as a Schedule I controlled substance. Listed instead are marijuana, tetrahydrocannabinols, and a large number of synthetic cannabinoids. CBD is neither a tetrahydrocannabinol nor a synthetic cannabinoid. The definition of “marijuana” found in

Minn. Stats. 152.01 includes the phrase “every *compound, manufacture, salt, derivative, mixture, or preparation* of such plant. . . .” Consequently, a compound, manufacture, preparation, or derivative of the marijuana plant is itself defined as marijuana. Since marijuana is a Schedule I controlled substance, its compounds and derivatives are also scheduled. But as noted above, industrial hemp is explicitly excluded from the definition of marijuana – so, when derived from a hemp plant, CBD is already not *directly* a Schedule I controlled substance.

There is a possibility that some might argue that hemp-derived cannabinoids *are* analogs of marijuana-derived cannabinoids – if it can be demonstrated that they have a depressant effect on the central nervous system. Analogs, as defined in Minn. Stats. §151.01, subd. 23 are Schedule I controlled substances per Minn. Stats. §152.02, subd. 2 (i). If CBD derived from hemp *could* be considered an analog of CBD derived from marijuana, it might very well *indirectly* be a Schedule I controlled substance. Also, it is most likely not easy to determine if the CBD found in a particular product was derived from hemp or from marijuana.

In short, there is probably no need to enact legislation declaring that CBD derived from hemp is not a controlled substance (other than, perhaps, declaring that CBD derived from hemp is not an analog of CBD derived from marijuana). If the intent of the Legislature to make it clear that possession of CBD derived from either hemp or marijuana is not a controlled substance violation, then language to that effect might be considered.

Note also that the FDA-approved product, Epidiolex, is federally a Schedule V controlled substance. By order, the Board placed Epidiolex into the state’s Schedule V and will be asking the Legislature to make that scheduling permanent.

Legislation that addresses only the controlled substance status of CBD will not legalize the sale of CBD products that are intended for human or animal consumption (hereinafter referred to as “products”). Instead, the provisions in Chapter 151 that make these products misbranded and adulterated would have to be modified. Even if those modifications were made, the sale of these products would remain illegal under federal law. The Board of Pharmacy strongly recommends that if the Legislature decides to legalize the sale of such products that certain principles are followed:

- Prohibit the sale of any product containing a cannabinoid other than CBD;
- Establish certain testing requirements;
- Establish certain labeling requirements; and
- Reinforce that products that don’t meet these requirements are adulterated and misbranded and therefore subject to the authority of the Board of Pharmacy to issue embargos and cease-and-desist orders.

The Legislature may also wish to contact the Minnesota Department of Health, Office of Medical Cannabis, for input concerning the potential impact of allowing sales of such products on the sale of CBD-containing products that are allowed to be sold under the Minnesota Medical Cannabis Act (Minn. Stats. §152.22. et. seq.). This paper does not address the addition of extracted CBD to food products, which would be under the jurisdiction of the Minnesota Department of Agriculture.

Cannabis sativa

Cannabis sativa is an herbaceous plant species that originated in central and south Asia but that is now cultivated around the world. It has been cultivated throughout human history and has been used as a source of fiber, food, seed oil, and medicinal substances. Due to the psychoactive effects of Δ^9 tetrahydrocannabinol (THC), it has also been used recreationally. Cannabis has also been used in religious ceremonies.

Different varieties of *Cannabis sativa* can have differing concentrations of the cannabinoids discussed below. In particular, hemp is a strain of Cannabis that has lower concentrations of THC. Hemp has been used for several millennia as a source of fiber to make ropes, cloth, paper, and other products. Hemp seeds are used as a food substance and are a source of protein, fiber, and magnesium. Varieties of *Cannabis sativa* that are high in THC concentration and that are used for recreational purpose due to their ability to produce a “high” are commonly referred to as marijuana or marihuana. The difference in concentration of THC has important legal ramifications, as explained below.

Cannabinoids

CBD and CBG are two of over one hundred known cannabinoid substances produced by the plant *Cannabis sativa*. Unlike THC, CBD and CBG do not produce the high associated with marijuana use. Some individuals mistakenly claim that CBD is not psychoactive. If by that they mean it doesn’t product a high, they would be correct. However, a psychoactive drug (or psychotropic substance) is a chemical substance that acts on the central nervous system and alters brain function, resulting in temporary changes in perception, mood, consciousness and behavior. For example, antidepressants have an effect on mood and are therefore considered to be psychoactive, even though they don’t produce a high.

CBD is one of the major substances in cannabis that does *not* produce a high. However, CBD most definitely acts on the central nervous system and it can alter perception and mood. (Proponents of its use often claim that CBD can have a calming effect, reduce anxiety, and even treat depression). CBG is the precursor substance from which other cannabinoids are synthesized – including both CBD and THC. CBD and CBG are pharmacologically active in humans and animals and act on various receptors and signaling systems. CBG acts on

adrenergic and serotonin receptors, but has low affinity for cannabinoid receptors. CBD acts on a variety of signaling systems within the body but does not activate cannabinoid receptors.

A product containing CBD (Epidiolex) was approved by the FDA for the treatment of Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. (On June 25, 2018). There are no FDA-approved products that contain CBG and it appears that there have been few, if any, human clinical trials for CBG. There have been in vitro trials of CBG using cell lines, etc. that show that CBG *might* have some potentially beneficial medical effects.

Legal Considerations

State and federal industrial hemp statutes

Section 7606 of the federal Agricultural Act of 2014 “legalized the growing and cultivating of industrial hemp for *research* purposes in States where such growth and cultivation is legal under State law, notwithstanding existing Federal statutes that would otherwise criminalize such conduct. *The statutorily sanctioned conduct, however, was limited to growth and cultivation by an institution of higher education or State department of agriculture **for purposes of agricultural or other academic research** or under the auspices of a State agricultural pilot program for the growth, cultivation, or marketing of industrial hemp.*” (From a joint statement issued by the USDA, DEA, and FDA – emphasis added). Section 7606 is reproduced in its entirety as Appendix A.

In 2015, the Minnesota Legislature enacted legislation that created Chapter 18K (reproduced in its entirety as Appendix B).

Both the federal and state industrial hemp laws only allow industrial hemp *research* programs. While those programs can include research into the marketing of products, the federal and state laws do not explicitly allow massive, nationwide, general commercial sales of products developed as part of the programs. The U.S. Dept. of Agriculture, the FDA and the DEA issued a *Statement of Principles on Industrial Hemp* in August 2016 in which they state (emphasis added):

For purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of marketing materials), ***but not for the purpose of general commercial activity***, industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs but may not be sold in States where such sale is prohibited. Industrial hemp plants and seeds may not be transported across State lines.

Those agencies do not appear to have withdrawn that statement. In fact, the FDA has issued numerous warning letters to companies that are selling CBD products for human consumption, alleging that the companies are making health claims about their products

which are prohibited by the FD&C Act – because the products have not gone through the FDA’s new drug application (NDA) process.

There is no language in Section 7606 of the federal Agricultural Act of 2014 that *specifically* pre-empts any provisions of the FD&C Act. The following language is found in that section (emphasis added):

Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of title 41, or **any other Federal law**, **an institution of higher education** (as defined in section 1001 of title 20) or a **State department of agriculture** may grow or cultivate industrial hemp if—

(1) the industrial hemp is grown or cultivated for *purposes of research* conducted under an agricultural pilot program or other agricultural or academic research; and

(2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

And

AGRICULTURAL PILOT PROGRAM The term “agricultural pilot program” means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

Someone might try to argue that the general reference to “other federal law” somehow pre-empts provisions found in the FD&C Act. However the *Statement of Principles on Industrial Hemp*, mentioned above, states: “Section 7606 did not amend the Federal Food, Drug, and Cosmetic Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.” In addition, Section 7606 clearly states that hemp can be grown or cultivated for “the purpose of research conducted under an agricultural pilot program.” Several online dictionaries were consulted and:

“research” is typically defined to mean: “The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.”

“pilot program” is typically defined to mean an “activity planned as a *test or trial*.”

The federal agencies mentioned above appear to be correct in their interpretation that Section 7606 only authorizes research in the form of pilot programs - not largescale production and distribution of products made from industrial hemp plants.

When enacting state law in this area, the Legislature specified that the Minnesota Department of Agriculture’s authority to adopt rules is not effective until “the day after the federal

government authorizes the **commercial production** of industrial hemp.” That seems to indicate that when the law was passed, the Legislature knew that the federal government had not authorized the commercial production of hemp when Section 7606 was passed. Further, the Legislature did not choose to allow commercial production, despite federal laws to the contrary. (As it did when it authorized the Minnesota Medical Cannabis Program).

Documentation put out by the growers of industrial hemp and/or their trade associations indicates that they believe Section 7606 and state laws allow them to sell products made from industrial hemp, including products containing pharmacologically active substances, on a largescale, nationwide basis. If, for the sake of argument, their beliefs were deemed to be true, there are still legal issues to be considered.

Drugs vs. dietary supplements, misbranding and adulteration

The next page contains photographs of a brochure that was put out by a local retail establishment. Note that it has a section titled: “Personalized Medicine.” That section talks about the “right treatment regimen” depending on the “condition being treated.” That section also uses the terms: “correct dosage” and states that CBD has “no known adverse side effects” (which is a false and dangerous statement, a number of adverse reactions were reported during clinical trials with CBD, as well as drug-drug interactions).

Elsewhere, the brochure mentions that CBD has “enormous therapeutic potential” and explains in detail how cannabinoids affect the structure and function of the body. It further states that: “CBD has strong anti-oxidant, anti-inflammatory, anti-spasm, anticonvulsant, anti-psychotic, anti-tumor and neuro-protective properties. It directly activates serotonin receptors, causing an anti-depressant effect as well.” (It is true that CBD is serotonergic, raising the possibility that it could potentiate the effect of other commonly prescribed serotonergic drugs, inducing life-threatening serotonin syndrome).

Finally, the brochure states: “Scientific and clinical studies have shown that CBD could be therapeutic for many conditions, including but not limited to: chronic pain, cancer, anxiety, diabetes, epilepsy, rheumatoid arthritis, PTSD, sleep disorders, alcoholism, cardiovascular disease, antibiotic-resistant infections and neurological ailments.”



Organic

Non-GMO

Zero THC

Full Spectrum

WHY CHOOSE HEMPDROPZ?

Our product comes from 100% USA grown organic hemp. It's all grown in Colorado under strict guidelines, and registered with the Colorado State Department of Agriculture.

We're also vertically integrated, meaning we control every aspect of the supply chain. From farming, to extraction, purification, product manufacturing, on-site laboratory testing and distribution. We ensure the highest quality control for all of our products.



Personalized Medicine

The right treatment regimen depends on the person and condition being treated. Finding your correct dosage is the first step to effective treatment. CBD has no known adverse side effects at any dose, and we are happy to suggest a dosage that may be right for you, individually.

Come meet our knowledgeable staff! We're thoroughly educated on the science and benefits of CBD, and can help determine which product or dosage may be right for you. We pride ourselves on our customer satisfaction. Let us show you what hemp can do for your health!



Find us on Facebook!

Explore the benefits of Hemp



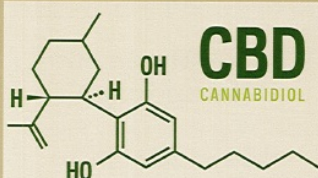
CBD of Maplewood Hempdropz

2225 White Bear Ave., Suite 5
Maplewood, MN 55109

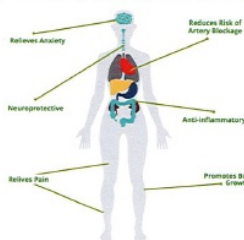
What is Cannabidiol?

Cannabidiol or CBD is a natural compound found in cannabis and hemp plants, with enormous therapeutic potential. Unlike its notorious cousin THC, CBD is non-psychoactive, meaning it does not get you high. Cannabinoids are chemicals that trigger the cannabinoid (and other) receptors in the brain and body. In addition to phyto-cannabinoids produced by the plant, there are endogenous cannabinoids that occur naturally in the body.

Just like your muscular, skeletal and cardiovascular system, you have an endocannabinoid system. That system is a group of neuromodulatory lipids and receptors in the brain that are involved in a variety of physiological processes, including appetite, pain-sensation, mood and memory, synaptic plasticity and motor learning.



HOW CBD WORKS IN THE HUMAN BODY



Benefits of CBD

CBD has strong anti-oxidant, anti-inflammatory, anti-spasm, anticonvulsant, anti-psychotic, anti-tumoral and neuro-protective properties. It directly activates serotonin receptors, causing an anti-depressant effect as well.

Scientific and clinical studies have shown that CBD could be therapeutic for many conditions, including but not limited to: chronic pain, cancer, anxiety, diabetes, epilepsy, rheumatoid arthritis, PTSD, sleep disorders, alcoholism, cardiovascular disease, antibiotic-resistant infections and neurological ailments.



Our Products

Out of our large variety of products, we highly recommend our water soluble CBD. It has been specially formulated to have a much higher absorption & bioavailability than normal CBD oil-based formulations.

Our bodies are mostly composed of water. If you consume something that isn't water soluble, your body will have trouble absorbing it. Water soluble CBD is important for two main reasons: efficacy and affordability.



Not all CBD products are made equally. With Hempdropz exclusive nano-emulsion technology, you get four times faster absorption than oil. That also means you need less product to get your desired effect, which saves you money.

On this and the next page, are photographs of products collected by a law enforcement agency in Minnesota from local retail establishments. Note that the cigar product states that it contains 15% “*Medical Grade*” hemp. The gummie product states on the package that it can be used for pain relief, anxiety, and stress. “Pain Freeze” states that it is a “triple *medicated* pain relief gel.”





The “gummie” package depicted above contains a statement that is placed on products by manufacturers of *legal* dietary supplements: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” This would appear to be an attempt by the manufacturers to position their products as dietary supplements, rather than as drugs. (As drugs, they would be subject to the drug approval, labeling, and manufacturing requirements found in the FD&C Act). A letter submitted to the California Department of Public Health by a law firm representing clients running industrial hemp businesses, states:

“The Products would, at minimum, be appropriately regulated as dietary supplements pursuant to the Dietary Supplement Health and Education Act of 1994,¹⁸ if not also as a conventional food pursuant to the Federal Food, Drug and Cosmetic Act.¹⁹ This treatment would be appropriate given the longstanding prevalence in the marketplace of products containing derivatives of industrial hemp, including various amounts of cannabinoids such as CBD. Such products were even the subject of above-referenced litigation in the early 2000s.²⁰”

However, the FDA states in several FAQS (see FAQs 12 – 16) that neither THC nor CBD can be a component in a dietary supplement – nor can they be *added* to a food product. Specifically:

FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA’s regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals’ investigations regarding Sativex and Epidiolex. (See Sativex Commences US Phase II/III Clinical Trial in Cancer Pain and GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome).

A comment document submitted to the FDA by the U.S. Hemp Roundtable, claims that hemp-derived CBD meets the FDA's definition of a dietary supplement. It addresses the FDA's determination that CBD is excluded from the definition of a dietary supplement, because it was the subject of substantial clinical investigations that had been made public, as follows:

“we contend that CBD does not fall under this preclusion because the clinical trials on CBD were extremely limited in scope and funding, and publication of these trials has also been limited.”

However, as noted by the FDA, Sativex and Epidiolex, which both contain CBD, were granted investigational new drug status before the federal Agricultural Act of 2014 was even enacted. (Sativex in 2006, Epidiolex in May of 2014).

Minn. Stats. §151.01, subd. 5 has a lengthy definition of the word “drug” (emphasis added):

"Drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof; biological products, other than blood or blood components; ***all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals***; and ***all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals***. The term drug shall also mean any compound, substance, or derivative that is not approved for human consumption by the United States Food and Drug Administration or specifically permitted for human consumption under Minnesota law, and, when introduced into the body, induces an effect similar to that of a Schedule I or Schedule II controlled substance listed in section 152.02, subdivisions 2 and 3, or Minnesota Rules, parts 6800.4210 and 6800.4220, regardless of whether the substance is marketed for the purpose of human consumption.

The only time “dietary supplement” is defined under state law is in Minn. Stats. §297A.67, subd. 2, which uses much of the federal definition of the phrase. Also, the definition applies only to that subdivision – which exempts dietary supplements from a tax.

From the labeling of some CBD products, it is clear that they are intended to affect the structure or function of the bodies of humans and animals. In some cases, blatant diagnosis, cure, treatment and mitigation claims are made. Also, CBD products derived from industrial hemp are not approved for human consumption by the FDA. In addition, they are not specifically permitted for human consumption under state law. (The only CBD products permitted for human consumption under state law are those products produced by the medical cannabis manufacturers regulated by the Minnesota Department of Health). Minn. Stats. Chapter 18K does not pre-empt any provisions of Chapter 151. Consequently, CBD products derived from industrial hemp are drugs, as defined in Minn. Stats. §151.01, subd.

5. And if they are drugs, their sale is illegal under Minn. Stats. §151.34, which begins as follows:

It shall be unlawful to:

- (1) manufacture, sell or deliver, hold or offer for sale any drug that is **adulterated or misbranded**;
- (2) **adulterate or misbrand** any drug;
- (3) receive in commerce any drug that is **adulterated or misbranded**, and to deliver or proffer delivery thereof for pay or otherwise;

(Note that the sections of Chapter 151 that have been referenced do not apply to products made by the manufacturers regulated by MDH under the state's Medical Cannabis program – because of this language in Minn. Stats. §152.29: “For purposes of sections 152.22 to 152.37, ***a medical cannabis manufacturer is not subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151.***”)

Among other reasons, a drug is *adulterated* if “the facility in which it was produced was not registered by the United States Food and Drug Administration or licensed by the board” or if the procedures used in the manufacture of the product are not in accordance with the FD&C Act. Among other reasons, a drug is *misbranded* if the labeling of the product “otherwise fails to meet the labeling requirements of the federal act.” CBD products derived from hemp are not manufactured in FDA registered and Board licensed facilities – nor has their labeling been approved by the FDA. Consequently, they are misbranded and adulterated drugs so their manufacture, sale, and delivery is illegal within Minnesota. Violation of Minn. Stats. §151.34 is a misdemeanor.

Controlled substance law

CBD (and other cannabinoids such as CBG), when derived from marijuana, are Schedule I controlled substances, both federally and per Minnesota Statutes – because they would be a compound, manufacture or derivative or those portions of the *Cannabis sativa* plant that are defined as marijuana. The definition of “marihuana” found in the federal Controlled Substances Act is (emphasis added):

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 definition of marijuana found in Minn. Stats. §151.01, subd. 9 is (emphasis added):

"Marijuana" means all parts of the plant of any species of the genus *Cannabis*, including all agronomical varieties, 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, but shall not include the mature stalks of such plant, fiber 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.

Minn. Stats. §152.02, subd. 2(h) places marijuana into Schedule I. However, except for THC, naturally-occurring cannabinoids are not specifically listed, by name. Minnesota Statutes Chapter 18K excludes hemp plants, as defined in that Chapter, from the definition of “marijuana” found in Section 152.01. So, it could be argued that naturally occurring, non-THC cannabinoids derived from industrial hemp plants would not *directly* be controlled substances – since they are not derived from marijuana, are not tetrahydrocannabinols, and are not synthetic substances.

There is a *possibility* that hemp-derived cannabinoids might be considered an analog of marijuana-derived cannabinoids – if it can be demonstrated that they have a depressant effect on the central nervous system. Analogs, as defined in Minn. Stats. §151.01, subd. 23 are Schedule I controlled substances per Minn. Stats. §152.02, subd. 2 (i). So, if CBD derived from hemp could be considered an analog of CBD derived from marijuana, it might very well be a Schedule I controlled substance.

Unlike Minnesota law, Section 7606 of the federal Agriculture Act of 2014 does not *explicitly* exclude industrial hemp from the federal definition of “marihuana.” Nor does it *explicitly* state that those parts of the *Cannabis* plant that are *included* in the definition of marijuana are *excluded* from being Schedule I controlled substances. It allows industrial hemp (*cannabis* plants that contain less than 0.3% THC) to be researched as part of an agricultural pilot program, notwithstanding the federal Controlled Substances Act.

The DEA classified “marihuana extracts” as controlled substances on December 14, 2016. That term is defined as defined as “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 Hemp Industry Association sued the DEA (Hemp Industries Assn. v. US Drug Enforcement Administration) but a three-judge panel of the 9th circuit ruled against the Association. Consequently, “marihuana extracts” remain Schedule I controlled substances under federal law. The DEA has issued clarifications concerning “marihuana extracts” but those clarifications continue to rely on the definition of marihuana found in the federal Controlled Substances Act - which only excludes certain parts of the *Cannabis* plant – but does not exclude all parts of industrial hemp plants. Cannabinoids such as CBD and CBG are primarily produced in those portions of the

Cannabis plant that are included in the definition of marihuana. It would be difficult, if not impossible, to extract significant amounts of CBD and CBG from those portions of the plant excluded from the definition of marihuana. Thus, CBD and CBG derived from industrial hemp plants might be considered marihuana extracts and, as such, Schedule I Controlled Substances.

Provisions in 2018 federal Agricultural Act

When it enacted the 2018 federal Agriculture Bill (Farm Bill), Congress included provisions concerning hemp. After enactment of the Farm Bill, the FDA issued a statement regarding the hemp provisions. The statement can be found at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm>.

The statement confirms that the Farm Bill did not legalize products made with CBD extracted from hemp.

The Farm Bill very explicitly states that none of the provisions of the Food, Drug & Cosmetic Act (FDCA) are pre-empted by the hemp provisions. That effectively means that products containing CBD can't be sold when drug claims are made – unless the product goes through the new drug approval process, the manufacturer is registered by the FDA, and current good manufacturing procedures are followed. In its statement, the FDA also reiterates that CBD can't be sold as a dietary supplement. As long as the FDA holds that CBD can't be sold as a dietary supplement, products that contain CBD that is extracted from hemp and that are sold with the intent that they be used to treat diseases or alter bodily structure and functions are classified as drugs under state law. (Simply excluding such claims from the label doesn't make it legal to sell a product when the seller and the purchaser both understand that the product is intended to be used as a drug). Drugs can't be sold in this state unless they are approved as a drug by the FDA, their labeling is approved by the FDA, and they are manufactured by a FDA-registered and board-licensed manufacturer that is following current good manufacturing procedures. Unless all of those conditions are met, a drug product is considered to be adulterated and misbranded. It is a crime under state law (a misdemeanor) to sell misbranded and adulterated products.

In short, the sale of most products that contain CBD, extracted from any type of cannabis plant, remains illegal under both federal and state law. The exceptions would be FDA-approved drugs, such as the recently approved Epidiolex – and the products allowed to be sold under state law by the manufacturers that are regulated by the Minnesota Department of Health, Office of Medical Cannabis.

The FDA statement does say that the agency will hold a public hearing and will take new steps to evaluate whether it should pursue the process it would have to follow to allow a pharmaceutical ingredient (like CBD) to be sold as a dietary supplement. From the

statement, it appears that the process would involve issuing a regulation – which can take months or even years – and presumably that process won't start until after the FDA makes a decisions about whether or not to pursue the action at all.

Principles for potential state legislation

The Minnesota Legislature may address this issue during the upcoming session. That being the case, the Board's Executive Director asked the Board at its January 9, 2019 meeting to consider endorsing the following principles so that he could convey the consensus of the Board if legislation is introduced. The Board voted unanimously to make that endorsement.

If the Legislature acts to make such products legal under state law, even though such products are illegal under federal law, it might wish to:

- Prohibit the sale of any product containing a cannabinoid other than CBD. Products containing CBG (the precursor to both CBD and THC) are already being marketed. Without this prohibition, there may be a proliferation of the sale of products containing any of the hundreds of cannabinoids found in the cannabis sativa plant. While there has been research conducted involving CBD the vast majority of the other cannabinoids have not been well-researched. Allowing the sale of products containing other cannabinoids would place the public at risk.
- Establish testing requirements for:
 - Verifying the quantity or percentage of CBD found in the product.
 - Verify that the product does not contain more than trace amounts, if any, of fertilizers, pesticides, herbicides, or heavy metals.
- Establish labeling requirements that:
 - Prohibit making any treatment or structure and function claims that have not been approved by the FDA;
 - Require the quantity or percentage of CBD to be listed;
 - Require the listing of the manufacturer of the product, as well as the address of the manufacturer.

Clearly state that products that don't meet these requirements are adulterated and misbranded and therefore subject to the authority of the Board of Pharmacy to issue embargos and cease-and-desist orders.

APPENDIX A

Section 7606 of the federal Agriculture Act of 2014 (as codified)

7 U.S. Code § 5940 - Legitimacy of industrial hemp research

(a) IN GENERAL Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp if—

(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

(2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

(b) DEFINITIONS In this section:

(1) AGRICULTURAL PILOT PROGRAM The term “agricultural pilot program” means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

(A) in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

(B) in a manner that—

(i) ensures that only institutions of higher education and State departments of agriculture are used to grow or cultivate industrial hemp;

(ii) requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and

(iii) authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States in accordance with the purposes of this section.

(2) INDUSTRIAL HEMP

The term “industrial hemp” means 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.

(3) STATE DEPARTMENT OF AGRICULTURE

The term “State department of agriculture” means the agency, commission, or department of a State government responsible for agriculture within the State.

APPENDIX B

Minn. Stats. Chapter 18K

18K.01 SHORT TITLE. This chapter may be referred to as the "Industrial Hemp Development Act."

18K.02 DEFINITIONS. Subdivision 1. **Scope.** The definitions in this section apply to this chapter.

Subd. 2. **Commissioner.** "Commissioner" means the commissioner of agriculture.

Subd. 3. **Industrial hemp.** "Industrial hemp" means the plant *Cannabis sativa* L. and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Industrial hemp is not marijuana as defined in section 152.01, subdivision 9.

Subd. 4. **Marijuana.** "Marijuana" has the meaning given in section 152.01, subdivision 9.

18K.03 AGRICULTURAL CROP; POSSESSION AUTHORIZED. Industrial hemp is an agricultural crop in this state. A person may possess, transport, process, sell, or buy industrial hemp that is grown pursuant to this chapter.

18K.04 LICENSING. Subdivision 1. **Requirement; issuance; presumption.**

(a) A person must obtain a license from the commissioner before growing industrial hemp for commercial purposes. A person must apply to the commissioner in the form prescribed by the commissioner and must pay the annual registration and inspection fee established by the commissioner in accordance with section 16A.1285, subdivision 2. The license application must include the name and address of the applicant and the legal description of the land area or areas where industrial hemp will be grown by the applicant.

(b) When an applicant has paid the fee and completed the application process to the satisfaction of the commissioner, the commissioner must issue a license which is valid until December 31 of the year of application.

(c) A person licensed under this section is presumed to be growing industrial hemp for commercial purposes.

Subd. 2. **Background check; data classification.**

The commissioner must require each first-time applicant for a license to submit to a background investigation conducted by the Bureau of Criminal Apprehension as a condition of licensure. As part of the background investigation, the Bureau of Criminal Apprehension must conduct criminal history checks of Minnesota records and is authorized to exchange fingerprints with the United States Department of Justice, Federal Bureau of Investigation for the purpose of a criminal background check of the national files. The cost of the investigation must be paid by the applicant. Criminal history records provided to the commissioner under

this section must be treated as private data on individuals, as defined in section 13.02, subdivision 12.

Subd. 3. Federal requirements.

The applicant must demonstrate to the satisfaction of the commissioner that the applicant has complied with all applicable federal requirements pertaining to the production, distribution, and sale of industrial hemp.

18K.05 ANNUAL REPORT; SALES NOTIFICATION. (a) Annually, a licensee must file with the commissioner:

(1) documentation demonstrating to the commissioner's satisfaction that the seeds planted by the licensee are of a type and variety that contain no more than three-tenths of one percent delta-9 tetrahydrocannabinol; and

(2) a copy of any contract to grow industrial hemp.

(b) Within 30 days, a licensee must notify the commissioner of each sale or distribution of industrial hemp grown by the licensee including, but not limited to, the name and address of the person receiving the industrial hemp and the amount of industrial hemp sold or distributed.

18K.06 RULEMAKING. (a) The commissioner shall adopt rules governing the production, testing, and licensing of industrial hemp.

(b) Rules adopted under paragraph (a) must include, but not be limited to, provisions governing:

(1) the supervision and inspection of industrial hemp during its growth and harvest;

(2) the testing of industrial hemp to determine delta-9 tetrahydrocannabinol levels;

(3) the use of background check results required under section 18K.04 to approve or deny a license application; and

(4) any other provision or procedure necessary to carry out the purposes of this chapter.

(c) Rules issued under this section must be consistent with federal law regarding the production, distribution, and sale of industrial hemp.

NOTE: This section as added by Laws 2015, First Special Session chapter 4, article 2, section 43, is effective the day after the federal government authorizes the commercial production of industrial hemp. Laws 2015, First Special Session chapter 4, article 2, section 43, the effective date.