Statutes, Rules, and Guidance: Legislation - Substances Derived from Hemp
901st Meeting of the Minnesota Board of Pharmacy

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 delta-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* 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 subsequently amended, as Appendix B).

Initially, both the federal and state industrial hemp laws only allowed industrial hemp *research* programs. While those programs were allowed to include research into the marketing of products, the federal and state laws did 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 stated (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 several years ago by a local retail establishment that may have since closed. 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."

(Note that many sellers of these products no longer make such health benefit claims).

CBD

Explore the benefits of Hemp

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!

WHY CHOOSE HEMPDROPZ?

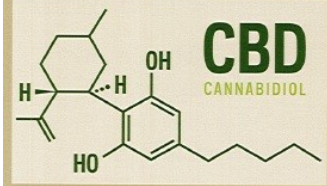
Our product comes from 100% USA grown organic hemp. It's all grown in Colorado under strict guidelines, and registered with the Colorado State Department of Agriculture.

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.

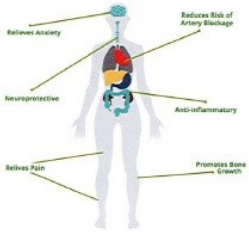
What is Cannabidiol?

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 gummy 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."


CBD HEMP CIGAR
NO THC
CONTAINS LAB TESTED 15% CBD MEDICAL GRADE HEMP
NO THC
A&D ELECTRONIC BALANCE
2.8 g
ON OFF
SAMPLE
MODE
PRINT
RE-ZERO
Max 6100g d=0.1g
FX-6000

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 several years ago, claimed that hemp-derived CBD meets the FDA's definition of a dietary supplement. It addressed

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). Many hemp-derived products still contain statements that are typically found on actual dietary supplement products, such as: "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." It is possible that the manufacturers of those products may still believe that they can be sold as dietary supplements.

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 or marketing of some hemp-derived 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, 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 – *unless they meet the requirements of Minn. Stats §151.72*. (CBD products produced by the medical cannabis manufacturers regulated by the Minnesota Department of Health are also permitted to be sold under other sections of Minnesota Statutes).

Minn. Stats. Chapter 18K does not pre-empt any provisions of Chapter 151. Consequently, products containing cannabinoids and tetrahydrocannabinols derived from industrial hemp are drugs, as

defined in Minn. Stats. §151.01, subd. 5. And if they are drugs, *and they don't meet the requirements of Minn. Stats. §151.72*, 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." Drug 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 are illegal within Minnesota – again, unless they meet the requirements of Minn. Stats. §151.72. Violation of Minn. Stats. §151.34 is a misdemeanor.

Controlled substance law

Prior to the passage of the 2018 Federal Agriculture Act, and modifications our Legislature made to the definition of hemp in 2019, CBD (and other cannabinoids), when derived from marijuana, used to be Schedule I controlled substances, both federally and per Minnesota Statutes – because they were a compound, manufacture or derivative or those portions of the *Cannabis sativa* plant that are defined as marijuana. CBD (and other cannabinoids) derived from hemp may not have been controlled substances.

Both the 2018 Federal Agriculture Act, and changes made by the Minnesota Legislature to the definition of hemp found in Minn. Stats. 18K.02, clarified that products containing ***cannabinoids*** derived from Cannabis sativa plants are not controlled substances, provided that those products contain less than 0.3% of delta-9 THC. (See below for a discussion of products containing tetrahydrocannabinols indirectly derived from hemp).

Impact of Other Provisions in the 2018 Federal Agricultural Act and Changes Made by the Minnesota Legislature in 2019

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 (or other cannabinoids) 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 an 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 order to allow for the sale of *nonintoxicating* cannabinoids *extracted* from hemp to be sold for human or animal consumption in Minnesota, the Legislature enacted Minn. Stats. §151.72 in 2019. That section states that a product containing *nonintoxicating cannabinoids extracted* from hemp may be sold for human or animal consumption if certain testing and labeling requirements are met. If those requirements are not met, the products are misbranded and/or adulterated and can't be legally sold in the State. Section 151.72 does *not* allow for the sale of tetrahydrocannabinols or intoxicating substances extracted or indirectly derived from hemp. (See the next section for additional analysis).

In short, the sale of products that contain cannabinoids or tetrahydrocannabinols, extracted or indirectly derived from any type of cannabis plant, remains illegal under federal and Minnesota state law, with certain exceptions. The exceptions would be FDA-approved drugs, such as the recently approved Epidiolex, 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, and products that meet the provisions of Section 151.72.

Tetrahydrocannabinols indirectly derived from hemp plants

Federal and Minnesota laws define industrial hemp to mean:

> "the plant Cannabis sativa L. and any part of the plant, whether growing or not, including the plant's seeds, and all the plant's derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Minnesota's definition also states that "Industrial hemp is not marijuana as defined in section 152.01, subd. 9. A faulty interpretation of this definition, and the failure to consider other relevant sections of statutes has led some individuals and companies to incorrectly believe that they can extract CBD from hemp, synthetically convert into delta-8 THC, and sell the delta-8 THC in products meant from human consumption.

Delta-8 tetrahydrocannabinol (Δ-8 THC), which is an isomer and analog of delta-9 tetrahydrocannabinol (Δ-9 THC). Δ-8 THC is an intoxicating substance, although it is slightly less potent than Δ-9 THC (meaning it takes a larger quantity to make some "high"). Δ-8 THC is being produced by some individuals and companies by extracting cannabidiol (CBD) from hemp and converting the CBD to Δ-8 THC.

The producers believe that Δ-8 THC products derived from hemp are not controlled substances as long as the product contains less than 0.3% of Δ-9 THC. That is because of the following definition of industrial hemp found Minn. Stats. §18K.02, subd. 2 is (emphasis added):

> "Industrial hemp" means the plant Cannabis sativa L. and any part of the plant, whether growing or not, including the plant's seeds, and all the plant's ***derivatives***, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, ***with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Industrial hemp is not marijuana*** as defined in section 152.01, subdivision 9.

In addition, the definition of "marijuana" in Minn. Stats. §151.01 includes this sentence "Marijuana does not include hemp as defined in section 152.22, subdivision 5a."

However, Minn. Stats §152.02, subd. 2 h. (2) makes tetrahydrocannabinols Schedule I controlled substances, *separately* from marijuana. The definitions of industrial hemp and marijuana given above make no mention of industrial hemp ***not*** being tetrahydrocannabinols. In addition, Δ-8 THC is not ***directly*** derived or extracted from industrial hemp, it is synthesized from CBD that is extracted from hemp. Therefore, an argument can be made that Δ-8 THC synthesized from CBD that is extracted from hemp, is a Schedule I controlled substance, even if the product that contains it has less than 0.3% of Δ-9 THC.

The Minnesota State Court of Appeals appears to have reached that same conclusion in the case of

State v. Loveless, pointing out (at least for liquid products containing any amount of any tetrahydrocannabinol):

> "Unlike the definition of marijuana, the inclusion of tetrahydrocannabinols in Minnesota's Schedule I does not make any exception for hemp or for a substance or mixture that has a concentration of delta-9 tetrahydrocannabinol that is 0.3 percent or less on a dry-weight basis."

The Court acknowledges that "the legislature enacted other laws that appear to recognize or assume the lawfulness of vaporizer cartridges containing low concentrations of delta-9 tetrahydrocannabinol." However, the Court also opined that:

> "the legislature did not amend the relevant provisions of chapter 152 to make it lawful to possess a liquid mixture with a low concentration of delta-9 tetrahydrocannabinol. If a statute's language is plain and its meaning is unambiguous, a court must interpret the statute according to its plain meaning, without resorting to canons of construction or legislative history. See, e.g., *State v. Serbus,* 957 N.W.2d 84, 87 (Minn. 2021); *State v. Struzyk*, 869 N.W.2d 280, 288 n.5 (Minn. 2015). Here, the relevant provision of Schedule I is unambiguous. It states simply, "tetrahydrocannabinols," without regard for the concentration of delta-9 tetrahydrocannabinol."

In addition, to the fact that Δ-8 THC is a Schedule I controlled substance, it is almost as intoxicating as Δ-9 THC. Minn. Stats. §151.72 only allows non-intoxicating substances directly *extracted* from hemp to be sold for human and animal consumption – and only when the provisions of that section are followed. (The scope of 151.72 is limited to "the sale of any product that contains nonintoxicating cannabinoids extracted from hemp." – there is no mention of products indirectly derived from hemp by synthetic conversion of another substance extracted from hemp). Since Δ-8 THC is intoxicating, and it is synthetically produced from CBD that is extracted from hemp, section 151.72 does not allow for its sale for human or animal consumption. Basically, such products would be both Schedule I controlled substances and misbranded and/or adulterated drugs).

The *Loveless* decision has created another issue. Since even CBD products that *do* meet the requirements of Minn. Stats. §151.72 contain at least trace amounts of tetrahydrocannabinols, they would appear to be Schedule I controlled substances under this ruling. Δ-8 THC products would definitely be Schedule I controlled substances under this ruling and for the other reasons mentioned above.

If the Legislature wishes to continue allowing the sale of nonintoxicating cannabinoids derived from hemp, it appears that Minn. Stats. §151.72 will need to be amended. If the Legislature also wishes to legalize the sale and possession of products containing Δ-8 THC, which is intoxicating, Minn. Stats. §152.02, subd. 2 h (2) would also need to be modified.

The Board is working with the Minnesota Departments of Agriculture, Health, and Public Safety on issues involving substances extracted from hemp and sold for human or animal consumption. It is the consensus of those agencies that the Legislature should modify Section 151.72 to allow for the continued sale nonintoxicating cannabinoids extracted from hemp, as long as the conditions found in that section are met – but to not make any changes to statutes that would allow for the continued sale of intoxicating tetrahydrocannabinols that are indirectly derived from hemp – at least not until legislation is passed that creates a better, comprehensive regulatory framework for the handling of

Cannabis sativa and all of the products derived from it. One that deals with medical cannabis, adult recreational use, and the manufacturing and sale of products that contain drugs extracted from marijuana and hemp plants. The agencies aren't trying to permanently prevent the sale or use of these products but do think there should be better standards in place to make sure the public is buying safe and reliable products. It would be perhaps a little strange to allow for the continued sale of a synthetic isomer of Δ-9 THC – before marijuana itself is legalized for recreational use.

Proposed language for a bill, to be carried as a Board of Pharmacy bill, is included as Appendix C.

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

Subd. 1a. **Applicant.** "Applicant" means an individual who submits an application for a license as required under this chapter. If the applicant is an entity, applicant means the owner or most responsible individual in charge of the entity.

Subd. 1b. **Authorized representative.** "Authorized representative" means any individual authorized by the licensee to make changes to the license and share data on behalf of the licensee.

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

Subd. 2a. **Entity.** "Entity" means a corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.

Subd. 3.**Industrial hemp.** "Industrial hemp" means the plant Cannabis sativa L. and any part of the plant, whether growing or not, including the plant's seeds, and all the plant's derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 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.

Subd. 5. **Processing.** "Processing" means rendering by refinement hemp plants or hemp plant parts from their natural or original state after harvest. Processing includes but is not limited to decortication, devitalization, chopping, crushing, extraction, and packaging. Processing does not include typical farm operations such as sorting, grading, baling, and harvesting.

Subd. 6. **Processing location.** "Processing location" means any area, building, plant, or facility registered with and approved by the commissioner in which a licensee converts raw hemp into a marketable product.

Subd. 7. **Processor.** "Processor" means a person or business that converts raw hemp into a product.

18K.03 AGRICULTURAL CROP; POSSESSION AUTHORIZED.

Subdivision 1. **Industrial hemp.** 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 or lawfully grown in another state.

Subd. 2. **Sale to medical cannabis manufacturers.** A licensee under this chapter may sell hemp products derived from industrial hemp grown in this state to medical cannabis manufacturers as authorized under sections 152.22 to 152.37.

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

18K.04 LICENSING.

Subdivision 1. **Requirement; issuance; presumption.** (a) A person must obtain a license from the commissioner before (1) growing industrial hemp for commercial or research purposes, and (2) before processing industrial hemp for commercial purposes.

(b) To obtain a license under paragraph (a), 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.

(c) For a license to grow industrial hemp for commercial or research purposes, 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 and any other information required under Code of Federal Regulations, title 7, part 990.

(d) For a license to process industrial hemp for commercial purposes, the license application must include the name and address of the applicant, the legal description of the processing location, and any other information required by the commissioner.

(e) A licensee is responsible for compliance with the license requirements irrespective of the acts or omissions of an authorized representative acting on behalf of the licensee.

(f) 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.

(g) A person licensed under paragraph (a) to grow industrial hemp is presumed to be growing industrial hemp for commercial or research 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 processing, production, distribution, and sale of industrial hemp.

Subd. 4. **Industrial hemp licensing data classification.** (a) In addition to data classified pursuant to section 13.41, the following data collected, created, or maintained by the commissioner

under this chapter is classified as private data, as defined in section 13.02, subdivision 12, or nonpublic data, as defined in section 13.02, subdivision 9:

(1) nondesignated addresses provided by licensees and applicants; and

(2) data that identify the specific locations where licensees and applicants grow or process, or will grow or process, industrial hemp, including but not limited to legal descriptions, street addresses, geospatial locations, maps, and property boundaries and dimensions.

(b) The commissioner may disclose data classified as private data or nonpublic data under this subdivision if the commissioner determines that there is a substantive threat to human health or safety or to the environment, or to aid in the law enforcement process.

Subd. 5. **Industrial hemp licensing data security and auditing.** (a) The commissioner must establish written procedures to ensure that only individuals authorized by law may access the private data and nonpublic data identified in subdivision 4. An authorized individual's ability to enter, update, or access data must correspond to the official duties or training level of the individual and to the statutory authorization granting access for that purpose. All queries and responses, including the specific purpose for which data is requested and, if applicable, disclosed, and all actions in which data are entered, updated, accessed, shared, or disseminated, must be recorded in the data audit trail. Data contained in the audit trail are public to the extent the data are not otherwise classified by law.

(b) The commissioner must immediately and permanently revoke the authorization of any individual who willfully entered, updated, accessed, shared, or disseminated data in violation of state or federal law. If an individual willfully gained access to data without authorization by law, the commissioner must forward the matter to the appropriate prosecuting authority for prosecution.

(c) By January 15 of each odd-numbered year, the commissioner must provide a copy of the data audit trail required under paragraph (a) to the commissioner of administration; the chairs and ranking members of the legislative committees and divisions with jurisdiction over agriculture policy and finance, public safety, and data practices; and the Legislative Commission on Data Practices and Personal Data Privacy or its successor commission.

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, processing, and licensing of industrial hemp. Notwithstanding section 14.125, the commissioner's authority to adopt these rules expires June 30, 2022.

(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.

APPENDIX C

A bill for an act
relating to health; requiring cannabinoid product labels to contain a bar code or QR code; amending Minnesota Statutes 2020, section 151.72, subdivision 5.
BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2020, section 151.72, subdivision 1, is amended to read:

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(b) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 3.

(c) "Certified hemp" means hemp plants that have been tested and found to meet the requirements of Chapter 18K and the rules promulgated thereunder.

~~(c)~~ (d) "Labeling" means all labels and other written, printed, or graphic matter that are:

(1) affixed to the immediate container in which a product regulated under this section is sold; ~~or~~

(2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets~~.~~; or

(3) provided on that portion of a manufacturer's website that is linked to through the use a scannable bar code or QR code.

(e) "Label" has the meaning found in section 151.01, subd. 18.

(f) "Nonintoxicating cannabinoid" means substances extracted from certified hemp plants that do not produce intoxicating effects when consumed by any route of administration.

Sec. 2. Minnesota Statutes 2020, section 151.72, subdivision 2, is amended to read:

Subd. 2. **Scope.** (a) This section applies to the sale of any product, other than food, that contains ~~nonintoxicating~~ cannabinoids extracted from hemp, ~~other than food~~ and that is intended for human or animal consumption by any route of administration.

(b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.

Subd. 3. **Sale of cannabinoids derived from hemp.**

(a) Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids may be sold for human or animal consumption if all of the requirements of this section are met~~.~~, provided that such product does not contain more than 0.3% of any tetrahydrocannabinol or 0.3% of any combination of tetrahydrocannabinols.

(b) No other substances may be extracted or otherwise derived from hemp, and sold for human or animal consumption, if:

(1) the substance is intended for external or internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(2) the substance is intended to affect the structure or any function of the bodies of humans or other animals.

(c) No product containing any cannabinoid or tetrahydrocannabinol extracted or otherwise derived from hemp, may be sold to any individual who is under the age of 21.

(d) products that meet the requirements of this section are not controlled substances under section 152.02

Sec. 3. Minnesota Statutes 2020, section 151.72, subdivision 4, is amended to read:

Subd. 4. **Testing requirements.** (a) A manufacturer of a product regulated under this section must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and, at a minimum, the testing must confirm that the product:

(1) contains the amount or percentage of cannabinoids that is stated on the label of the product;

(2) does not contain more than trace amounts of any mold, pesticides, fertilizers, or heavy metals; and

(3) does not contain more than 0.3% of any tetrahydrocannabinol or 0.3% of any combination of tetrahydrocannabinols ~~a delta-9 tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in section 18K.02, subdivision 3~~.

(b) Upon the request of the board, the manufacturer of the product must provide the board with the results of the testing required in this section.

(c) Testing of the hemp from which the nonintoxicating cannabinoid was derived, or possession of a certificate of analysis for such hemp, does not meet the testing requirements of this section.

Sec. 4. Minnesota Statutes 2020, section 151.72, subdivision 5, is amended to read:

Subd. 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:

(1) the name, location, contact phone number, and website of the manufacturer of the product;

(2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product; and

(3) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed~~; or~~.

~~(4) instead of the~~ (b) The information in clauses (1) to (3) may be provided on an outer package if the immediate container that holds the product is too small to contain all of the information.

(c) The information required in clauses (1) to (3)~~,~~ may be provided through the use of a scannable bar code or QR code that links to a page on the manufacturer's website if that page contains all of the information required by this subdivision.

(c) The label must also include a statement stating that ~~this~~ the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

~~(b)~~ (d) The information required by this subdivision ~~to be on the label or~~ must be prominently and conspicuously placed on the label or displayed on the website, ~~and~~ in terms that can be easily read and understood by the consumer.

~~(c)~~ (e) The ~~label~~ labeling must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Section 5. Minnesota Statutes 2020, section 151.72, subdivision 6, is amended to read:

Subd. 6. **Enforcement.**

(a) A product made from any substance extracted or derived from hemp and ~~sold under this section~~ intended for external or internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, or that is intended to affect the structure or any function of the bodies of humans or other animals, shall be considered an adulterated drug if:

(1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;

(2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;

(3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(4) it contains any color additives or excipients that have been found by the FDA to be unsafe for human or animal consumption; ~~or~~

(5) it contains an amount or percentage of nonintoxicating cannabinoids that is different than the amount or percentage stated on the label;

(6) it contains more than 0.3% of any tetrahydrocannabinol or 0.3% of any combination of tetrahydrocannabinols; or

(7) it contains more than trace amounts of mold, pesticides, fertilizers, or heavy metals.

(b) A product ~~sold under this section~~ made from any substance extracted or derived from hemp and intended for external or internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, or that is intended to affect the structure or any function of the bodies of humans or other animals, shall be considered a misbranded drug if the product's labeling is false or misleading in any manner or is in violation of the requirements of this section.

(c) The board's authority to issue cease and desist orders under section 151.06; to embargo adulterated and misbranded drugs under section 151.38; and to seek injunctive relief under section 214.11, extends to any violation of this section.