July 2021

Delta-8 Tetrahydrocannabinol (THC)

Prepared by: Amber Otis and Steve McCarthy, Senior Staff Attorneys

The cannabis plant contains several cannabinoids, with non-psychoactive cannabidiol (CBD) and psychoactive delta-9 THC among the most well-known. A cannabis plant with levels of delta-9 THC at or below 0.3 percent is considered hemp under federal and state law. The federal Agriculture Improvement Act of 2018 (AIA) legalized hemp and its derivatives, but synthetic THC remains an illegal substance. Another cannabinoid, delta-8 THC, has recently gained commercial popularity, in part because this potentially lawful psychoactive product may be converted from hemp-derived CBD. Although a substance meeting the definition of "hemp" is legal for purposes of state and federal controlled substances laws, uncertainty surrounds whether delta-8 THC, when converted from hemp-derived CBD, falls within the definition of hemp or instead constitutes synthetic THC.

CONTROLLED SUBSTANCES LAWS

State and federal law each contain a Controlled Substances Act (CSA) under which substances are "controlled" by being placed on schedules numbered I to V, with Schedule I substances considered to have the highest potential for abuse and the least usage medically. The state and federal CSAs generally prohibit the possession, distribution, and manufacture of controlled substances, though the specific prohibited acts vary depending on the applicable schedule.²

Under the federal CSA, marijuana and THC are both considered Schedule I controlled substances. THC is defined to include THC that is naturally contained in a cannabis plant, as well as synthetic equivalents of the substances contained in the cannabis plant. However, the definitions of marijuana and THC both contain exceptions; substances that meet these exceptions are not subject to the prohibitions under the federal CSA and are generally lawful.³

THE AIA'S LEGALIZATION OF HEMP

Concurrent with creating a regulatory scheme for hemp production, the AIA excluded hemp from the definition of "marijuana" and further provided that THC under Schedule I does not include THC contained in hemp. Under the AIA, "hemp" means "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 [THC] concentration of not more than 0.3 percent on a dry weight basis." Like federal law, Wisconsin's CSA includes an exception for THC in hemp, defined under state law nearly identically to the AIA's hemp definition.⁴

On August 21, 2020, the federal Drug Enforcement Administration (DEA) issued an <u>interim final rule</u> to conform its regulations to the AIA's legalization of hemp. As expected, the rule exempted from the Schedule I listing of THC any "material, compound, mixture, or preparation" that falls within the AIA's definition of hemp. However, the rule also highlighted the continued illegality of *synthetic* THC, thereby causing significant industry debate as to whether the rule rendered unlawful delta-8 THC derived from hemp. The relevant rule language states:

For [THCs] that are naturally occurring constituents of the plant material, Cannabis sativa L., any material that contains 0.3% or less of D9-THC by dry weight is not controlled, unless specifically controlled elsewhere under the CSA. Conversely, for [THCs] that are naturally occurring constituents of Cannabis sativa L., any such material that contains greater than 0.3% of D9-THC by dry weight remains a controlled substance in schedule I. The AIA does not impact the control status of

synthetically derived [THCs] (for Controlled Substance Code Number 7370) because the statutory definition of "hemp" is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived [THCs], the concentration of D9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived [THCs] remain schedule I controlled substances.

LEGALITY OF DELTA-8 THC: HEMP DERIVATIVE VERSUS SYNTHETIC THC

The legality of delta-8 THC, when converted from hemp-derived CBD, depends on whether it meets the definition of "hemp" or, instead, constitutes synthetic or chemically synthesized THC. In order to meet the federal and state definitions of hemp, a substance must: (1) be any part of the cannabis plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers; and (2) have a delta-9 THC concentration of 0.3 percent or less. However, synthetic THC remains a controlled substance under federal and state law, as highlighted by the DEA's interim final rule, though controlled substances laws do not define the term "synthetic."

Many industry participants assert that, because delta-8 THC naturally occurs in hemp, delta-8 THC converted from hemp-derived CBD retains a lawful status as a hemp-derived substance and that the conversion process does not equate to the type of human-controlled procedures that create artificial substances. Advocates further argue that if the use of human-controlled procedures render a substance synthetic, then many hemp-derived products would be unlawful – an outcome that arguably undermines the AIA's legalization of hemp and its derivatives.

In contrast, others argue that the AIA's strict delta-9 THC threshold of 0.3 percent reflects an intent not to legalize substances with a psychoactive effect like that of delta-8 THC. Additionally, critics of delta-8 THC's legality cite the DEA's explicit reference to delta-8 THC as a synonym for scheduled THC in its publication titled *List of Scheduling Actions*. Although this publication does not have the effect of law, it arguably provides insight into the DEA's position on delta-8 THC. However, even if the DEA deems delta-8 THC synonymous with scheduled THC, some maintain that delta-8 THC derived from hemp remains lawful, because the AIA exempted THC in hemp from controlled substances laws.

In sum, the legality of delta-8 THC under controlled substances laws remains an open question. Naturally occurring delta-8 THC extracted from hemp is likely not controlled by federal or state law. However, if the conversion of delta-8 THC from hemp-derived CBD renders the substance "synthetically" derived or "chemically synthesized," then it constitutes a Schedule I substance under federal and state law. Until regulators or lawmakers provide further clarity, the legality of delta-8 THC appears to depend significantly on the nature and characterization of the process used for its production.

¹ For more information, see <u>Congressional Research Service</u>, <u>Defining Hemp: A Fact Sheet</u>, <u>March 22</u>, <u>2019</u>.

² See, generally, <u>21 U.S.C. ch. 13</u> (federal CSA) and <u>ch. 961, Stats</u>. (state CSA).

³ <u>21 U.S.C. s. 812</u> (c) (Schedule I) (c) (10) and (17); <u>21 C.F.R s. 1308.11</u> (d) (31) (i). Wisconsin's CSA is similar to the federal CSA, in that it lists as a Schedule I substance THC in any form, including THC contained in marijuana, obtained from marijuana, or chemically synthesized. However, unlike the federal CSA, marijuana is not a scheduled drug under the state CSA.

⁴ See, <u>7 U.S.C. s. 16390</u> (1); ss. <u>94.55 (1)</u> and <u>961.14 (4) (t)</u>, Stats. Wisconsin's CSA exempts THC in certain portions of the cannabis plant, similar to exceptions to the definition of marijuana under federal law, and also exempts THC contained in any of the following: (1) CBD products without psychoactive effect, in certain circumstances; (2) hemp, as defined under state law; and (3) a drug product, known as Epidiolex, approved by the Federal Drug Administration (FDA). Unlike federal law, state law specifies that "hemp" does not include FDA-approved prescription drug products.

⁵ Informally referred to as "the orange book," this publication lists the substances scheduled under the federal CSA and related rules in the Code of Federal Regulations and serves as a general reference guide for various information, such as the effective date of scheduling and the code number assigned to the substance for purposes of identification.

⁶ In addition, cannabis-derived products may be subject to other laws not addressed in this issue brief, such as those governing synthetics or analogs, or those related to food and drug safety. This issue brief is not intended to provide legal advice.