

July 28, 2022

To: Secretary Lohr
Virginia Department of Agriculture and Consumer Services

Re: Task Force Meeting July 7, 2022



Please accept my comments on the recent task force meeting “Task Force to Analyze Industrial Hemp Extracts and other Substances Containing Tetrahydrocannabinol Intended for Human Consumption” held on July 7, 2022.

In 2018, domestic hemp production was fully legalized under the U.S. Farm Bill.¹ Prior to 2018, hemp and hemp-containing products could be imported into the U.S. or manufactured into finished goods that would ultimately enter the U.S. market; however, the crop itself could not be domestically grown.² The 2018 farm bill expanded the definition of hemp, originally established in statute as part of the 2014 farm bill (7 U.S.C. §5940(b)(2)), codified in Section 297A of the Agricultural Marketing Act of 1946 (AMA). The amended definition defines hemp to mean: 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 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

While there has been debate about the intent of the 2018 Farm bill and while it was not meant to address hemp-derived Delta-8 products specifically, the farm bill effectively legalized it and other hemp-derived cannabinoids. In a position statement (attached) dated June 22, 2021, Kight Law, on behalf of the Hemp Industries Association, affirmed, unequivocally, that delta-8 THC is neither federally illegal nor a synthetic product.

Making the cannabis plant itself a Schedule 1 substance to begin with was a tragic error that has had countless negative impacts on our society. By redefining hemp to include its “extracts, cannabinoids and derivatives,” Congress explicitly removed popular hemp products — such as hemp-derived cannabidiol (CBD) — from the purview of the Controlled Substances Act (CSA). Accordingly, the Drug Enforcement Administration no longer has any possible claim to interfere with the interstate commerce of hemp products.³

In a letter (attached) dated September 15, 2021, from Terrence L. Boos, Ph.D., Chief Drug & Chemical Evaluation Section, Diversion Control Division of the Drug Enforcement Agency to Donna C. Yeatman, R.Ph., Executive Secretary of the Alabama Board of Pharmacy Mr. Boos states that “cannabinoids extracted from the cannabis plant that have a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis meet the definition of “hemp” and thus are not controlled under the Controlled Substances Act.

¹ *Agriculture Improvement Act of 2018*, Public Law 115-334 (Dec.2018)

² But for the USDA limited pilot program launched in 2014, *Legitimacy of Industrial Hemp Research* (U.S. Farm Bill of 2013, Section 7606, H.R. 2642), and prior to the 1930s.

³ <https://madebyhemp.com/2018-farm-bill-hemp-cbd/>

Hemp-derived cannabinoids comprise the bulk of finished products goods in the hemp industry. Chase Hubbard, senior analyst at The Jacobsen/FastMarkets, recently estimated that 75% to 90% of crude extract is used for isomerization to cannabinoids like delta-8 THC.⁴ Restricting them would take away the largest (by far) market hemp farmers have for their products.



During the taskforce meeting, several references to safety concerns were made.

Mr. Ryan Davis noted that there have been no studies of short or long-term effects of hemp-derived cannabinoids like delta-8. However, the first article on delta-8 ("Isomerization of Cannabidiol to Tetrahydrocannabinoids") was published in 1941 and research into delta-8 began in 1942 which led to preliminary studies regarding delta-8's medicinal uses.⁵

There are more recent studies as well. For example, a unique collaboration between researchers from the University at Buffalo and the University of Michigan is shedding important new light on this compound. The team published two papers based on their survey of more than 500 participants' experiences with delta-8-THC and how it compared to cannabis. The words of one user best describe the overarching views shared by survey participants: That delta-8-THC is like delta-9's "nicer younger sibling"⁶ because it provides all the benefits with fewer adverse reactions. Separately, another study found that hyperactivity, paranoia, and anxiety are very rare among delta-8 THC users.⁷

According to Daniel J. Kruger, Ph.D., one of the team members and a research investigator in the Population Studies Center at the University of Michigan who also has a faculty affiliation at University of Buffalo, "It's paradoxical that different states and municipalities are opening up to delta-9, it's becoming more available and increasingly legalized, and yet they're putting the brakes on delta-8, even though it seems to have a better profile in terms of its effects".⁸

Other studies include:

- A Double-Blind, Randomized, Placebo-Controlled Test of the Effects of Cannabidiol on Experiences of Test Anxiety Among College Students⁹
- Cannabinoids to Improve Health-Related Quality of Life in Patients with Neurological or Oncological Disease: A Meta-Analysis¹⁰
- Consumer Experiences with Delta 8 THC: Medical Use, Pharmaceutical Substitution, and Comparisons with Delta-9-THC¹¹

⁴ <https://thejacobsen.com/price-reporting/hemp-pricing/>

⁵ <https://vidaoptimacbd.com/blogs/cannabis-encyclopedia/who-discovered-delta-8-thc>

⁶ <https://jcannabisresearch.biomedcentral.com/articles/10.1186/s42238-021-00115-8>

⁷ <https://cfah.org/is-delta-8-thc-safe/>

⁸ <https://medicalxpress.com/news/2022-01-largest-date-delta-thc-users-delta-.html>

⁹ <https://pubmed.ncbi.nlm.nih.gov/35861792/>

¹⁰ https://www.researchgate.net/publication/362165836_Cannabinoids_to_Improve_Health-Related_Quality_of_Life_in_Patients_with_Neurological_or_Oncological_Disease_A_Meta-Analysis

¹¹ <https://pubmed.ncbi.nlm.nih.gov/34797727/>

Even without the myriad of studies on hemp derived cannabinoids it is clear they are safer than, for example, alcohol. Hemp-derived cannabinoids like delta-8 have been on the market for two years, during which time more than 280,000 people have died from excessive alcohol use in the U.S. Contrast that to zero overdose deaths from hemp derived cannabinoids.



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Concerns about consumer safety demand that regulations on these products focus on ensuring the products are safe for ingestion by adults. Given the explosive demand for these products, and because they can be produced easily and cheaply (if you don't care about quality/purity), banning hemp-derived cannabinoids will inevitably lead to black markets full of unsafe products. Several states have addressed this concern by requiring third party lab testing to ISO 17025 standards, basic information on product labels, child-resistant packaging and, of course, adult-use only. A simple scan of QR codes can provide a consumer test results prior to them making a purchase.

We do not manufacture products meant to treat, diagnose, or improve medical conditions but it bears noting that there are many other entities focused on providing relief to adult consumers via alternative routes, some of which are focused on reducing opioid overdoses, deaths and cost to state medical programs. One study concluded that laws permitting cannabis use laws are "associated with significantly lower state-level opioid overdose mortality rates."¹² Another concluded state-wide medical cannabis legalization appears to have been associated with reductions in both prescriptions and dosages of Schedule III (but not Schedule II) opioids received by Medicaid enrollees in the United States.¹³

Ms. Erin Williams provided information on how other states are addressing regulating hemp derived cannabinoids. For context, it is important to note that "Big Cannabis" and major cannabis law firms have lobbied legislators and regulators to block the sale of hemp-based cannabinoids in many states to protect *their* adult-use and medical cannabis markets.¹⁴

Absent from Ms. Williams presentation were the following data points:

- The three states (New York, Colorado, and Oregon) highlighted at the taskforce meeting all have robust recreational marijuana programs, creating an environment where alternatives like hemp-derived cannabinoids like delta-8 are viewed as overt competition.
- New Jersey, Louisiana, Florida, Oklahoma, North Carolina, Georgia, Connecticut, Illinois, Tennessee, Maryland, Montana, Vermont, and Washington have declined to prohibit hemp derived cannabinoids like delta-8 or have regulated them reasonably to ensure consumer safety via testing requirements and common-sense labeling and descriptors.
- To block access to retail markets, cannabis trade organizations' attempts to collude against hemp cannabinoid suppliers are also impacting the fiber, grain, and cannabinoid sectors, pushing them to the brink of failure. This has resulted in enormous economic impact to the hemp industry, with estimated impacts in 2021 to the hemp fiber and grain sectors exceeding \$20 billion – \$25 billion; the impact estimated in 2021 for hemp is larger than the entire legal cannabis market in 2020.¹⁵

¹² <https://pubmed.ncbi.nlm.nih.gov/25154332/>

¹³ <https://pubmed.ncbi.nlm.nih.gov/29989239/>

¹⁴ <https://letstalkhemp.com/duped-by-big-dope/>

¹⁵ <https://letstalkhemp.com/duped-by-big-dope/>

Despite only being legalized in 2018, the CBD industry launched well over a decade ago. The global cannabidiol (CBD) market is estimated to reach \$47.22 billion¹⁶ by 2028, up from \$4.9 billion in 2021 with no regulation from FDA. The delta-8 and hemp-derived cannabinoid market is estimated between \$5 billion and \$8 billion with 75-90% of biomass being used in finished goods like gummies, tinctures, vapes.



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You have one chance to support a nascent but growing industry which, at this time, is almost entirely bolstered by hemp-derived cannabinoids like delta-8. We urge you to consider all factors and support farmers, processors, finished goods manufacturers and consumers by turning away from prohibition and supporting innovation, small business, and the economy.

Sincerely,

A handwritten signature in black ink, appearing to read 'Cabrera', enclosed within a circular scribble.

Cynthia Cabrera
Chief Strategy Officer
Hometown Hero CBD

¹⁶ <https://rss.globenewswire.com/en/news-release/2022/02/08/2380516/0/en/CBD-Cannabidiol-Market-Size-to-Reach-USD-47-22-Billion-by-2028-Increased-Demand-for-CBD-Cannabidiol-for-Health-and-Wellness-Purposes-to-Drive-Market-Vantage-Market-Research.html>

June 11, 2021

POSITION STATEMENT OF THE HEMP INDUSTRIES ASSOCIATION REGARDING DELTA-8 THC AND OTHER HEMP-DERIVED CANNABINOIDS

This position statement addresses the legal status of hemp-derived cannabinoids, including delta-8 tetrahydrocannabinol ($\Delta 8$ THC), under federal law. The specific issue addressed is: “*Are hemp-derived cannabinoids and compounds, including $\Delta 8$ THC, with delta-9 tetrahydrocannabinol ($\Delta 9$ THC) concentrations that do not exceed three tenths of one percent (0.3%) on a dry weight basis controlled substances under United States (US) federal law?*” For the reasons set forth in this position statement, and subject to the qualifications contained in it, the position of the Hemp Industries Association (HIA) is that the answer to this question is “no”.

The analysis contained in this position statement is based on the Agricultural Act of 2014 (2014 Farm Bill)¹, the Agriculture Improvement Act of 2018 (2018 Farm Bill)², the federal Controlled Substances Act (CSA)³, the federal Analogue Act (AA)⁴, and the Drug Enforcement Administration’s (DEA) recently published Interim Final Rule (IFR)⁵. This position statement is limited to analyzing the legal status of $\Delta 8$ THC and other hemp-derived cannabinoids and compounds under the CSA. It does not discuss the laws of any particular state nor any requirements under the Food, Drug & Cosmetic Act (FDAC) and associated regulations by the Food and Drug Administration (FDA)⁶ or any other federal agency.

The undersigned are attorneys for the HIA. This document is the official position of the HIA regarding the matters it addresses. **This position statement and its contents are not intended to be legal advice and should not be construed or relied upon as legal advice.** If you have questions regarding the issues discussed in this position statement you should consult with an attorney.

EXECUTIVE SUMMARY

a. $\Delta 8$ THC is a cannabinoid produced by hemp

$\Delta 8$ THC is a cannabinoid of the tetrahydrocannabinol (THC) “family” of compounds commonly derived from the cannabis plant, including hemp as defined in the 2018 Farm Bill. It is a double bond isomer of $\Delta 9$ THC, a more well-known cannabinoid in the

¹ 7 U.S. Code § 5940

² 7 U.S. Code § 1639o *et seq.*

³ 21 U.S. Code § 801 *et seq.*

⁴ 21 U.S. Code § 813

⁵ *Implementation of the Agriculture Improvement Act of 2018*, 85 Fed. Reg. 51639

⁶ 21 U.S. Code §§ 1-2335

tetrahydrocannabinol family that is also produced by the cannabis plant. An isomer is one of two or more compounds that contain the same number of atoms of the same elements but differ in structural arrangement and properties. There are thirty (30) known THC isomers. With respect to $\Delta 8$ THC and $\Delta 9$ THC, they differ with respect to the location of a double bond. Specifically, the THC molecule contains a structure called a “cyclohexane ring” composed of six carbon atoms arranged in a ring, each of which is bonded to two hydrogen atoms. All but one pair of the carbon atoms in the ring are linked by single covalent bonds. The remaining pair is linked by a double bond. The location of the double bond distinguishes $\Delta 8$ THC from other isomers of THC, such as $\Delta 9$ THC and $\Delta 10$ THC, in which the double bond is on a different location in the cyclohexane ring.⁷

b. $\Delta 8$ THC extracted from hemp is not a controlled substance under federal law

Despite their similarities, the structural difference between $\Delta 8$ THC and $\Delta 9$ THC makes a substantial difference in how they affect our bodies. It also affects their legal status. $\Delta 8$ THC from hemp is not a controlled substance. This is because the 2018 Farm Bill broadly legalized hemp, the definition of which specifically includes hemp “derivatives”, “extracts”, “cannabinoids”, “isomers”, etcetera that do not contain $\Delta 9$ THC concentrations that exceed 0.3% on a dry weight basis. Moreover, $\Delta 8$ THC is not a controlled substance under the federal Analogue Act⁸ due to the fact that the tetrahydrocannabinols found in hemp are exempt from the CSA by virtue of the 2018 Farm Bill. Additionally, the effects of $\Delta 8$ THC are not substantially similar to the effects of $\Delta 9$ THC, a schedule 1 controlled substance under federal law except as set forth in the 2018 Farm Bill.

c. $\Delta 8$ THC derived from CBD does not meet the definition of “synthetic THC”, but even if it does it is not a controlled substance

There is significant confusion regarding the legal status of $\Delta 8$ THC produced from cannabidiol (CBD) extracted from hemp.⁹ This confusion is primarily due to the chemical process used to derive $\Delta 8$ THC from CBD. This process raises the question of whether the resulting $\Delta 8$ THC is “synthetic” or not. It is not entirely clear whether $\Delta 8$ THC produced from CBD qualifies as a “synthetic” form of THC under US law since no generally accepted legal definition of the term “synthetic” exists. As discussed below, the better view is that it is not synthetic. However, even if is categorized as “synthetic THC”, this does not render hemp-derived $\Delta 8$ THC a controlled substance since the 2018 Farm Bill clearly defined “hemp” to include its “derivatives”, which by definition are “synthetic” (specifically, “bio-

⁷ <https://sensiseeds.com/en/blog/cannabinoid-science-101-what-is-thc-tetrahydrocannabinol/#:~:text=The%20THC%20molecule%20contains%20a,bonded%20to%20two%20hydrogen%20atoms.&text=The%20position%20of%20this%20double,extent%20of%20its%20psychoactive%20effect>.

⁸ Ibid. FN 4.

⁹ Unless otherwise stated, all references to CBD in this letter are to CBD that has been extracted from hemp.

synthetic”) compounds.

As a matter of statutory interpretation, when two federal laws appear to be in conflict on an issue and one of the laws is older and more general than the other, the more recent and specific law controls. Legally speaking, this is referred to as the doctrine of “*lex specialis*”, which means that “*the more specific controls over the general.*” In this case, the older and more general law is the CSA, which generally includes “THC”, including its synthetic forms, on the list of controlled substances. The more recent and specific law is the 2018 Farm Bill, which expressly removes “hemp” from the CSA. Under the 2018 Farm Bill, “hemp” includes its derivatives, among which is $\Delta 8$ THC. For this reason, hemp-derived $\Delta 8$ THC is lawful under federal law.

d. The hemp industry should advocate for safe $\Delta 8$ THC products and production methods

Despite the fact that hemp-derived $\Delta 8$ THC is lawful under US federal law, its rapid proliferation combined with a general lack of regulation has precipitated the entrance of substandard products into the market, many of which contain adulterants, contaminants, and toxins that may be harmful to consumers. The HIA strongly encourages safety in manufacturing, production, and consumption of hemp cannabinoids in order to ensure safe use by consumers and market expansion for the industry.

e. Prohibition is a failed concept that should not be applied to $\Delta 8$ THC or other hemp-derived cannabinoids

Finally, we note from a historical perspective that the idea of prohibition is a failed concept.¹⁰ Recently, a few states across the country have begun regulating $\Delta 8$ THC, including by banning it outright. An archaic and prohibitionist approach to this and other hemp cannabinoids will likely result in $\Delta 8$ THC products entering the illicit “black market”, rendering them nearly impossible to regulate. On the other hand, responsible regulation of $\Delta 8$ THC products will allow the hemp industry to continue its rapid expansion while maintaining a consumer protection driven approach to the marketplace. In an attempt to have consistency across the country, the HIA encourages the FDA to regulate $\Delta 8$ THC and other hemp compounds, including CBD, based on the fact they have been safely consumed by humans and animals for thousands of years.¹¹

¹⁰ See, eg. “*Prohibition Was a Failed Experiment in Moral Governance*”, Annika Neklason, published in The Atlantic, January 16, 2020: <https://www.theatlantic.com/ideas/archive/2020/01/prohibition-was-failed-experiment-moral-governance/604972/>

¹¹ See, eg. “*Oldest evidence of marijuana use discovered in 2500-year-old cemetery in peaks of western China*”, Andrew Lawler, published in Science, June 12, 2019: <https://www.sciencemag.org/news/2019/06/oldest-evidence-marijuana-use-discovered-2500-year-old-cemetery-peaks-western-china>

Δ8THC FROM HEMP IS NOT A CONTROLLED SUBSTANCE

Hemp initially became exempt from the CSA, and thus removed from the list of controlled substances, by virtue of the 2014 Farm Bill¹² when produced pursuant to a state's industrial hemp pilot program. The current Farm Bill¹³, enacted at the end of 2018, expressly provides that hemp-derived cannabinoids, derivatives, extracts, and isomers are included within the definition of lawful hemp. In other words, from a legal standpoint they are all "hemp". Specifically, the 2018 Farm Bill distinguishes lawful hemp from illegal marijuana¹⁴ and defines hemp as follows:

(1) HEMP.—The term ‘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-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. (emphasis added)¹⁵

The 2018 Farm Bill treats hemp as an agricultural commodity, putting it on par with wheat, grain, and soy. Hemp is not a controlled substance under the CSA.¹⁶ Importantly, under the 2018 Farm Bill hemp-derived "cannabinoids", "derivatives", "extracts", "isomers", etcetera are themselves "hemp" and thus not controlled substances. Δ8THC and other minor cannabinoids found in hemp are "cannabinoids". They are not controlled substances when derived from hemp, regardless of their concentrations.

Δ8THC DERIVED FROM CBD IS NOT A CONTROLLED SUBSTANCE

It is clear that Δ8THC which is naturally expressed in, and extracted from, the hemp plant is not a controlled substance. Currently, most Δ8THC on the market is a derivative of CBD from hemp. This is because current hemp cultivars do not express Δ8THC in sufficient concentrations or quantities to be viable economically. For the reasons stated below, Δ8THC derived from CBD¹⁷ is not a controlled substance.

As discussed above, under the 2018 Farm Bill's definition of "hemp", cannabinoids from hemp are the same thing as "hemp". This includes CBD extracted from hemp, which falls within the definition of "hemp" under the 2018 Farm Bill. The statute does not distinguish between a hemp plant and its cannabinoids, extracts, derivatives, etcetera. From a legal

¹² Ibid. FN 1.

¹³ Ibid. FN 2.

¹⁴ 21 U.S.C. § 802(16)

¹⁵ 7 U.S.C. § 1639o(1)

¹⁶ 21 U.S.C. § 802(16)(B): "The term "marihuana" does not include— (i) hemp, as defined in section 1639o of title 7."

¹⁷ CBD is one of the most abundant cannabinoids in cannabis and can be extracted from either a marijuana or a hemp plant. In this statement, all references to CBD are to CBD from hemp.

standpoint, all of these things are lawful “hemp”. A derivative of CBD is by definition a derivative of hemp and is thus not a controlled substance. A fundamental legal question is whether or not $\Delta 8$ THC produced from CBD is a “derivative” of CBD. For the reasons discussed below, the answer is “yes”.

The Chemicool Dictionary defines a “derivative” as *“a compound that can be imagined to arise or actually be synthesized from a parent compound by replacement of one atom with another atom or group of atoms.”*¹⁸ Wikipedia defines a chemical derivative as *“a compound that is derived from a similar compound by a chemical reaction.”*¹⁹

All of the standard operating procedures (SOP) we have reviewed for deriving $\Delta 8$ THC from CBD describe a chemical reaction initiated by a catalyst in which the CBD is converted to $\Delta 8$ THC and other minor cannabinoids and compounds. In fact, the US government holds a patent for converting CBD to $\Delta 8$ THC.²⁰ In an informal survey of four highly respected US analytical scientists, three of whom are the chief science officers for hemp and cannabis analytical testing laboratories²¹, all unanimously agreed that $\Delta 8$ THC does not degrade, oxidize, or otherwise convert to $\Delta 9$ THC by the mere application of heat. In fact, it appears that $\Delta 8$ THC is more stable than $\Delta 9$ THC²², which degrades over time into a different cannabinoid, cannabinol (CBN).

Based on most commonly used processes for producing $\Delta 8$ THC from CBD, including a US government patented SOP, $\Delta 8$ THC “*arises from a parent compound*” (i.e., CBD) through a true “*chemical reaction*” (i.e., not just a heat-induced transformation or degradation). For this reason, $\Delta 8$ THC is a “derivative” of CBD under the above definitions.

Finally, since the statutory definition of “hemp” includes CBD, of which $\Delta 8$ THC is a derivative, $\Delta 8$ THC falls within the statutory definition of hemp and is not a controlled substance. This conclusion follows the general rule, adopted in the 2018 Farm Bill, that the source of a cannabinoid determines its legal status. When a cannabinoid is derived

¹⁸ <https://www.chemicool.com/definition/derivative.html>

¹⁹ [https://en.wikipedia.org/wiki/Derivative_\(chemistry\)](https://en.wikipedia.org/wiki/Derivative_(chemistry))

²⁰ “Conversion of cbd to delta8-thc and delta9-thc”, US Patent No. US20040143126A1.
<https://patents.google.com/patent/US20040143126A1/en>

²¹ The names of these four scientists are not included in this position statement, nor are their individual responses. This is because our inquiry regarding this particular issue was general in nature and none of the scientists were made aware of this position statement or any facts whatsoever about the basis for our inquiry. They responded in good faith as friends and professionals in the industry to the following question: “*In your opinion, is it possible for delta-8 to convert to delta-9 via the heat applied through vaping and/or a GC crime lab test?*”

²² Abrahamov, Aya; Abrahamov, Avraham; Mechoulam, R. (1995). “An efficient new cannabinoid antiemetic in pediatric oncology”. *Life Sciences*. 56 (23–24): 2097–2102. doi:10.1016/0024-3205(95)00194-b. ISSN 0024-3205. PMID 7776837.

from marijuana it is a controlled substance; however, when it is derived from hemp it is not a controlled substance. This is known in the hemp industry as the “Source Rule”.²³

Δ8THC FROM HEMP IS NOT A CONTROLLED SUBSTANCE UNDER THE FEDERAL ANALOGUE ACT

Δ8THC from hemp is not a controlled substance under the federal Analogue Act (AA)²⁴. The AA provides for any chemical that is “*substantially similar*” to a controlled substance listed in Schedule I or II of the CSA, and which has a “*stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS) that is substantially similar to or greater than*” the controlled substance, to be treated as if it were listed in Schedule I when intended for human consumption. There are several reasons that hemp-derived Δ8THC is not a controlled substance under the AA.

First, the CSA expressly provides that “*tetrahydrocannabinols in hemp*” are not controlled substances.²⁵ This specificity in the CSA as to THC in hemp overrides any contrary general provisions in the AA. (See, eg, discussion of *lex specialis*, above.) Second, the effect that Δ8THC has on the CNS is not substantially similar to the effects of Δ9THC, a Schedule 1 controlled substance except as set forth in the 2018 Farm Bill. Its effects are up to ten (10) times less potent.²⁶ Third, hemp has been removed from the CSA. As discussed above, hemp-derived Δ8THC meets the legal definition of “hemp” under the Farm Bill. Legally speaking, it is “hemp” and is not a controlled substance. For these reasons, Δ8THC from hemp is not a controlled substance under the AA.

THE DRUG ENFORCEMENT ADMINISTRATION MAY CONTEND THAT Δ8THC FROM CBD IS AN UNLAWFUL FORM OF SYNTHETIC THC

The DEA has not taken a public position on hemp-derived Δ8 THC. However, it is worth mentioning that on August 21, 2020, the DEA published its IFR in the federal register.²⁷ In

²³ See, eg., <https://cannabusiness.law/cbd-and-the-source-rule/>;
<https://www.cannabisbusinessexecutive.com/2018/06/cbd-not-controlled-substance-source-rule-applies/>;
<https://www.lexology.com/library/detail.aspx?g=4ca075a2-599c-401f-a069-ba5cda71b721>;
<https://www.forbes.com/sites/roberthoban/2020/06/24/cbd-has-never-been-a-controlled-substance/?sh=1af03d594569>

²⁴ *Ibid.* FN 4.

²⁵ 21 U.S.C. § 812(c)(17)

²⁶ See, eg, *Ibid.* FN 22, which asserts that Δ8THC “*is generally considered to be 50% less potent than Δ9-THC and has been shown in some cases to be 3-10 times less potent.*” See also, “*Delta-8- and delta-9-tetrahydrocannabinol; Comparison in man by oral and intravenous administration*”, by Leo E. Hollister M.D. and H. K. Gillespie B.A., Volume 14, Issue 3 of *Clinical Pharmacology and Therapeutics*, 1973, which found that the potency of Δ8THC relative to Δ9THC is two-thirds (2/3).

²⁷ “*Implementation of the Agriculture Improvement Act of 2018*”, Federal Register Volume 85, Number 163 (Friday, August 21, 2020).

its IFR, the DEA set forth its position on the 2018 Farm Bill. The IFR contains the following statement:

“The [2018 Farm Bill] does not impact the control status of synthetically derived tetrahydrocannabinols (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 tetrahydrocannabinols, the concentration of Δ9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” (emphasis added)

This prohibition on “synthetically derived tetrahydrocannabinols” does not explicitly mention Δ8THC. Additionally, the DEA recently released the following statement regarding Δ8THC:

“Delta 8 THC was added to the controlled substances list in August 2020 on an interim basis while pending final disposition. As DEA is currently undergoing the rulemaking process regarding the implementation of the Agriculture Improvement Act of 2018 - which includes the scope of regulatory controls over marijuana, tetrahydrocannabinols, and other marijuana-related constituents - we would be unable to comment on an any impact in legality of tetrahydrocannabinols, Delta 8 included, until the process is complete. We are in the process of reviewing thousands of comments and do not speculate on what could happen as a result.”²⁸

However, since it is *possible* that the DEA may ultimately construe the chemical reaction that is required to derive Δ8THC from CBD as a process that results in a “synthetic” form of THC, and thereby contend that it is a controlled substance, the following discussion is to proactively rebut the contention that Δ8THC from CBD is an illegal synthetic form of THC.

a. Is Δ8THC from CBD “synthetic”

The term “synthetic” is not a term of art under US law. It has no set legal definition. Although the DEA has used the term “synthetic THC” in a number of publications its definitions vary.²⁹ In a 2017 letter to the US Sentencing Commission³⁰, the DEA proposed

²⁸ <https://abc13.com/society/what-is-delta-8-and-why-is-it-considered-legal-weed-in-texas/10674338/>

²⁹ See eg, https://www.deadiversion.usdoj.gov/synthetic_drugs/about_sd.html;
https://www.deadiversion.usdoj.gov/fed_regs/rules/2001/fr10092.htm;
https://www.dea.gov/sites/default/files/sites/getsmartaboutdrugs.com/files/publications/DoA_2017Ed_Up_dated_6.16.17.pdf#page=88; <https://www.dea.gov/factsheets/spice-k2-synthetic-marijuana>

³⁰ <https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-comment/20171027/DEA.pdf>

to define a “synthetic cannabinoid” as a “substance that acts as an agonist at the CB1 receptor.” While this definition may be helpful to the DEA and federal prosecutors in sentencing hearings due to years of confusion about whether or not the inclusion of THC in the CSA refers only to synthetic THC or to all forms of THC, it does not illuminate what is actually meant by “synthetic” since it captures most cannabinoids, including those naturally occurring in hemp.

According to a 2014 DEA Rule³¹, “[s]ynthetic cannabinoids are a large family of compounds that are functionally (biologically) similar to delta9-tetrahydrocannabinol (THC), the main active ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory.” The DEA employs a similar, but not quite identical, definition in a 2011 Rule³²: “[s]ynthetic cannabinoids are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principle of marijuana.” The DEA further asserts in the 2011 Rule that “synthetic” refers to “non-organic... chemicals created in a laboratory.”

Additionally, an expert witness for the DEA stated the following about synthetic cannabinoids while under examination in a hearing:

“[U]nlike THC, which is a partial agonist, synthetic cannabinoids are full agonists. This means, according to Dr. Trecki [a DEA pharmacologist who routinely testifies for the Government in criminal cases about the nature and effects of synthetic cannabinoids], synthetic cannabinoids produce a more intense reaction than THC.”³³

Given the above, it is difficult to determine what the DEA means by “synthetic THC”. Based on the various definitions and positions cited above, we can arrive at multiple conclusions about whether or not delta-8 THC is “synthetic”. On the “synthetic” side, we can point to the fact that Δ 8THC can be produced in a laboratory from another compound, namely CBD.

On the “not synthetic” side, we can point to the fact that Δ 8THC is chemically related to THC. As discussed above, it is a THC isomer. According to the DEA, a cannabinoid must be “chemically *unrelated*” to THC in order to be “synthetic”. While this definition clearly includes “Spice”, “K2”, and other synthetic compounds designed to be full agonists of CB1 receptors that are not derived from cannabis and are not chemically related to THC³⁴, it does not include Δ 8THC. Additionally, to meet the DEA’s definition of “synthetic”, Δ 8THC

³¹ “Schedules of Controlled Substances: Temporary Placement of Four Synthetic Cannabinoids Into Schedule I”, Federal Register Volume 79, Number 27 (Monday, February 10, 2014)

³² “Schedules of Controlled Substances: Temporary Placement of Five Synthetic Cannabinoids Into Schedule I”, Federal Register Volume 76, Number 40 (Tuesday, March 1, 2011).

³³ United States v. Hage, 741 Fed. Appx. 194, 195, 2018 U.S. App. LEXIS 18752, *1, 2018 WL 3385467

³⁴ See, eg, <https://www.drugabuse.gov/publications/drugfacts/synthetic-cannabinoids-k2spice>

must be a non-organic chemical created in a laboratory. $\Delta 8$ THC from CBD is created in a laboratory, though it is also an organic chemical naturally expressed in the hemp plant. Additionally, in response to the DEA's star expert witness, Dr. Trecki, $\Delta 8$ THC is not a full CB1 agonist nor does it produce as intense a reaction as delta-9 THC, both of which are required for $\Delta 8$ THC to meet the definition of "synthetic THC".

Based on the above, the question of whether $\Delta 8$ THC is "synthetic" appears to be unresolved, though the best answer appears to be "no".

b. Even if $\Delta 8$ THC from CBD is "synthetic", it is not a controlled substance

With respect to the legal status of $\Delta 8$ THC under federal law, it does not matter if hemp-derived $\Delta 8$ THC is deemed to be "synthetic" or not. Either way, it is not a controlled substance. Neither the 2018 Farm Bill, nor any other federal statute, defines what is meant by a hemp "derivative". Absent a statutory definition, it is reasonable to rely on the definition that is commonly used in the context in which the term appears. In this context, the term "derivative" arises in the 2018 Farm Bill's definition of "hemp". Specifically, the 2018 Farm Bill uses the term "derivative" in a scientific context and so a scientific definition is most appropriate. As stated above, the Chemicool Dictionary defines "derivative" as:

"a compound that can be imagined to arise or actually be synthesized from a parent compound by replacement of one atom with another atom or group of atoms." (emphasis added)

Importantly, the definition actually includes the term "*synthesis*". Additionally, the process that is described in the Chemicool definition is exactly what happens when hemp-derived CBD is *isomerized* (another 2018 Farm Bill term) and becomes $\Delta 8$ THC. When viewed in this light, it is clear that the 2018 Farm Bill both anticipated and expressly includes hemp derivatives, such as $\Delta 8$ THC, within the definition of "hemp".

This leads to the final point on this issue, which is that the 2018 Farm Bill, which removed hemp from the CSA, controls with respect to the legal status of $\Delta 8$ THC. When two federal laws appear to be in conflict on an issue and one of the laws is both older and more general than the other, the more recent and specific law will control. As discussed above, this maxim is called "*lex specialis*", which means that "*the more specific controls over the general.*"³⁵ In this situation, the older and more general law is the CSA, which generically includes "THC", including its synthetic forms, on the list of controlled substances. The more recent and specific law is the 2018 Farm Bill, which expressly removes "hemp" from the CSA. Under the 2018 Farm Bill, "hemp" includes its derivatives, among which is $\Delta 8$ THC.

³⁵ See, eg. United Ref. Co. Incentive Sav. Plan v. Morrison, 2013 U.S. Dist. LEXIS 166186, *11, 2013 WL 6147672

THE HEMP INDUSTRY SHOULD ADVOCATE FOR SAFE Δ8THC AND OTHER HEMP PRODUCTS

As a final note, the HIA believes it is important to address a growing concern about the safety of Δ8THC products that contains adulterants, contaminants, and/or other toxins that arise from the production process.³⁶ Δ8THC itself appears to be safe.³⁷ In fact, there have been zero cases of death associated with cannabinoid overdoses, including THC cannabinoids. However, Δ8THC produced using substandard methods and facilities can be harmful both to consumers and the hemp industry. Additionally, irresponsible manufacturing methods have the potential to create massive legal and financial liability for such producers. For these reasons, it is important for the hemp industry to be a strong advocate for safe Δ8THC products and to discourage substandard or questionable production methods while seeking to put an end to the distribution of Δ8THC products that contain adulterants. It is the HIA's position that hemp products should help people, not harm them.

CONCLUSION

The cannabinoid Δ8THC is not a controlled substance under the federal CSA when it is from hemp, including when derived from CBD. This is because the federal legal definition of hemp, which has been removed from the CSA, includes “cannabinoids” and “derivatives”. Additionally, tetrahydrocannabinols in hemp are not controlled substances. With respect to the AA, Δ8THC from hemp is not a controlled substance because Δ8THC does not have an effect on the CNS that is substantially similar to a controlled substance and hemp-derived Δ8THC meets the definition of “hemp” under the Farm Bill. Although Δ8THC derived from CBD may be classified as a “synthetic” form of THC, the better view is that it does not meet the definition of a “synthetic” cannabinoid. Regardless of whether it is deemed to be “synthetic” or not, Δ8THC is not a controlled substance since hemp derivatives have been removed from the CSA and a derivative is, by definition, a synthetic compound.

³⁶ See eg, a recent Bloomberg article by Tiffany Kary, “Pot Producers Are Pushing to Clamp Down on Delta-8 THC” (“*The lack of oversight in this relatively new market is raising concerns about what unexpected and potentially dangerous substances are ending up in commercially available products.*”) <https://www.bloomberg.com/news/articles/2021-06-02/a-pot-knockoff-sometimes-made-with-household-acid-draws-scrutiny?fbclid=IwAR2yibAJGfb8lCwkPiKDPDakqDulq7x91MTx9RFfBHKZhWIO6zbkoQR6OHo>

³⁷ See FNs 22 and 26, above. The article referenced in FN 22 discusses a clinical study of children undergoing chemotherapy who were administered Δ8THC as an antiemetic. The study found that for all of the children, “*vomiting was completely prevented [and] the side effects observed were negligible.*”

While $\Delta 8$ THC has been known and studied in a scientific context for several decades³⁸, it is new to the consumer market. The HIA is unaware of any court cases that have addressed the legal status of $\Delta 8$ THC. Although the legal views presented in this position statement have not been vetted in a court and it is not known whether a court would adopt them, the HIA contends that its position is supported by a fair, reasonable, and coherent analysis of the pertinent laws. Unfortunately, there currently exists uncertainty and risk, including the risk of criminal prosecution, associated with manufacturing, possessing, selling, and using $\Delta 8$ THC. The HIA laments this risk and advocates for laws and regulations that support the hemp industry. To this end, the HIA believes that prohibitions on hemp compounds, including $\Delta 8$ THC, are wrongheaded and counterproductive. Instead, the HIA advocates for safe production and consumption of all hemp products.

Even though $\Delta 8$ THC from hemp is not a controlled substance under federal law, it is important to consider how it is marketed and sold. While studies have shown $\Delta 8$ THC to be effective in pediatric oncology applications³⁹, the HIA does not support its use by minors outside of a therapeutic context. The HIA further takes the position that marketing materials should conspicuously identify potency and caution against driving, using heavy machinery, and participating in other similar activities when consuming it.

Finally, while $\Delta 8$ THC itself appears to be safe, $\Delta 8$ THC products that contain adulterants, contaminants, and other toxins may not be safe. The HIA believes that the hemp industry should take a strong stance against unsafe $\Delta 8$ THC production methods and products.

Sincerely,


Rod Kight


Philip M. Snow
Philip Snow

Attorneys for the HIA

³⁸ See FNs 22 and 26, above.

³⁹ Ibid. FN 22.



Donna C. Yeatman, R.Ph.
Executive Secretary
Alabama Board of Pharmacy
111 Village Street
Birmingham, Alabama 35242

Dear Dr. Yeatman:

This is in response to your letter dated August 19, 2021, in which you request the control status of delta-8-tetrahydrocannabinol (Δ^8 -THC) under the Controlled Substances Act (CSA). The Drug Enforcement Administration (DEA) reviewed the CSA and its implementing regulations with regard to the control status of this substance.

Δ^8 -THC is a tetrahydrocannabinol substance contained in the plant *Cannabis sativa L.* and also can be produced synthetically from non-cannabis materials. The CSA classifies tetrahydrocannabinols as controlled in schedule I. 21 U.S.C. 812, Schedule I(c)(17); 21 CFR § 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term “tetrahydrocannabinols” means those “naturally contained in a plant of the genus *Cannabis* (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant.” 21 CFR § 1308.11(d)(31). Thus, Δ^8 -THC synthetically produced from non-cannabis materials is controlled under the CSA as a “tetrahydrocannabinol.”

The CSA, however, excludes from control “tetrahydrocannabinols in hemp (as defined under section 1639o of Title 7).” Hemp, in turn, is defined as “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 tetrahydrocannabinol [Δ^9 -THC] concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. 1639o(1).

Accordingly, cannabinoids extracted from the cannabis plant that have a Δ^9 -THC concentration of not more than 0.3 percent on a dry weight basis meet the definition of “hemp” and thus are not controlled under the CSA. Conversely, naturally derived cannabinoids having a Δ^9 -THC concentration more than 0.3 percent on a dry weight basis is controlled in schedule I under the CSA as tetrahydrocannabinols.¹

¹ The Agricultural Improvement Act of 2018 (AIA), Pub. L. 115-334, § 12619, amended the CSA to remove “tetrahydrocannabinols in hemp” from control. See 21 U.S.C. § 812, Schedule I(c)(17). As noted, however, “hemp” is defined to “mean 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-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” 7 U.S.C. 1639o (emphasis added). Thus, only tetrahydrocannabinol in or derived from the cannabis plant—not synthetic tetrahydrocannabinol—is subject to being excluded from control as a “tetrahydrocannabinol[] in hemp.”

If you have any further questions, please contact the Drug and Chemical Evaluation Section at DPE@usdoj.gov or (571) 362-3249.

Sincerely,

A handwritten signature in black ink, appearing to read 'Terrence L. Boos'.

Terrence L. Boos, Ph.D., Chief
Drug & Chemical Evaluation Section
Diversion Control Division

cc: Birmingham Office