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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 (Δ 8THC), under federal law. The specific issue addressed is: "Are hemp-derived cannabinoids and compounds, including Δ 8THC, with delta-9 tetrahydrocannabinol (Δ 9THC) 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 Δ 8THC 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. $\triangle 8$ THC is a cannabinoid produced by hemp

 Δ 8THC 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 Δ 9THC, a more well-known cannabinoid in the

¹ 7 U.S. Code § 5940

² 7 U.S. Code § 16390 *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 Δ 8THC and Δ 9THC, 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 Δ 8THC from other isomers of THC, such as Δ 9THC and Δ 10THC, 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 Δ 8THC and Δ 9THC makes a substantial difference in how they affect our bodies. It also affects their legal status. Δ 8THC 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 Δ 9THC concentrations that exceed 0.3% on a dry weight basis. Moreover, Δ 8THC 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 Δ 8THC are not substantially similar to the effects of Δ 9THC, a schedule 1 controlled substance under federal law except as set forth in the 2018 Farm Bill.

c. Δ 8THC 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 Δ 8THC produced from cannabidiol (CBD) extracted from hemp.⁹ This confusion is primarily due to the chemical process used to derive Δ 8THC from CBD. This process raises the question of whether the resulting Δ 8THC is "synthetic" or not. It is not entirely clear whether Δ 8THC 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 Δ 8THC 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%20h ydrogen%20atoms.&text=The%20position%20of%20this%20double,extent%20of%20its%20psychoactiv e%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 Δ 8THC. For this reason, hemp-derived Δ 8THC is lawful under federal law.

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

Despite the fact that hemp-derived Δ 8THC 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 Δ 8THC, including by banning it outright. An archaic and prohibitionist approach to this and other hemp cannabinoids will likely result in Δ 8THC products entering the illicit "black market", rendering them nearly impossible to regulate. On the other hand, responsible regulation of Δ 8THC 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 Δ 8THC 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 <u>and all derivatives</u>, <u>extracts</u>, <u>cannabinoids</u>, <u>isomers</u>, acids, salts, and salts of isomers, <u>whether growing or not</u>, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. (<u>emphasis</u> 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. Δ 8THC and other minor cannabinoids found in hemp are "cannabinoids". They are not controlled substances when derived from hemp, regardless of their concentrations.

$\Delta 8 THC$ derived from CBD is not a controlled substance

It is clear that Δ 8THC which is naturally expressed in, and extracted from, the hemp plant is not a controlled substance. Currently, most Δ 8THC on the market is a derivative of CBD from hemp. This is because current hemp cultivars do not express Δ 8THC in sufficient concentrations or quantities to be viable economically. For the reasons stated below, Δ 8THC 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 <u>21 U.S.C. § 802(16)(</u>B): "The term "marihuana" does not include— (i) hemp, as defined in section 16390 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 Δ 8THC 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 <u>synthesized</u> from a parent compound by replacement of one atom with another atom or group of atoms."(<u>emphasis</u> added) 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 Δ 8THC from CBD describe a chemical reaction initiated by a catalyst in which the CBD is converted to Δ 8THC and other minor cannabinoids and compounds. In fact, the US government holds a patent for converting CBD to Δ 8THC.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 Δ 8THC does not degrade, oxidize, or otherwise convert to Δ 9THC by the mere application of heat. In fact, it appears that Δ 8THC is more stable than Δ 9THC²², which degrades over time into a different cannabinoid, cannabinoi (CBN).

Based on most commonly used processes for producing Δ 8THC from CBD, including a US government patented SOP, Δ 8THC "*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, Δ 8THC is a "derivative" of CBD under the above definitions.

Finally, since the statutory definition of "hemp" includes CBD, of which Δ 8THC is a derivative, Δ 8THC 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 <u>https://www.chemicool.com/definition/derivative.html</u>

¹⁹ <u>https://en.wikipedia.org/wiki/Derivative (chemistry)</u>

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. <u>doi:10.1016/0024-3205(95)00194-</u>

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

 Δ 8THC 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 Δ 8THC 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 Δ 8THC has on the CNS is not substantially similar to the effects of Δ 9THC, a Schedule 1 controlled substance except as set forth in the 2018 Farm Bill. Its effects are up to ten (10) times <u>less potent</u>.²⁶ Third, hemp has been removed from the CSA. As discussed above, hemp-derived Δ 8THC meets the legal definition of "hemp" under the Farm Bill. Legally speaking, it is "hemp" and is not a controlled substance. For these reasons, Δ 8THC from hemp is not a controlled substance under the AA.

THE DRUG ENFORCEMENT ADMINISTRATION MAY CONTEND THAT $\Delta 8$ THC FROM CBD IS AN UNLAWFUL FORM OF SYNTHETIC THC

The DEA has not taken a public position on hemp-derived $\Delta 8$ THC. However, it is worth mentioning that on August 21, 2020, the DEA published its IFR in the federal register.²⁷ In

https://www.cannabisbusinessexecutive.com/2018/06/cbd-not-controlled-substance-source-ruleapplies/; 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-controlledsubstance/?sh=1af03d594569

²³ See, eg., <u>https://cannabusiness.law/cbd-and-the-source-rule/;</u>

²⁴ Ibid. FN 4.

²⁵ 21 U.S.C. § 812(c)(17)

²⁶ See, eg, Ibid. FN 22, which asserts that Δ 8THC "*is generally considered to be 50% less potent than* Δ 9-*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 Δ 8THC relative to Δ 9THC 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 Fam 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 Δ 9-THC is not a determining factor in whether the material is a controlled substance. <u>All synthetically derived tetrahydrocannabinols remain schedule I controlled substances</u>." (emphasis added)

This prohibition on "synthetically derived tetrahydrocannabinols" does not explicitly mention $\Delta 8$ THC. Additionally, the DEA recently released the following statement regarding $\Delta 8$ THC:

"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 Δ 8THC 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 Δ 8THC from CBD is an illegal synthetic form of THC.

a. Is ∆8THC 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, <u>https://www.deadiversion.usdoj.gov/synthetic_drugs/about_sd.html;</u>

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. Δ 8THC 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, Δ 8THC is not a full CB1 agonist nor does it produce as intense a reaction as delta-9 THC, both of which are required for Δ 8THC to meet the definition of "synthetic THC".

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

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

With respect to the legal status of Δ 8THC under federal law, it does not matter if hempderived Δ 8THC 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 <u>actually be synthesized</u> from a parent compound by replacement of one atom with another atom or group of atoms." (<u>emphasis</u> added)

Importantly, the definition actually <u>includes</u> 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 Δ 8THC. When viewed in this light, it is clear that the 2018 Farm Bill both anticipated and expressly includes hemp derivatives, such as Δ 8THC, 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 Δ 8THC. 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 Δ 8THC.

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

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 Δ 8THC products that contains adulterants, contaminants, and/or other toxins that arise from the production process.³⁶ Δ 8THC itself appears to be safe.³⁷ In fact, there have been zero cases of death associated with cannabinoid overdoses, including THC cannabinoids. However, Δ 8THC 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 Δ 8THC products and to discourage substandard or questionable production methods while seeking to put an end to the distribution of Δ 8THC products that contain adulterants. It is the HIA's position that hemp products should help people, not harm them.

CONCLUSION

The cannabinoid Δ 8THC 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, Δ 8THC from hemp is not a controlled substance because Δ 8THC does not have an effect on the CNS that is substantially similar to a controlled substance and hemp-derived Δ 8THC meets the definition of "hemp" under the Farm Bill. Although Δ 8THC 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, Δ 8THC 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=IwAR2yibAJGfb8ICwkPiKDPDakqDuIg7x91MTx9RFfBHKZhWIO6zbkoQR6OHo 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 Δ 8THC 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 Δ 8THC. 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 Δ 8THC. 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 Δ 8THC, are wrongheaded and counterproductive. Instead, the HIA advocates for safe production and consumption of all hemp products.

Even though Δ 8THC 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 Δ 8THC 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, Kip M Snow Philip Snow od Kiaht

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³⁸ See FNs 22 and 26, above.

³⁹ Ibid. FN 22.